ADDENDUM III TO THE INITIAL STATEMENT OF REASONS

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

This third Addendum to the Initial Statement of Reasons provides rationale and explains specified amendments indicated in the Proposed Modified Text of the Proposed Regulations.

Additions to the regulation text are indicated within the regulation text by **bold font and <u>double underline</u>**, and <u>deletions are indicated by bold font, double underline, and</u> <u><u>double strike through</u></u>. Changes to spelling, grammar, syntax, references, citations, and formatting, are indicated in the text of the regulations and do not necessitate explanation in this Addendum.

When the same change is made to multiple provisions for the same reason, only the first of the changes is explained in this document.

Section 10000. Definitions.

10000(e): a definition for "Applicant" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(j): "or distribution" was added clarify that "certification" or "certified" is a determination applied not just to a cultivation operation but to either a cultivation or a distribution operation.

10000(w): a definition for "Cultivation" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8

chapter one includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(ba): a definition for "Nonmanufactured cannabis product" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(bd): a definition for "Nursery" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(bg): for the definition of "OCal Program," to clarify that the regulations apply only to Business and Professions Code (BPC) 26062(1)(a), a certification program for nonmanufactured cannabis products, the BPC citation was amended and "or a certification program for manufactured cannabis products" was removed.

10000(bi): "California" was added to clarify that an operator must hold a commercial cannabis license issued by the State of California and "cultivator or distributor" was added to clarify that an operation must hold a cultivator or distributor license. "From a licensing authority" was removed because the aforementioned changes made it redundant.

10000(bl): a definition for "Pest" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(bp): a definition for "Premises" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(bs): a definition for "Process," "Processing," and "Processes" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

10000(cg): a definition for "Track-and-trace system" was added because the OCal regulations will move from division 8 of the California Code of Regulations (CCR) when the three commercial cannabis licensing agencies combine to form a new agency and the OCal Program stays with the California Department of Food and Agriculture. CCR division 8, chapter 1 includes this definition so it would not be necessary if the OCal regulations and chapter one were remaining within the same division of the CCR.

Section 10001. Incorporation by reference.

REGULATION TEXT

Global Changes 10001(a) through 10001(aa): 10001(a) through 10001 (aa) were changed to 10001(a)(1) through 10001(a)(26) and specified guidance document names were amended to match the actual title of the guidance document.

10001(b): This FDA regulation was incorporated by reference to comply with the Administrative Procedures Act.

GUIDANCE DOCUMENT TEXT

Global Changes: Specified guidance document names were amended so that they match the title of the guidance document within the regulation text; the dates in each footer were updated to reflect the new date of incorporation by reference, April 23, 2021; and, where "7 CFR" is cited without a section number, "part 205" has been added.

10001(a)(1) OCal 1000: Subjects were rearranged in alphabetical order to support use of this document as a reference.

All information regarding Genetically Modified Organisms (GMO) was consolidated under one GMOs heading with no subheadings. Within the text under GMOs, "under 3 CCR §10000" was replaced by "in the OCal regulations" because the reference should apply to the OCal regulations in full.

A References section was added with references to NOP Handbook polices that discuss each of the subjects addressed in OCal 1000 in more detail. NOP policy memos contain background information that may be of interest to regulated entities.

10001(a)(2) OCal 2006: "A Notice of Proposed Suspension or Revocation will become a Suspension or Revocation if it is not appealed within the time allotted in section 10706 of the OCal regulations. After an appeal, if the Notice of Proposed Suspension or Revocation is upheld, the department will issue a Notice of Suspension or Revocation" was added to clarify that a Proposed Notice of Suspension or Revocation issued by a certifying agent will convert to a Notice of Suspension or Revocation if it's not appealed. In instances of an upheld Proposed Notice of Suspension or Revocation, the department will reissue the notice as a final Suspension or Revocation. The department, therefore, will issue all final Notices of Suspension or Revocation.

10001(a)(5) OCal 2609: Under the Policy section, "Monday through Friday, excluding holidays" was added for clarity. "Scope" was replaced with "type" because OCal certifications, commensurate with California commercial cannabis licensing, calls its certifications "types" rather than denoting a "scopes."

Under Records, subsection 4.1, "accredited by the department" and "certifying agents accredited by the NOP will maintain records according to the NOP regulations" were added to clarify that certifying agents certified by the department are required to maintain records according to the OCal regulations and certifying agents accredited by the NOP are required to maintain records according to the NOP are required to maintain records according to the NOP regulations, though the record maintenance requirements are the same for both programs.

10001(a)(6) OCal 2610: Under the Policy section, "For example, during a complaint investigation that involves application of prohibited substances, the OCal Program may request copies of an NOP-accredited certifying agent's procedures" was added to improve transparency by illustrating a context in which the department may ask for a copy of an NOP-accredited certifying agent's procedures for sampling and testing.

Under Procedure subsection 4.2, "Sample collectors may choose to select samples which attempt to detect contamination where it is most likely to occur due to risk factors present at a given operation or a location within an operation" was added and "Risk of contamination may be considered when selecting samples or sample location" was removed. The program had substituted the more concise sentence for the longer NOP language but determined that the NOP language provided needed information.

Also under Procedure, subsection 4.5 was removed because the department determined it was unworkable.

Under the References section, the website address

"www.codexalimentarius.net/download/standards/43/CXG_041e.pdf" was added to assist with accessing the Codex Alimentarius Commission guidance.

10001(a)(7) OCal 2611: Under the Policy section, "in circumstances such as an appeal by a certified operation of a certifying agent's notice of proposed revocation due to application of prohibited substances" was added to increase transparency by providing an example of a situation in which an NOP accredited certifying agent may be asked to provide the department with a copy of their procedures for sampling and testing.

Under Procedures, subsection 4.1, "Whatever method is used to detect pesticide residue" was added to clarify that although the QuECheERS method is mentioned,

using an alternate method is fine as long as it can test for analytes listed on OCal 2611-1, substances prohibited for use on cannabis by California state law, and any additional analytes required by the certifying agent.

Also under Procedures, subsection 4.1, "Included in the Bureau of Cannabis Control's regulations § 5719" was replaced by "for substances prohibited for use on cannabis by California state law" to avoid confusion. The Department of Pesticide Regulation (DPR) determined which substances are prohibited for use on cannabis but this information is located in Bureau regulations. Because the Bureau will soon combine with other cannabis licensing agencies to form a new state entity, its name and the specific regulations are not cited but the regulations can, now and in the future, be found easily through an online search for "substances prohibited for use on cannabis by California state law." This is consistent with the language used in section 10105(a)(3).

Under the Laboratory selection requirements:

- The text is rearranged so that laboratories that hold accreditation to ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories do not need to be approved by OCal on a case-by-case basis. The department determined that this accreditation is sufficient to determine the lab's fitness.
- "Or" was added to the end of the ISO/IEC bullet to clarify that the reader may pick one of the choices presented.
- In subsection (b), bullet two, "pursuant to section 10711(f) of the OCal regulations" was added for clarity and consistency because the referenced section of the OCal regulations provides the criteria the department will use to evaluate an alternate standard.

10001(a)(9) OCal 2613: Under Procedure, subsection 5.3.2, "The notice should require corrective actions to prevent future contamination" was added for comparability to the corresponding NOP guidance document.

10001(a)(11) OCal 2615: Under Policy and Procedures, subsection 3.1.2 (b)(5)(E), the construction "and/or" was added to clarify that a cultivator can choose from the listed inputs and does not need to use all of them.

10001(a)(12) OCal 3012: Under the Policy section, item two was amended to say "Certifying agents may consult with material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65). These material review organizations must abide by, OCal guidance document series' 5033, which detail the procedures and decision trees for classifying materials used for OCal cannabis production, and 5034, which clarify certain materials for use in OCal production. These documents include an illustrative list of allowed natural and synthetic materials and a limited appendix of materials prohibited in OCal production. The California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program may be consulted for their review of organic crop materials. The Organic Materials Review Institute (OMRI) may be consulted for materials used in OCal production." This language is in the corresponding NOP document except instead of referring to the Agricultural Marketing Service, which references NOP guidance documents NOP 5033 and 5034, the text refers directly to OCal guidance documents 5033 and 5034. This addition is comparable to the NOP. It was initially removed because OCal is not associated with the USDA, Organic, or OIM, but it was determined that material reviews performed by material review organizations accredited to the ISO standard referenced should be accepted by the department in order to be comparable with the NOP.

10001(a)(14) OCal 5008: Under the Background section, the bullets "Polyglycerol phthalate ester of coconut oil fatty acid (CAS Reg. No. 66070-87-9); Revoked in 71 FR 45415, August 9, 2006" and "Sodium fluoride (CAS Reg. No. 7681-49-4); Revoked in 70 FR 31401, June 1, 2005" were added. This is comparable to NOP 5008. They were unintentionally omitted.

10001(a)(15) OCal 5020: Under Appendix A, item b3, the text "For lands coming into production for the first time or returning to production (e.g. Conservation Reserve Program (CRP) lands leaving the federal program and requesting organic certification), a new conservation plan can examine and implement a range of alternative practices to

enhance the natural resources of the land" was added. It is comparable to the corresponding NOP document. This item was initially omitted from the OCal guidance document because it applies to federal lands. Upon re-reading, however, the department determined that actually does not apply to federal land but to land that is leaving the federal program.

10001(a)(17) OCal 5023: Under the Policy and Procedures section, subsection 3.3, "agree" was added to the last sentence in the subsection. This word was inadvertently omitted. Under Appendix A, item 7, third bullet, "handler" was replaced by "producer." The department does not refer to certified operations or operators as "handlers" but as either cultivation or distribution operations, which can be referred to together as "producers."

10001(a)(18) OCal 5025: Under the Policy section, subsection 3.3, b, number 2, "Types of crops grown nearby (e.g. genetically modified crops)" and number 5, "Any other potential point or non-point sources of contamination" were added to the list. This is comparable to the corresponding NOP document. These items were inadvertently omitted.

10001(a)(19) OCal 5026: Under the Policy section, a reference to the title 22, California Code of Regulations, § 64533.5 was added to the Safe Drinking Water Act (collectively, SDW Laws) because certified operations would need to comply with state as well as federal law. Likewise, under the References section, the California citation was added.

10001(a)(20) OCal 5029: Under the Policy section, "A cultivator must follow the OCal sourcing procedures outlined in section 3.1 and document this process. Evidence of a cultivator's documented process for procuring OCal seeds as well as all agricultural inputs used during cannabis cultivation, as described in section 3.2, must be provided to the inspector during the annual inspection. A certifying agent must assess whether the procedures, agricultural inputs, documentation, and verifying evidence provided by the certified operation are compliant with the OCal regulations, as outlined in section 3.3" was replaced by the original language used in the corresponding NOP guidance documents, "Producers should develop and follow procedures for procuring OCal

seeds, annual seedlings, and planting stock and maintain adequate records as evidence of these practices in their OCal system plan (OSP). Producers must also provide clear documentation regarding the inputs and materials used during cannabis production (as required at § 10201(c)(2) of the OCal regulations)). Certifying agents must assess procedures and documentation of certified production and handling operations as they source seeds, annual seedlings, and planting stock on an annual basis. Each of these concepts is described in more detail below." The department determined that the language used in the NOP document was clearer.

Under subsection 3.1.3, "as defined in the OCal regulations" was removed because it was redundant. "When sourcing non-OCal seeds and planting stock, certified operations must comply with the following" was added to clarify that instruction regarding sourcing is contained in the list that follows.

10001(a)(22) OCal 5033-1: Under the Purpose section, the text was corrected to say the National List is "cited in" the regulations rather than "incorporated into" them.

Under section 4, Classification examples of agricultural inputs, the duplicate Calcium Oxide and its accompanying information were removed.

The additional resources provided in OCal 5033-2 were copied under section 5, More Classification Resources, in order to support ease of use and because 5033-2, will not be included in the OCal Handbook.

10001(w) OCal 5033-2: This document was a compilation of footers from NOP 5033-1. It was created as separate document because the same size footer and body text may cause confusion (fonts less than 12 points are not accessible online per ADA guidelines). The department determined it does not need to go through rulemaking because it does not include instruction.

10001(a)(23) OCal 5034: Under the Policy section, subsection 4.1, "by the certifying agent" was added to clarify who will allow materials for use on a case-by-case basis. Under section 5, Procedure, item e, "OCal 5033-2 Definitions of Terms Used in Classification" has been removed because it will not be included in the OCal Handbook.

10001(a)(24) OCal 5034-1: "nonmanufactured cannabis and cannabis products" was added to the first paragraph to support consistency with the regulations and to clarify that the guidance applies only to production of nonmanufactured cannabis and cannabis products. Within the list of materials, Ethylene Gas was removed because it is specific to manufacturing.

10001(a)(26) OCal 5036: Under the OCal regulations section, "3 CCR § 10202. Land Requirements" was added for clarity.

Under the Policy section, the definition for treated lumber has been reframed as a definition and relocated to the beginning of the policy section to increase clarity. "Treated lumber is in contact with OCal cannabis or with soil located within the OCal cannabis cultivation site (a location where commercial cannabis is planted, grown, harvested, dried, cured, graded, or trimmed, or a location where any combination of those activities occurs, per CalCannabis regulations, 3 CCR section 8000(j)), or on which treated lumber is used for new or replacement purposes (see examples in section 3.2)" was added to clarify that the policy applies only to soil that's located within the cultivation site, where the soil may come into contact with OCal cannabis. "Or on which treated lumber is used for new or replacement purposes" was relocated from the last paragraph in the policy section to improve clarity. "Within the context of an operation's OSP" was added to increase comparability with the corresponding NOP document and to clarify that use of treated lumber should be documented in the OSP and evaluated within that context.

Under Policy subsection 3.1, "as long as the lumber does not come into contact with nonmanufactured OCal cannabis or soil" was added to clarify that although a newly acquired parcel may have treated lumber, it cannot come into contact with OCal cannabis or soil. "Crops" was replaced by "OCal cannabis" because the OCal program is specific to cannabis and the prohibition applies to OCal cannabis, not all cannabis grown on the premises if the operation is a split operation.

Under the References section, "Federal" was replaced by "State and federal" to accommodate the additional CalCannabis regulations citation, added because

definitions from the CalCannabis regulations are used within the document. "References" was replaced by "regulations" and the NOSB citation was moved under the Other references section so that the sections' titles more accurately forecast their contents.

Section 10104. Recordkeeping by certified operations.

10104 (d): The text "cultivation or distribution" and "respectively" were added to clarify that the added regulation citations, for CalCannabis and the Bureau of Cannabis control, refer respectively to these operations. "Monday through Friday, excluding holidays" was added for clarity.

Section 10105. Allowed and prohibited substances and methods in OCal production.

10105(a)(3): "under state law as determined by the Department of Pesticide Regulation" (DPR) replaced "as described in the Bureau of Cannabis Control regulations, 16 CCR section 5719" to avoid confusion. While the DPR determined which substances are prohibited for use on cannabis for the Bureau of Cannabis Control, this information is located in Bureau of Cannabis Control regulations.

Section 10209. Commingling and contact with prohibited substance prevention practice standard.

10209(a): "OCal cannabis and" was added for clarity and consistency because the first part of the sentence refers to "OCal and non-OCal cannabis and nonmanufactured cannabis products"

Section 10302. OCal Seal.

10302(b), **(b)(1) and (b)(2):** The color seal was removed because the colors will not be visible when the regulations are encoded and published.

Section 10400. Areas and duration of accreditation and registration.

10400(b): "not more than" was removed for clarity and consistency; in section 10405, the accreditation period is referred to as "five years." The department chose to use "five

years" consistently throughout, rather than "not more than five years," because it's more concise and clearer.

Section 10401. Requirements for accreditation.

10401(a)(10): "and provide such records to authorized representatives of the department" was replaced with "mail to the physical or email address listed on the OCal Program website" to clarify how the records would be provided to the department. "By the department" was added to the end of the sentence to clarify that the records are to be provided at the request of the department.

10401 (a)(19): "any other" was replaced with "all" and "or determined by the department to be necessary" was struck to clarify that an accredited entity must comply with the terms outlined within the chapter, not any other terms determined by the department.

Section 10402. Application for accreditation.

10402(a)(10): "electronically or by mailing a hard copy of the application to the department at OCal Accreditation, P.O. Box 942872, Sacramento, CA 94271-2872" was replaced with "by mail to the physical or email address listed on the OCal Program website" to provide the department with more flexibility, considering the impending consolidation of the commercial cannabis agencies, and to specify email as the method of electronic submission.

10402(a)(7): "the applicant shall provide" was added to clarify that the certificate of qualification will come from the applicant.

10402(g): "Including, but not limited to, additional inspection reports, an external program review, and evidence that an applicant without certification experience can comply with the regulations" was added for transparency and to make clear what types of other information the department may require to evaluate an application for accreditation.

Section 10409. Registration.

10409(a): "for an accredited certifying agent" was added to clarify that only an accredited certifying agent is eligible to register as a certifying agent under the department.

10409(a)(10): "as applicable" was added to clarify that certifying agents accredited by the department will provide a conflict-of-interest disclosure report pursuant to section 10402(d)(2) of the OCal regulations and certifying agents accredited by the National Organic Program (NOP) will provide a conflict-of-interest disclosure report pursuant to the NOP regulations, 7 CFR section 205.504(c)(2).

10409(a)(12): This provision was removed because all eligibility criteria are set forth in the regulations.

Section 10410. Registration renewal and reporting.

10410(a): "January 2" was replaced with "January 1" because the registration is not annual if it starts January 2 and ends January 1. "By" was added before "January" to clarify that the registration renewal is not due on January 1, since January 1 is a holiday.

10410(b): "of registration, regardless of the fine's due date," was replaced with the reference "pursuant to section 10701(e)(4) of this chapter" because the referenced section of the regulations requires that fines be paid prior to renewal.

10410(d)(9): "Including, but not limited to, an OCal system plan, a copy of a notice of nonviolation issued to an operation, and results of an NOP audit that took place during the previous year" was added to support transparency and to make clear what other types of information the department may require to evaluate a renewal application.

Section 10501. Application for certification.

10501(a)(8): "department" was removed because the department will not certify operations. "Including, but not limited to, additional information regarding the origin of

inputs, amendments to the OSP, and information regarding substances used on adjacent land" was added to support transparency and to make clear what other types of information the certifying agent may deem necessary to determine compliance with the regulations.

Section 10502. Review of certification application.

10502(c): "Similarly, an applicant that voluntarily withdraws its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial" was added to be comparable with the NOP, which includes this language in 7 CFR section 205.402(c). This was inadvertently omitted from the OCal regulations.

Section 10506. Continuation of certification.

10506(a)(4): "Including, but not limited to, additional information regarding the origin of inputs and evidence of correction of minor noncompliances" was added to support transparency and to make clear what other types of information the certifying agent may deem necessary to determine compliance with the regulations.

Section 10600. Fees and other charges for accreditation and accreditation renewal.

10600(b): "Accreditation fees are based on the time required to render the service provided calculated to the nearest 15-minute period. Fees cover the review of applications and accompanying documents and information, evaluator travel time, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service" was added to provide transparency and to be comparable with the corresponding NOP regulation, 7 CFR section 205.640(a).

Section 10601. Fees for registration and registration renewal.

10601(a)(1) and (a)(2): These sections were revised so that the incentive fees offered for 2020 are now offered for the first 12 months following the start date of the program.

Section 10701. Adverse actions.

10701(e): "The amount of the fine assessed for each violation shall be based upon the scope of the violation, the seriousness of the deception, and the impact of the fine on the violator, including the deterrent effect on future violations" was added to provide transparency regarding the criteria the department will consider when determining the amount of a fine. This is commensurate with criteria used to determine other fines within the department.

Authority: Business and Professions Code (BPC) sections 26030 and 26031.5 were added. They were inadvertently omitted from the regulations.

Section 10702. Investigation of certified operations.

10702 (d) and (e): "determined in subdivision (c)" was added to specify when the "specified timeframe" was determined and where it came from. Subdivision (c) explains that the department may specify a timeframe for investigation when assigning a complaint against a certified operation to its certifying agent.

Section 10703. Non-compliance procedures for certified operations.

10703 (a): "proposed" was inserted before "suspension" and before "revocation" to clarify that this provision refers to the authorized action of a certifying agent, which may issue notice of proposed certification suspension or revocation but may not suspend or revoke a certification.

10703(e): "Act or" was a typo and was removed.

10703 (f)(1): This provision was removed in response to a comment that it was confusing since certifiers cannot issue Notices of Suspension or Revocation. The provision was left in the regulations inadvertently during drafting when the Department revised section 10701 to say only the Department, not the certifying agent, may suspend or revoke a certification.

10703(g)(1)(D): "due to the department" was replaced with "in accordance with section 10701(e)(3) and (4))" because the referenced section provides more clarity regarding payment of fines and their impact on reinstatement.

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

10705(g)(1): "prior to consideration for reinstatement" was replaced with "pursuant to section 10701(e)(3) and (4)" because the referenced section provides more clarity regarding payment of fines and their impact on reinstatement.

Section 10707. Appeals - submission.

10707(b): this subsection was added to clarify that the respondent may request a telephonic hearing and how a telephonic hearing may be requested.

Section 10708. Appeals-evidence provided by certifying agent

10708 (a): "proposed" was inserted to clarify that this provision refers to the authorized action of a certifying agent, which may issue notice of proposed certification suspension or revocation but may not suspend or revoke a certification. "Notice of denial, or fines" was added to clarify that these items, in addition to those already included in the provision, may also be appealed. This change was in response to a comment submitted during the 45-day comment period.

10708 (b): "proposed" was inserted before "suspension or revocation" to clarify that this provision refers to the authorized action of a certifying agent, which may issue notice of proposed certification suspension or revocation but may not suspend or revoke a certification.

Section 10710. Appeals - conduct of informal hearing.

10707(b): "pursuant to section 10707" was added to clarify that the appeal should be submitted as directed in section 10707.