

Material Review

1. Purpose and sScope

This instruction specifies the criteria and process that registered certifying agents (certifiers) must follow when approving substances for use in OCal production. This instruction is for certifiers, who must meet § 10401(a)(19) of the OCal regulations as part of their accreditation.

- <u>2.</u> <u>OCal #Regulations,</u> <u>Title 3 California Code of Regulations (3 CCR)</u>
- 3 CCR § 10000. Definitions.
- 3 CCR § 10201. OCal cultivation and distribution system plan.
- 3 CCR § 10203. Soil fertility and crop nutrient management practice standard.
- 3 CCR § 10401. Requirements for accreditation.

3. Policy

Certifiers must review all materials used by OCal cultivators and distributors for compliance with § 10201(c)(2) of the OCal regulations, and specifically the National List of Allowed and Prohibited Substances (National List), title 7 of the Code of Federal Regulations (CFR) § 205.601 and § 205.602, and any annotations provided therein.

Certifiers have several options available for determining whether materials may be used in OCal cultivation or distribution:

- 1. Certifiers can verify that the material is allowed for use in OCal production by using the OCal regulations and the National List to evaluate the product, all of the ingredients within the product, and, if applicable, the manufacturing processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/formulator/manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).
- 2. <u>Certifying agents may consult with material review organizations</u>



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. Certifying agents may consult with the California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program.

In all cases, 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, Material Review Organization (MRO) or the Environmental
 Protection Agency or the CDFA OIM program;
- Make synthetic vs. nonsynthetic determinations in compliance with the OCal regulations and this document regarding the classification of materials;
- 3. Ensure that personnel conducting material reviews demonstrate appropriate education, training, and experience; and
- 4. <u>Create clear written protocols and procedures that the outline the depth and frequency of material reviews.</u>

4. Products with mMultiple Reviews

Some manufacturers of materials may submit their products for review to more than one certifying agent or Material Review Organization (MRO). For the purposes of this section, an MRO is an entity with expertise in verifying compliance of production and handling materials with the USDA organic regulations. MROs provide certifiers, input manufacturers, suppliers, and organic or OCal operations with an independent review and assessment of materials intended for use in organic or OCal production.



In the majority of cases, certifying agents and MROs reach the same determination regarding the allowance or prohibition of a product. On rare occasions, certifying agents and MROs reach different conclusions.

Where different certifying agents or MROs reach different conclusions on the allowance or prohibition of a material, the OCal Program will make a final determination regarding whether the product is allowed or prohibited for use in OCal production and any additional use criteria.

When certifying agents or MROs reach different conclusions, the certifying agent should:

- 1. Notify the OCal Program in writing.
- The OCal Program will review information from all parties to make a determination. The OCal Program does not approve or endorse branded (formulated) input products.
- 3. If the OCal Program concludes that the determination of allowance was in error and the material is prohibited for use in OCal production the OCal Program will instruct the certifying agent to rescind its approval of the product.
- 4. The OCal Program will communicate the determination to all certifying agents with a timeline, if appropriate, for the discontinuation of product use by certified OCal operations.

A decision made by certifying agents about the status of a branded (formulated) product remains in effect until the OCal Program notifies all certifying agents about the status of a material under the OCal Program.

5. References

<u>National Organic Program </u><u>≠Regulations</u>, Title 7_₹ Code of Federal Regulations (7 CFR part 205)

7 CFR § 205.601. Synthetic **sS**ubstances **aA**llowed for **uU**se in **o**rganic **c**rop **p**roduction.

7 CFR § 205.602. **<u>sS**</u>ubstances <u>pP</u>rohibited for <u>**uU**</u>se in <u>**oO**</u>rganic <u>**eC**</u>rop <u>**pP**roduction.</u>