SUPPLEMENT II 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 Supplement II to the Initial Statement of Reasons provides amendments to the Initial Statement of Reasons (ISOR) made after it was published for the 45-day public comment period that began May 1, 2020. A first Supplement to the ISOR was published August 31, 2020 for 15-days of public comment.

Supplement II corrects and completes the purpose and necessity explanations in the ISOR. ISOR purpose and necessity explanations that require modification and were not modified in the first Supplement, are amended in this document.

The purpose and necessity statement from the ISOR has been copied here and corrected. **Additions are indicated by bold text**. **Deletions are indicated by bold and ~~strike through text~~.** Where a purpose and necessity explanation in the ISOR contains an error that does not substantively affect a reader's understanding of the text, such as a formatting error, the correction(s) will be described in the Final Statement of Reasons.

POLICY STATEMENT OVERVIEW

Business and Professions Code (BPC) section 26062 (a)(1) requires the CDFA certification to be comparable to Article 7 (commencing with section 110810) of Chapter 5 of Part 1 of Division 104 of the Health and Safety Code (Article 7).

While the purpose and necessity explanations do not directly reference comparability with Article 7, Article 7 often repeats or refers to National Organic Program (NOP) regulations and is meant to be interpreted in conjunction with the

NOP and State Organic Program regulations, with which comparability is documented throughout the Initial Statement of Reasons.

GUIDANCE DOCUMENTS - BACKGROUND

Many OCal guidance document purpose and necessity explanations have been amended. In addition to providing more comprehensive explanations for the differences between each OCal guidance document and its corresponding NOP guidance document, a brief explanation of how the guidance documents came to be and why they have been incorporated by reference may assist commenters by providing a context for their purpose and function.

The department is required by Business and Professions Code section 26062 (a)(1) to create a certification program that is comparable with the National Organic Program (NOP). The NOP regulations and guidance documents are interdependent. The OCal Program must, then, complement its regulations with instructions found in the NOP guidance documents that support the department's statutory mandate to be comparable to the NOP. Following are the considerations that went into deciding how this would be accomplished.

The department initially planned, once the program started, to reference the NOP guidance documents to assist with interpreting the regulations. Unfortunately, the California Administrative Procedures Act (APA) forbids reliance on outside documents for regulation interpretation. These outside documents are called "underground regulations."

Incorporating the NOP guidance documents by reference seemed like the next best solution. The NOP guidance documents, however, could not be incorporated by reference because the department cannot hold its regulated entities accountable for following instructions written for other regulations.

Transferring the appropriate directions from the guidance documents to the regulations was briefly considered but important instructions could be lost in parsing what should and shouldn't be included.

Finally, in conference with the Office of Administrative Law, the department determined that all necessary NOP guidance should be re-created specifically to accompany the OCal regulations and that, in compliance with the APA, this guidance would be incorporated by reference.

Most of the guidance documents contain a References section. References are for information only.

PURPOSE AND NECESSITY

Instructions and policies set forth in the NOP guidance documents that will increase OCal Program comparability to the NOP have been reproduced in corresponding OCal guidance documents. The department made only superficial changes—changes that do not substantively alter the policies and instructions set forth in the corresponding NOP document—to the NOP guidance documents in creating them as OCal guidance documents. The overriding necessity for every guidance document is comparability to the NOP. Most superficial changes are described below and accompanied by a necessity explanation.

- **Explanations, justifications, industry discussion summaries, scope statements, and National Organic Standards Board (NOSB) related references and considerations are not included in the OCal guidance documents. Unlike the NOP, which has myriad reasons for creating and amending guidance documents, including a statutory mandate to consult with the NOSB, the basis for the creation of every OCal guidance document is the same: comparability to the NOP.**

- **Policy language intermingled with the excluded justification, discussion summaries, and scope statements in the NOP guidance documents are integrated elsewhere within the OCal document. Making sure all policy statements, even those not listed or repeated under the Policy section in the NOP document, were included in the corresponding OCal document was necessary for program comparability.**

- **Except in cases where a guidance document focuses on a subject area that has a set of specialized words or terms, definitions sections have been removed. This is necessary to reduce repetition as definitions are included in Section 10000 of the regulations. Occasionally, a specialized word or term is defined within the text of a guidance document.**

- **NOP guidance and instruction were adapted to accommodate production of nonmanufactured cannabis products in compliance with commercial cannabis regulations. For example, directions specific to producing nonmanufactured cannabis and cannabis products, such as post-harvest processing activities, have been added; directions specific to producing manufactured products, such as instruction regarding product ingredients, have been removed; NOP directions that either overlap or conflict with commercial cannabis regulations, such as NOP chain of custody instruction, were replaced with instructions that account for commercial cannabis regulation.**

- **Where necessary, provisions of the OCal regulations are re-stated in the guidance documents in order to increase clarity and support ease of use. The department anticipates that the guidance documents will often be used independent of the regulations.**

- **In an effort to increase readability and improve clarity while maintaining the spirit of the original NOP documents, the Department made the following revisions to the text and organization of the guidance documents:**
  - **All relevant OCal regulations are listed in Section 2.**
  - **In general, to the extent possible while maintaining the general spirit of the corresponding NOP guidance document, the Policy section provides "what" while the Procedures section explains "how."**
  - **Many redundancies were removed.**
  - **Each section more closely focuses on a single topic area in order to avoid confusion.**
  - **Some section titles were revised to more accurately reflect the section's contents.**
  - **Consistent terminology is used.**

- **OCal guidance documents were reformatted to be ADA compliant. Therefore, items like footnotes, because they can be confusing when they are the same font size as the body text, were reproduced as separate documents if they provided additional instruction.**

- **Language has been revised and added to reflect the OCal Program's focus on cannabis and the program's location within the cannabis regulatory environment.**

More generic global explanations and necessity statements that covered all OCal regulations, including the guidance documents, were published May 1, 2020 in the Initial State of Reasons under the Purpose and Necessity section. They are copied below for commenter convenience.

- The term organic has been replaced with OCal unless used as the labeling term organic as defined in the NOP regulations (title 7 of the Code of Federal Regulations

(CFR), part 205). This was a necessary change because organic is a federally designated term that may only be used to sell, label, or represent products with the express consent of the NOP. The department came up with the alternate term, OCal, and determined it was reasonable to use this labeling term to avoid conflict with the federal designation.

- The NOP certifies producers and handlers as defined in its regulations. These terms have been changed to coincide with the commercial cannabis license types, cultivation and distribution (collectively referred to as producers). This change is necessary because each commercial cannabis licensee already has a license type so the department determined it was reasonable for the OCal Program to reference the existing license types rather than renaming them according to the NOP defined terms producer and handler, which may cause confusion.

- Accredited certifying agent is often replaced by registered certifying agent. The department determined it was necessary to change accredited certified agent because as explained in section 10400, the department, in addition to accrediting certifying agents, will also register certifying agents. A certifying agent may be accredited, by the department or the NOP, but it may not certify under the OCal Program unless it is also registered by the department. Therefore, while the term accredited certifying agent may apply to entities not authorized to certify under the OCal Program, registered certifying agent, for the purpose of these regulations, applies only to those entities authorized to certify under the OCal program.

- The term agricultural product was changed to non-manufactured cannabis product. This change was necessary because the proposed department program will certify only non-manufactured cannabis products.

- Administrator and Secretary are replaced by the department, meaning the California Department of Food and Agriculture or the representative to whom authority has

been delegated. This is necessary because the authority to establish the OCal program was granted to the department.

- Except where the National List of Allowed and Prohibited Substances (National List), starting at 7 CFR section 205.600, is referenced, references to the NOP regulations have been replaced by references to the OCal regulations because the department does not have the authority to enforce the NOP regulations. It was necessary for clarity to change regulation references to OCal regulations.

- Unless explained within the necessity statement, syntax changes are for clarity and do not alter the meaning or purpose of the referenced comparable NOP section or provision.

If an OCal Guidance Document diverges from its corresponding NOP Guidance Document in a manner not covered by the above global necessity statements, thereby requiring additional necessity explanation that wasn't included in the ISOR, or the necessity explanation in the ISOR requires some other correction, an amended explanation is presented below.

Section 10001. Incorporation by Reference.

Subdivision (a) (1) incorporates OCal 1000 Methods and Materials in OCal Production, April 6, 2020. This is necessary to clarify whether certain methods and materials are prohibited or permitted under the OCal regulations. The specified methods and materials were questioned by NOP stakeholders and researched, examined and addressed by the NOP—in NOP Policy Memorandums **10-1,** 11-~~12~~**13**, **12-1,** ~~13-1~~, 13-2, 13-3, 14-1, and 15-2—in the same manner as they are addressed in this document. Incorporation of this document is intended to support the OCal Program in maintaining comparability with the NOP.

Subdivision (a) (5) incorporates OCal 2609 Unannounced Inspections April 6, 2020. This is comparable to NOP guidance document number 2609 **except that NOP document section 4.1.5, "Unannounced inspections may fulfill the requirements for annual on-site monitoring inspections…if the inspector is able to conduct a full inspection of the operation as required by this section" was not included in the OCal document because it seemed in conflict with NOP document section 4.1.6, which says "certifying agents should direct the inspector to a portion of the operation to review during an unannounced inspection."**

Subdivision (a) (6) incorporates OCal 2610 Sampling Procedures April 6, 2020. This is comparable to NOP guidance document number 2610 **except for the following:**

- **The annual requirement to submit Certificates of Analysis (§ 10410(d)(8)) as evidence of compliance with OCal regulation § 10711(d) was added. This addition was necessary so that this document provides complete sampling and testing instructions.**
- **The phrase "certifying agents should work with the lab to determine a sufficient sample amount" replaced the suggested sample amounts provided by the NOP. This replacement was necessary because the department determined through research that laboratories that test cannabis require vastly different sample amounts. This may be specific to cannabis testing. It's possible that mandatory commercial cannabis testing has spawned improvements that allow testing of very small samples. Labs that aren't as advanced require larger samples.**
- **Section 4.5 of the NOP document provides detailed instructions regarding maintaining sample integrity. These instructions are listed in the OCal document under section 4.4 *except for* instructions regarding labeling the package for shipping and making sure the samples do not arrive on a weekend. This change was necessary because of state and federal laws. Cannabis is a Schedule 1 drug and cannot be shipped through the federal**

mail system. Per State law, it must be transported by a licensed commercial cannabis transport-only distributor who will not drop-off cannabis to a lab when it is closed.

- **Section 4.5 of the NOP document also includes detailed instructions regarding refrigeration. This instruction is boiled down in the OCal document to "Certifying agents should follow any additional lab requirements for maintaining sample integrity for wet cannabis samples." This change was necessary for the same reasons the OCal document does not include sample size instructions. The OCal program determined through research that labs would prefer to provide direction regarding temperature as it will vary depending upon the type of sample taken.**

Subdivision (a) (15) incorporates OCal 5020 Natural Resources and Biodiversity Conservation, April 6, 2020. This is comparable to NOP guidance document number 5020 except the Biodiversity Conservation Resources **footnotes** have been removed ~~**OCal 5020-1, to comply with Americans with Disabilities Act requirements for documents available online.**~~

Subdivision (a) (25) incorporates OCal 5034-2 List of Materials Prohibited for Use, April 6, 2020. This is comparable to NOP guidance document number 5034-~~**2**~~**24**.

Section 10200. General.

Subdivision (b) specifies production practices implemented in compliance with this chapter must maintain or improve the natural resources of the operation, including soil, water, wetlands, woodlands, and wildlife, and respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. This is comparable to NOP section 205.200 except that the requirement to "respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity" was added to clarify this

required element of OCal production as defined in section 10000 (bb) of this chapter~~.~~**, which is comparable to NOP section 205.2.**

Section 10201. OCal system plans.

Subdivision (a) specifies that a licensed cultivator or distributor intending to sell, label, or represent cannabis or nonmanufactured cannabis products as OCal shall develop an OSP that is agreed to by the cultivator or distributor and the registered certifying agent. This subdivision is necessary to clarify the registered certifying agent must approve, or agree to, the cultivator or distributor's OSP **because a registered certified agent is qualified, through accreditation and registration, to evaluate whether an OSP is in compliance with the OCal regulations. This subdivision is comparable to 7 CFR section 205.201 (a).**

Section 10203. Soil fertility and crop nutrient management practice standard.

Subdivision (a) (b) and (c) (1-4): direct a cultivator to select tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of the soil and minimize soil erosion. Specifically, a cultivator must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials. Plant and animal materials must maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include raw animal manure which must be composted unless applied as specified. Composted plant and animal materials must be produced through the process described. Uncomposted plant materials and vermicompost may also be used to maintain or improve the biological condition of the soil. This is comparable to NOP section 205.203 (a-c), **except that the department added the term "vermicompost", (section 10203 (c)(4)). NOP guidance document number NOP 5021, "Compost and Vermicompost in Organic Crop Production," cites 7 CFR section 205.203(c) as the regulation it addresses. OCal created a comparable guidance document with the same name and determined that adding**

the term "vermicompost" to the regulation was necessary to improve cohesion with the corresponding guidance document and increase clarity.

Section 10300. Non-manufactured cannabis products labeled OCal.

Subdivision (b) (1-3) specifies that all cannabis products labeled as OCal and all ingredients identified as OCal in the ingredient statement of any product must not be produced using excluded methods, pursuant to section 10105(a)(4) of this chapter, be produced using ionizing radiation, pursuant to section 1010**4**5(a)(5) of this chapter, be processed using sewage sludge, pursuant to section 10105(a)(6) of this chapter, ~~**or include OCal and non-OCal forms of cannabis**~~. This is comparable to NOP section 205.301(f).

Subdivision (c) **(1-3)** provides that OCal cannabis product packages may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product: the term OCal to modify the name of the product; the OCal seal; or the seal, logo, or other identifying mark of the certifying agent which certified the cultivation or distribution operation producing the finished product provided that such seals or marks are not individually displayed more prominently than the OCal seal. This subdivision is intended to ensure that the term OCal and other similar terms or phrases are not used on a product package in a way that misleads consumers as to the contents of the package. This includes wording similar to some provisions of NOP section 205.304 (a) (3).

Section 10400. Areas and duration of accreditation and registration.

Subdivision (a) specifies that the department shall accredit or register a qualified applicant to certify cannabis operations for the OCal Program ~~**in the areas of cultivation, distribution, or both.**~~ This is comparable to NOP section 205.500 (a).

Subdivision (b) specifies that accreditation shall be for a period of **~~not more than~~** five **~~(5)~~** years from the date of approval of accreditation pursuant to section 10405 of this chapter. This is comparable to NOP section 205.500 (b).

Subdivision (c) specifies registration shall be valid until January 1 of the following year pursuant to section 10409 of this chapter. This is necessary because the department determined that having all registration renewals fall on the same date provides for administration efficiency and it is reasonable for the renewal date to be the start of the year because it is a standard date. Initial registration may be for a term of less than one year but renewal registration will last one year, starting January **~~2~~1** and expiring January 1 of the following year unless registration is terminated by the registered certified agent or suspended or revoked by the department.

Section 10402. Application for accreditation.

Subdivision (e) (1-3) specifies the activities of applicants who currently certify cultivation or distribution operations and requires these applicants to submit a list of all cultivation or distribution operations **certified during the current or previous year** by the applicant, copies of at least 3 different inspection reports and certification evaluation documents for cultivation, distribution, or manufacturing operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and the results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities. This subdivision is necessary because it allows the program to evaluate whether a certifying agent is competent and able to certify to the program's standards, which aids the auditor's decision whether or not move to the next step in the accreditation process. This is comparable to NOP section 205.504 (d) **except that OCal is requesting a list of operations certified during the current and previous year only, rather than a list of all certified operations. This is necessary because upon accreditation and registration of the applicant, these operations may**

automatically receive OCal certification. The certification, therefore, should have been conferred within the past year since OCal requires annual re-certification.

~~**Subdivision (g) requires that an applicant pay and submit fees to the department in accordance with section 10700 of this chapter. This is comparable to NOP section 205.501 (a) (17).**~~

Section 10403. Review of accreditation application.

Subdivisions (a) (1) and (a) (2) (A-B) require that the department notify the applicant in writing that the application has been accepted for further review or that the application is incomplete and the reasons for the incompleteness. It also stipulates that the department must receive the missing information or fee, payment, or fine from the applicant no more than 30 calendar days from the date of notification. In addition, failure to provide the designated missing information or any fees, payments, or penalties that are due and payable will result in disqualification of the application from further consideration and the applicant will have to reapply and pay a new application fee. This is necessary because it establishes the process the department will use to notify applicants of missing information and give applicants the opportunity to supply the information. The department determined the submission time frame to be adequate for an applicant to provide missing information without unreasonably delaying the processing of an application and impacting staff efficiency. This is consistent with other department regulations. If the application is **deemed** abandoned, **the applicant may reapply and pay a new application fee. Again, in order to avoid unreasonable delay and promote efficiency, an abandoned application will be disqualified from consideration.** The forfeited fee will cover the time the department will spend processing and reviewing the application in order to assess its completeness. **This is necessary to provide clarity and transparency regarding reapplication.**

~~**Subdivision (c) provides that if the application is deemed abandoned the applicant may reapply and pay a new application fee. This is necessary to provide clarity and transparency regarding reapplication.**~~

Section 10405. Granting accreditation and registration.

Subdivision (e): Specifies that accreditation shall be valid for a period of five (5) years from the effective date of accreditation. The department shall grant the accredited certifying agent a grace period between the accreditation expiration date and January 1 of the following year so that accreditation and registration renewals may be applied for and completed simultaneously. Accreditation may be renewed pursuant to section 10409 (c) of this chapter unless the accredited certifying agent voluntarily ceases its certification activities or the accreditation is suspended or revoked pursuant to the requirements of section 10703 of this chapter. This is necessary to establish the period of accreditation, describe where to find renewal procedures within this chapter, and to explain that there will be a grace period between the accreditation expiration and the registration expiration so that the accreditation and registration renewal process may be undertaken and completed simultaneously in order to eliminate redundancy. The 5 year time period for accreditation is consistent with the NOP **section 205.500(b)**.

Section 10407. Accreditation renewal.

Subdivision (f): provides that the accredited certifying agent who no longer wishes to maintain its department accreditation must surrender its accreditation by submitting written notification to the department and must also transfer to the department or make available all records or copies of records concerning the accredited certifying agent's certification activities. Written notice is necessary to make sure the department is aware that the certifier no longer wishes to be an OCal certifying agent. Records may be used to verify that an operation was certified in compliance with the OCal regulations.

Section 10409. Registration

Subdivision (a) (1-12): specifies the items the application shall include: the registration fee, proof of accreditation by the NOP if applicable, business information, areas of operation, a fee schedule, a conflict of interest report, the most recent annual internal program review, any other information the department requires to assist in the department's evaluation of the application; and a declaration that all information provided in the application is true and correct. **OCal and NOP regulations are cited in subdivisions (a)(10) and (a)(11) because certifying agents accredited by the department will provide a conflict-of-interest disclosure report and summary of findings pursuant to the OCal regulations and certifying agents accredited by the NOP will provide the same items pursuant to the NOP regulations.** This information is necessary for the department to identify the registrant and confirm eligibility for registration. This provision provides transparency by detailing required information and specifies that certifying agents accredited by OCal do not need to provide proof of accreditation.

Section 10504. Granting certification.

Subdivision (c) (1-6) specifies the information that will be printed on a certificate of OCal operation, including the name and premises address of the certified operation, the department-issued certification number, the effective date of certification, most recent inspection date , the active and valid commercial cannabis license numbers and license type names associated with the OCal operation, and the name, address, and telephone number of the certifying agent. This is necessary so all OCal certificates will provide the same information for verifying certification. This is comparable to NOP section 205.404**, except for the requirement for the most recent inspection date. This requirement was added because we would like for anyone who sees the certificate to know that certification requires an inspection—another mechanism, comparable to the NOP, for ensuring the integrity of the certification.**

Section 10703. Non-compliance procedures for certified operations.

Subdivision (g) (3) specifies a certified operation whose certification has been revoked will be ineligible to receive certification for a period of five years following the effective date of such revocation. This is necessary to establish the penalty period for revocation. This penalty period is based on that assigned for revocations by the NOP. This is comparable to NOP section 205.662 (f) (2) **except that, in the interests of transparency and fairness, the department does not allow that it may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility. A certification program has the opportunity to appeal a revocation. The best interest of the certification program may be considered within this process. If the outcome of the appeal is to uphold the revocation, however, the penalty will be applied according to the regulations.**

Section 10711. Inspection, testing, and reporting.

Summary of corrections to this section:

- Subdivision (g) was incorrectly numbered Subdivision (h) in the ISOR.
- Subdivision (h) was inadvertently omitted from the ISOR
- Subdivision (i) was incorrectly numbered Subdivision (g) in the ISOR. This numbering was also corrected in Supplement I.
- Subdivision (j) was inadvertently omitted from the ISOR but added in Supplement I. It is struck because the provision was struck from the regulations during a comment period.

Subdivision ~~(h)~~**(g)** when residue testing detects prohibited substances, the certified operation must be investigated by the registered certifying agent or by the department to determine the cause of the prohibited substance. This subdivision is necessary to establish that a registered certifying agent must investigate any prohibited substance detection. While the detection may not reach the level of exclusion, certified operations should be made aware of the issue, evaluate the risk of increased contamination and, if necessary, take measures to decrease or eliminate this risk.

Subdivision (h) specifies that a certified operation must provide its registered certifying agent with a copy of the Certificate of Analysis (COA) for any batch tested, pursuant to section 26100 of the Business and Professions Code, that is destroyed within 3 business days after notification of destruction. If the batch was held or destroyed due to residue from prohibited substances, the registered certifying agent shall investigate pursuant to section 10702 of this chapter.

Subdivision ~~(g)~~**(i)** specifies that results of all analyses and tests performed under this chapter will be available for public access unless the testing is part of a compliance investigation or action and that results may be reviewed as part of a department audit pursuant to section 10412 of this chapter. This is necessary because transparency is critical to consumer trust, which is fundamental to the success of any certification. This is comparable to section 205.670 (f) of NOP the regulations.