



Proposed Article 8 Sanitation Regulations: Origins Council Comments

Date: February 6, 2025

On behalf of Origins Council, we're writing to provide comment on the Article 8 on-farm sanitation regulations proposed by DCC in September 2024.¹

We appreciate the DCC's decision to make these regulations available as a discussion draft prior to formally noticing a comment period. The proposed regulations led to considerable discussion among our membership on the details of the regulation, existing on-farm practices, and comparable precedents in other agricultural contexts. A full discussion on these dynamics would have been difficult in a typical 45-day comment period, and we appreciate the opportunity for a more extended deliberation on the proposed rules.

For these reasons, our initial public comment² submitted on September 18 ahead of a scheduled Cannabis Advisory Committee meeting indicated our need for additional time to review the details of the Article 8 regulations, and to compare these proposed regulations to regulatory frameworks in comparable agricultural contexts.

Since that time, we've had the opportunity for more thorough review of the proposed standards, which has led us to develop a number of concerns about the discussion draft proposal. In short, our concerns include the following:

¹ https://cannabis.ca.gov/wp-content/uploads/sites/2/2024/09/20240919_Regulation-Text.pdf

² <https://drive.google.com/file/d/1axWMNw13j3IQdPewjLhHU14zjt51ksCu/view?pli=1>

- It is not currently clear to us why the proposed regulations are necessary in light of existing quality assurance standards.
- We were unable to find precedent for the proposed regulations either in other agricultural contexts, or in other DCC contexts.
- Absent clear justification, we believe there are several reasons why DCC should err strongly against imposing additional regulatory burdens on small cultivators.
- We're concerned that a large proportion of the specific rules proposed in Article 8 are unnecessary, duplicative, and/or not viable to comply with.

For these reasons, which are discussed in more detail below, we are opposed to proposed Article 8 regulations. Further, if Article 8 regulations do move forward, we believe it would be necessary to modify them substantially in comparison to the September 2024 discussion draft.

Lack of Clear Need for Proposed Article 8 Regulations

Given existing DCC regulations for quality assurance, the rationale for the additional regulations proposed under Article 8 is not clear to us. Under existing DCC rules, each batch of cannabis products must be tested in final form for microbiological contamination, moisture content, water activity, foreign materials, and other potentially harmful contaminants. This regulatory standard already substantially exceeds the standards applicable to other consumer products where microbiological contaminations may be a concern, including smokable products such as tobacco.

Additionally, OSHA sanitation standards,³ including standards related to handwashing, toilets, and potable water, are already applicable to all agricultural employers, including cannabis cultivators.⁴

While recent reporting has raised concerns on the reliability of existing lab testing practices, we view this as a reason to urgently ensure the reliability of these practices, rather than adopting additional regulations through a different quality control mechanism based on an assumption that final product testing is not reliable. Additionally, this reporting has primarily focused on pesticide contamination - which would not be addressed by proposed Article 8 rules - rather than microbiological contamination.

If the DCC has data which suggests a need for expanded sanitation standards, we would appreciate a better understanding of this data so that we can best consider solutions to any problems that have been identified.

Proposed Sanitation Regulations Lack Precedent in Comparable Cannabis or Agricultural Uses and are Substantially more Stringent than Comparable Uses

In reviewing sanitation regulations in other comparable contexts, we were not able to find an example that mirrors the approach proposed in Article 8.

³ <https://www.dir.ca.gov/title8/3457.html>

⁴ BPC 26051.5(a)(8)

- Comparable non-food agricultural products are not subject to additional on-farm sanitation regulations.

Beyond baseline OSHA standards, our understanding is that agricultural products which are not considered foods - such as cotton, tobacco, or hemp - as well as foods which are not typically consumed raw, are not subject to additional sanitation regulations either federally or under California law.

- Sanitation regulations for raw produce under the Food Safety Modernization Act are a poor model for proposed DCC regulations.

Sanitation standards for raw produce are governed under the Food Safety Modernization Act (FSMA), federal legislation passed in 2011 which granted FDA new authority to regulate on-farm activities to prevent microbiological contamination in food. In California, the FSMA is implemented largely through CDFA's Produce Safety Program.⁵

Overall, we view FSMA standards as a poor model for DCC sanitation regulations. Cannabis is not raw produce, and standards applicable to raw produce are not necessarily appropriate for non-food products. Further, as discussed earlier, cannabis is already subject to a specialized quality control regime for microbiological contamination and foreign materials in the form of mandatory testing for each batch of cannabis products.

When Congress originally passed the FSMA, there was significant concern regarding how additional regulatory burden would impact small farms. At the time of the FSMA's passage, stakeholders raised concerns that while industrial-scale food operations posed much greater threats to public health than small-scale farms, these smaller farmers would ironically be disproportionately impacted by burdensome new regulations.⁶

As a result, the FSMA contains several accommodations and exemptions for small farms, including phased implementation for farms based on size, exemptions for small farms, and reduced regulatory burdens for smaller farms. For example, the Tester-Hagan amendment to the FSMA provides a "qualified exemption" to farms grossing less than \$500,000 annually that also sell the majority of their product to in-state retailers or directly to consumers⁷ - standards which would apply to most small California cannabis farmers, who are definitionally limited to in-state sales, if FSMA standards were theoretically applied to them.

Recognizing the educational and technical barriers for small farmers to comply with FSMA, state and federal agricultural agencies also provide technical and financial assistance to small

⁵ <https://www.cdfa.ca.gov/producesafety/>

⁶ <https://grist.org/article/food-2010-11-15-food-fight-safety-modernization-act-harm-small-farms/>

⁷ <http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-PRODUCE-RULE-FINAL.pdf>

farmers for FSMA compliance through CDFA's Technical Assistance Program⁸ and USDA's Food Safety Certification Program.⁹

For all of these reasons, the standards within and context for the FSMA differ substantially from the current situation in cannabis. Additionally, as discussed further below, proposed Article 8 regulations are in many respects significantly more stringent than FSMA standards.

- Proposed DCC sanitation regulations are significantly more prescriptive than FSMA regulatory requirements.

As discussed above, we do not believe the FSMA provides a precedent or model that justifies additional on-farm sanitation regulations for cannabis cultivators. Even if the DCC intended to implement an FSMA-type model for cannabis cultivation, however, we're concerned that the specifics of the proposed DCC regulations are substantially more specific and prescriptive than the approach taken in the FSMA.

The DCC's proposed sanitation standards for cannabis cultivators include the following:

- Requiring tools, utensils, and equipment to be cleaned and sanitized each day they're in use.
- Requiring containers used to store and transport cannabis to be cleaned and sanitized at specified time intervals.
- Requiring "clean" tools and surfaces to be entirely "free of visual dust, dirt, debris, cannabis residue, and food residue."
- Specifying a limited number of acceptable sanitizing chemicals and methods.
- Unconditionally prohibiting animals from indoor areas of the premises.
- Unconditionally prohibiting animal waste (including manure) from any area of the licensed premises.

Later in this comment, we'll outline specific concerns with some of these proposed standards. At a high level, however, what we want to emphasize here is that the proposed sanitation standards are unusually prescriptive, specific, and mandatory compared with regulatory frameworks for comparable uses - i.e., sanitation would be required by regulation to take place at specific times and using specified methods. As we discuss below, this approach contrasts with a much more general, results-oriented approach utilized in other regulatory contexts.

Title 21, Chapter I, Subchapter B, Part 112 of the FSMA rules specifically pertain to "Equipment, Tools, Buildings, and Sanitation"¹⁰ and parallel many of the issues addressed in proposed DCC regulations.

⁸ <https://www.cdfa.ca.gov/is/technicalassistance/>

⁹ <https://www.farmers.gov/coronavirus/pandemic-assistance/food-safety#how-works>

¹⁰ <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112/subpart-L>

The wording of FSMA regulations, however, is considerably less prescriptive and specific than proposed DCC regulations. FSMA regulations emphasize the end goal of cleanliness, while granting farmers flexibility in how to achieve these goals. For example, the FSMA requires cleaning and sanitization “as frequently as reasonably necessary” rather than at specified time intervals:

“(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

“(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.”

As another example, the FSMA requires containers to be “adequately clean” rather than the DCC’s proposed standard of “free of visual dust, dirt, debris, cannabis residue, and food residue.”

“Equipment that is subject to this subpart that you use to transport covered produce must be:

- (a) Adequately clean before use in transporting covered produce; and*
- (b) Adequate for use in transporting covered produce.”*

- Proposed DCC sanitation regulations on cultivators are significantly more prescriptive than DCC sanitation requirements on manufacturers.

Under existing DCC regulations, cannabis manufacturers are the only DCC license type required to follow DCC-specific sanitation standards. These standards are outlined in Chapter 8, Article 4 of existing DCC regulations, titled “Good Manufacturing Practices.”

In general, we do not believe cannabis manufacturing standards should be applied directly to cannabis cultivation, just as the regulation of manufacturing and agriculture has traditionally remained separate at every level of government, including the FDA. Mandatory GMP standards under FDA regulations or DCC manufacturing regulations reflect the controlled, consistent processes typical in manufacturing, and the tendency for manufacturers to be more scaled and better equipped to handle burdensome regulatory compliance standards. By contrast, USDA GAP regulations are voluntary,¹¹ reflecting the enormous variation in size, crops, methods, and environmental conditions among farms.

Even in the case of DCC manufacturing regulations, however, DCC standards for cleanliness and sanitation are in many ways less prescriptive and specific than the proposed regulations for cannabis cultivation.

¹¹ <https://www.fns.usda.gov/f2s/overview-good-agricultural-practices>

- DCC regulation §17210(c) for cannabis manufacturers states simply that *“equipment and utensils shall be maintained in a clean and sanitary condition and kept in good repair.”* “Cleanliness” is not defined in the prescriptive manner of the proposed DCC cultivation regulations, and “sanitation” is defined broadly (*“to treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens...”*) rather than the short list of allowable sanitation methods prescribed under proposed cultivation regulations.
- The only DCC regulation pertaining to containers for manufacturers, §17212(a)(6), simply states that: *“raw materials and other components shall be held in containers designed and constructed to protect against allergen cross-contact or contamination, and shall be held at a temperature and relative humidity and in a manner that prevents the cannabis products from becoming adulterated.”* There is no requirement to clean and sanitize containers at regular intervals.
- There is no DCC regulation prohibiting animals in indoor areas of manufacturing premises.

DCC regulations do require that manufacturers maintain a written quality control program to outline their approach to sanitation, and to document their adherence to that approach. The specific contents of these programs, however, are not prescribed by regulation to the degree proposed for cultivators.

- DCC does not impose sanitation standards for cannabis distributors.

Although cannabis distributors are authorized to handle unpackaged plant material, distributors are not required to abide by any sanitation standards under existing DCC regulations or in the proposed discussion draft regulations.

DCC Should Not Impose Additional Regulatory Burden on Farmers Unless Clearly Warranted

For several reasons, we believe the DCC should err against imposing additional regulatory burdens on farmers unless clearly needed.

- **Regulatory burden on cannabis farmers is already excessive** - cannabis farmers already face tremendous regulatory burdens that far exceed the regulatory burdens placed on any other form of agriculture. These include expensive and disproportionate licensing fees, required site-specific CEQA analysis, special environmental requirements, required end-product testing for each batch, special requirements for transport and distribution, detailed operational requirements, and more. For small farmers to be successful, it is critical that policy work to decrease unnecessary regulatory burdens for farmers, not increase them further.

- **Agriculture requires flexibility** - farmers use a wide variety of cultivation methods and are subject to a wide range in cultivation conditions (climate, soils, etc.) As discussed further below, the prescriptive and detailed rules proposed under Article 8 are often inconsistent with the flexibility realistically needed in agriculture.
- **Alignment with evolving federal policy** - as the federal government moves towards cannabis legalization, quality control practices for cannabis are likely to be standardized at the federal level and implemented by agencies such as USDA and FDA that already have their own regulatory systems in place. Adopting further California-specific rules which may be subsumed by federal regulations or burgeoning interstate commerce standards in the near future may be an inefficient use of resources.
- **Regulatory disparity with hemp agriculture** - cannabis cultivation is already far more highly regulated than hemp cultivation, despite the fact that hemp cultivators grow the same plant as cannabis cultivators and, in many cases, sell the same types of cannabinoid products to end consumers. Hemp cultivators would not be required to follow the proposed Article 8 regulations, further expanding this disparity. Further, if California ever chooses to integrate hemp into the cannabis supply chain - as was proposed in California's AB 2223 in 2024 - consumers would have access to hemp-derived cannabinoid products at dispensaries which were not required to follow Article 8 regulations, and cannabis cultivators would be faced at an even further disadvantage in comparison with hemp producers while competing for the same market share.
- **Preserving DCC resources** - we understand that DCC has limited resources and must prioritize where those resources are allocated. At the December 18 Cannabis Advisory Committee hearing, DCC staff suggested that expanded responsibilities at DCC may be a reason for increasing licensing fees on cannabis businesses, an outcome which would further increase burdens specifically on legal and compliant businesses. In the context of these limited resources, we believe additional regulatory burdens should require a strong rationale to move forward.

Specific Concerns Regarding Proposed Sanitation Standards

For the above reasons, we do not believe additional regulations on cultivators under Article 8 are warranted. In addition to these general concerns, however, we have a number of specific concerns with the proposed regulations.

- §15060(b): Prohibition of animal waste anywhere on a premises.

This is effectively a prohibition on the use of manure within the cultivation area, and is contrary to best practices for organic agriculture. Additionally, outdoor cultivators may be located near wildlife (bears, etc.) that leave animal waste on the farm. For comparison, FSMA regulations

prohibit raw manure from contacting covered produce, but do not establish a blanket prohibition on animal waste.¹²

- §15060(a)(1): Prohibition of an animal in any indoor area of a licensed premises.

Not all areas of a licensed premises risk contamination of product: for example, an office, or in an area of the premises that only sometimes contains cannabis material. Cultivators may reasonably want a dog or other pets in these areas. For comparison, the FSMA requires “reasonable precautions” around the presence of domesticated animals in indoor areas, but does not prohibit this activity.¹³

- §15061(a)(1-2): Requirement to clean and sanitize tools and equipment “each day” they’re in use.

In many cases, it’s unnecessary or impractical to clean and sanitize tools and equipment at this time interval. Cultivators may use tools only for a brief period of time each day, not necessarily in multi-hour shifts. Equipment such as trimming machines is difficult to clean and daily cleaning is not necessary. Daily cleaning and sanitation of equipment is not unconditionally required in any other agricultural context we’re aware of. As discussed earlier, FSMA standards only require cleaning to take place “as frequently as reasonably necessary.”¹⁴

Additionally, we have concerns on the enforceability of this requirement. The proposed regulation is only applicable to equipment, tools, and surfaces used in relation to cannabis plant material. However, cultivators may have equipment, tools, and surfaces that are used for purposes other than storing or processing cannabis plant material (e.g., a trash can). How will inspectors differentiate these implements (not required to be cleaned and sanitized daily) from implements used for cannabis?

- §15061(a)(3)(A-B): Requirement to clean and sanitize containers for transport at specified intervals.

Many cultivators utilize tote liners, and it’s unclear whether the proposed standards apply to the tote liner or the bin. Use of tote liners should be an acceptable method to fulfill cleanliness and sanitation requirements.

Additionally, the proposed requirement to clean and sanitize containers “between storage and transport of each harvest batch” is unclear to us. This period may encompass many months. Is the intended wording “prior to transport?”

For comparison, FSMA regulations only require containers to be “adequately clean before use in transporting covered produce.”

¹² <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>

¹³ <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112#112.127>

¹⁴ <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112/subpart-L>

- §15061(b): Definition of "clean" as "free of visual dust, dirt, debris, cannabis residue, and food residue."

The wording of this section implies that tools, etc. must be *entirely* free of dust, dirt, debris, or residue. We believe this standard is unreasonable. Cannabis residue can be extremely difficult to remove in many cases, and does not pose an inherent sanitation risk. Additionally, a zero-tolerance standard for dust, etc. is not reasonable and puts cultivators at risk of enforcement action for minor violations which pose no risk to public health.

As discussed above, a zero-tolerance standard is not applied in any other regulatory context we're aware of. Regulatory frameworks like the FSMA, as well as DCC regulations for manufacturers, use language like "adequate," "reasonable," or "in a manner as to prevent adulteration" to specify the required standard.

- §15061(c): Specification of allowable sanitation methods.

This section specifies just four chemicals as acceptable for use in sanitation, and excludes countless other methods utilized by cultivators for sanitation, including non-chemical methods. No other regulatory context we're aware of specifies allowable sanitation methods at all, including DCC regulations for laboratories and manufacturers.

- §15062: Handwashing and glove use.

These rules appear to be duplicative of existing OSHA regulations for businesses with employees.¹⁵ For businesses without employees, these regulations could open non-premises residential areas to DCC inspections, infringing on the reasonable privacy expectations of homestead cultivators.

Policy Recommendations

While an effective quality control framework for cannabis products is essential, we're concerned that the proposed Article 8 standards would not effectively advance this goal, and would instead distract from more important efforts to ensure that the existing framework for quality control retains public confidence.

For these reasons, we recommend that DCC does not move forward with the Article 8 requirements proposed in the September 2024 discussion draft. If DCC does move forward with Article 8 requirements, we recommend that these standards are substantially amended to address the concerns discussed above.

Thank you for your consideration, and we look forward to continuing a conversation with DCC on these important issues.

¹⁵ <https://www.dir.ca.gov/title8/3457.html>

Sincerely,



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