# California Code of Regulations Title 3. California Department of Food and Agriculture Division 8. Cannabis Cultivation Chapter 3. OCal Program

### ADDENDUM TO THE INITIAL STATEMENT OF REASONS

This Addendum to the Initial Statement of Reasons provides rationale and clarifies specified changes to the modified regulation text published for the 15-day comment period.

The rationale for all modifications to references and numbering throughout is clarity. References have been modified in subsections/paragraphs 10101(a), 10201(c)(4), 10202(b), 10300(e), 10302(a), 10400(b), 10402(c)(3),(4) and (6), 10402(d), 10405(b),(d), and (e), 10407(d), 10409(d), 10410(d)(5) and (7), 10505(e), and 10506(c).

#### **Article 1. Definitions**

#### Section 10000. Definitions.

**10000(e):** Removed the definition for **Annual seedling**. This change was in response to a comment received during the 45-day comment period asking why annual seedlings are not included in the Seeds and Planting Stock section. When revising the National Organic Program (NOP) definitions for the OCal regulations, the phrase "except annual seedlings" was removed from the definition of "Planting stock," hence "annual seedlings" are included in the definition of Planting stock. Having a separate definition for "Annual seedlings" created confusion.

**10000(br):** Added a definition for **Responsibly connected**. This change was in response to a comment requesting "Responsibly connected" be defined in the OCal regulations, as it is in the NOP regulations. The OCal Program initially planned to substitute an equivalent CalCannabis Licensing Division term for "responsibly connected" but did not use the other term.

# Section 10001. Incorporation by reference.

**10001(g):** OCal 2611, section 4.1, was amended to clarify that a laboratory should be able to test for analytes listed on OCal 2611-1, analytes required by the Bureau of Cannabis Control and any additional analytes required by the certifying agent. This clarification was in response to comments that it was unclear whether a laboratory was required to test for the entire list of analytes on OCal 2611-1 and if there were other analytes that could be or needed to be tested outside of the list of analytes on OCal 2611-1.

**10001(h):** OCal 2611-1, section 4.1, was amended to say, "A laboratory must be able to test for analytes listed on OCal 2611-1, the required pesticide tests included in the Bureau's regulations, and any additional analytes required by the certifying agent." This change was in response to a comment that it was unclear if a laboratory is required to test for the entire list of analytes included in OCal 2611-1 or just the Bureau's list of analytes and if a laboratory must also be able to test for analytes in addition to those included in OCal 2611-1 and the Bureau's list.

**10001(I):** OCal 3012, section 3, was amended to say a certifier must maintain documentation to support its determination regarding whether a product is allowed or prohibited for use in OCal production, including those products that are approved based on prior determination by another certifier, a Material Review Organization (MRO) or the Environmental Protection Agency (EPA). This modification was in response to a comment noting that the NOP guidance document requires a certifier to maintain documentation to support its determinations based on prior determination by any MRO or the EPA, not just the California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program as was required by the department. The department expanded its documentation maintenance requirement to include any MRO or the EPA because, while most cannabis products will be approved by the CDFA OIM program, it's possible some products approved by other MROs or the EPA may also be used on cannabis.

**10001(p):** OCal 5021, section 3.2, was amended to include guidance on vermicomposting of animal materials. This modification was in response to a comment that this information is included in NOP guidance document number 3012. It was inadvertently omitted from the OCal guidance document.

# **Article 2. Applicability**

Section 10101. What must be certified.

**10101(b)(1-2):** Amended for clarity and to remove the phrase "privately certified," which was not used elsewhere or defined. This change was in response to a comment that the phrase "privately certified" seems to conflict with Section 10100, "Who may certify."

**10101(c):** Removed "privately" in response to a comment that the phrase "privately certified" seems to conflict with Section 10100, "Who may certify."

## **Article 3. OCal Cultivation and Distribution Requirements**

Section 10201. OCal system plans.

**10201:** The section title, "OCal cultivation and distribution system plans," was amended to say "OCal system plans." This change was in response to a commenter who pointed out that the phrase "OCal system plans" is used within the section and throughout the regs to refer to the item described in the section titled "OCal cultivation and distribution plans."

Section 10202. Land Requirements.

**10202(c):** Revised syntax for clarity.

# Article 4. Labels, Labeling, and Market Information

Section 10300. Non-manufactured cannabis products labeled OCal.

**10300(c)(1-3):** Amended to clarify that cannabis product packages may display one or more of the 3 options named in paragraphs 1-3. This change was in response to a

commenter who interpreted the subsection as saying all 3 of the named options must be displayed on the package.

**10300(d):** Amended to specify that the cultivator or distributor that handled the finished product and the certifying agent that certified that operation must be identified on the cannabis package. This change was in response to a commenter who pointed out the provision was not comparable to the NOP because it specified that the cultivator and the cultivator's registered certifying agent should be identified on the package rather than the cultivator or distributor that handled the finished product and the certifying agent that certified that operation.

**10300(e):** Added so that cannabis that has been certified OCal will be identified as such in the ingredient statement. This addition was in response to a commenter who pointed out that this section was not comparable to the NOP.

# **Article 5. Accreditation and Registration of Certifying Agents**

Section 10401. Requirements for accreditation.

**10401(a)(7):** Amended to add the certifying agent's staff as an entity that may conduct the internal program review. This modification is comparable to the NOP and provides more flexibility to the certifying agent without compromising integrity.

**10401(a)(12)(A):** The word "provision" was replaced with "delivery" to increase clarity. The substance of this subsection is unchanged.

Section 10403. Review of accreditation application.

**10403:** List introduction edited for clarity. The substance of the introduction is unchanged.

**10403(a)-(b):** Edited to match the grammar of the list items with the list introduction. The substance of the list items is unchanged.

**10403(b)(1)-(2):** The word "disqualified" was replaced with "abandoned" to increase clarity because in this case the application would have been abandoned first and then disqualified by virtue of being abandoned.

Section 10407. Accreditation renewal.

**10407(d):** Amended for clarity. The substance is unchanged.

Section 10409. Registration.

**10409(d):** Amended for clarity. The substance is unchanged.

Section 10410. Registration renewal and reporting.

**10410(d)(7):** Amended to say certifying agents must submit an inspection report for each cannabis operation granted certification during the previous year. This change was in response to a comment that requiring annual submission of the OCal system plan (OSP) and the inspection report was duplicative and inefficient, in part because the regulations contain a provision that accredited certifying agents must make the OSP available upon request. The department determined that in most cases it will be able to evaluate compliance without the OSP but kept the inspection report requirement because it was recommended by the OCal stakeholder group.

#### **Article 6. Certification of Operations**

Section 10503. On-site inspections.

**10503(a)(1):** Amended for clarity. This change was in response to a comment that the department should use consistent language regarding what must be inspected. The commenter said the provision first directs certifying agents to inspect "each unit, facility, or site that produces OCal cannabis" and then directs certifying agents to perform annual inspections at "each certified operation that produces nonmanufactured cannabis products." The department found that while the paragraph was not inconsistent, the language was confusing. The paragraph was amended to clarify that every on-site inspection (initial and annual) must include all of an operation's units,

facilities, or sites (i.e., not just the main site or a few sites) that are intended for the production of OCal cannabis.

**10503(a)(3):** This paragraph was removed. This change was in response to a comment that the paragraph was not comparable to the NOP. In addition, the paragraph was in conflict with section 10203 of the OCal regulations, which requires a cultivator to implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

#### Article 7. Fees

Section 10602. Fees and other charges for certification.

**10602:** Added to be comparable to the NOP, to establish the department's expectation that certifying agent fees will be reasonable, and to outline transparency requirements that will help an applicant for certification to make informed decisions. This change is in response to a comment that this section is included in the NOP regulations. This section was inadvertently omitted from the OCal regulations.

Section 10603. Payment of department fees and other charges.

**10603:** The word "department" was added to the title to indicate that this section applies only to fees paid to the department. This clarification was needed due to the addition of Section 10602, which discusses fees paid to the certifying agent.

#### **Article 8. Compliance**

#### Section 10701. Adverse actions

**10701(e)(2):** Amended to say that, except in the case of a labeling violation, the department may issue a fine along with a Notice of Proposed Suspension or Revocation, a Suspension, a Revocation, or in response to a Willful violation. This change was made in response to commenters concerned that a fine may be issued at any point for any notice of noncompliance. Another commenter was concerned that issuance of a notice of noncompliance by a certifying agent could be delayed by

department fines. This comment was not addressed in this change because the department will not add fines to notices issued by certifying agents unless a certifying agent specifically requests the issuance of such fine. The department removed the fine amount requirement from notices of noncompliance, sections 10703(d)(4) and 10705(c)(4).

**10701(e)(3):** This paragraph was removed because the department determined that one fine amount, specified in paragraph (2), for both certifying agents and certified operations would be less confusing and still achieve the goals of the fine.

### <u>Section 10703. Non-compliance procedures for certified operations.</u>

**10703(d)(4):** This paragraph was removed because an administrative fine will only be issued by the department, per the amendment to section 10701(e)(2).

**10703(f):** Amended to include mediation as an option for resolving a non-compliance. This change was made in response to a comment that this subdivision was not comparable to the NOP because it was missing this mediation option. Mediation was inadvertently left out.

**10703(g)(3):** The phrase "or a person responsibly connected with an operation" was added to this paragraph in response to a comment that it was not comparable to the NOP without this. The department considered, while drafting the regulations, replacing this with a comparable phrase used by CalCannabis. It was inadvertently omitted from the regulations.

#### Section 10705. Non-compliance procedure for registered certifying agents

**10705(c)(4):** This paragraph was removed because an administrative fine will only be issued by the department, per the amendment to section 10701(e)(2).

**10707(a):** Amended to specify all notices that may be appealed. This change was made in response to a comment that a denial is not an adverse action and therefore was not included in this subsection as appealable.

# Section 10711. Inspection, testing, and reporting.

**10711(j):** This provision was removed because there are no FDA, EPA, or Bureau tolerance or action levels for cannabis to indicate contamination and trigger reporting.