



Agricultural
Marketing
Service

National
Organic
Program

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0268

May 11, 2010

David Carlson, Senior Special Investigator
California State Organic Program
California Department of Food and Agriculture
1220 N Street
Sacramento, CA 95814

Dear Mr. Carlson:

In December 2009, the Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) conducted an onsite review of the California Department of Food and Agriculture (CDFA), State Organic Program (SOP). On February 5, 2010, the NOP issued its final report of the review, detailing 8 findings and 4 recommendations on the California SOP. In response, the CDFA submitted proposed changes to its SOP policies and procedures on March 4, 2010, and subsequently provided supplementary information on April 1, and April 22, 2010.

CDFA proposed specific corrective actions, including timeframes for their completion, addressing each of the Findings and Conclusions of the review report. The NOP's determination as to the acceptability of each of these responses is itemized below.

FINDINGS

NOP Report Finding 1. The documents reviewed and interviews conducted indicated that the revised SOP program has not been implemented at the County level. The County offices have not received copies of the revised manual and have not received training with regard to its implementation. One County reviewed was using procedures dated 1999, while the other County reviewed was using a draft revision of the same checklist dated June 2004. The revised inspection report format with the new SOP revised procedures is dated January 2009. The current draft version does not provide adequate detail to clearly describe what was inspected and the nature of any noncompliances found.

SOP Response: The SOP is pursuing a bifurcated approach in order to resolve this finding. The SOP has recently completed a Quality Systems Manual intended to improve guidance and instruction to SOP staff and county agricultural commissioners contracting with the SOP. The Quality Systems Manual contains policies and procedures for all areas of SOP responsibility, including registration, investigations, due process and enforcement, and program administration. Controlled copies of the Quality Systems Manual have been distributed to all counties contracting with the SOP. Training on the processes and procedures, excluding Spot Inspections, in the QSM has commenced and will be completed by October 1, 2010.

The inspection report referenced in Finding 1 was utilized for SOP's Spot Inspection Program, which is an additional enforcement mechanism utilized for randomized inspections. The Spot

Inspection Program is designed to supplement traditional enforcement and investigative activities. On September 8, 2008, CDFA Legal Counsel determined that the Food and Agricultural Code provides clear statutory authority that the Secretary may conduct organic spot inspections. However, CDFA Legal Counsel determined that there was a lack of regulations necessary to carry out Food and Agricultural Code Section 46018.1, which establishes that " ... [the CDFA Secretary] and the county agricultural commissioners may conduct a program of spot inspections to determine compliance with [the COPA]." Consequently, all counties were directed to immediately cease conducting spot inspections until regulations are promulgated. All other enforcement and administrative aspects of the SOP remain in place.

Upon promulgation of proposed regulations intended to establish the regulatory authority for spot inspections, the SOP will provide regulations to the NOP for review and approval in accordance with Title 7, Section 205.621 of the Code of Federal Regulations. At that time, the Department will concurrently begin conducting county training sessions for all counties contracting with the SOP. After establishing the regulatory authority, conducting county training and receiving approval from the NOP, the SOP will recommence the Spot Inspection Program. The SOP will complete county training and audits by October 1, 2010. The SOP is in the process of revising its Spot Inspection Report format and revised procedures dated January 2009. These procedures will be amended to clearly describe what shall be inspected and the nature of any noncompliances identified by April 1, 2010. As these activities are carried out by the counties under contract with CDFA, language will be inserted into each contract that stipulates that the county will carry out these activities in accordance with the Quality Systems Manual and that the SOP will conduct program reviews of county records to verify compliance not less than once during each five-year period following the date of the initial approval.

NOP Determination: On April 22, 2010, the NOP received draft changes to the Spot Inspection Program procedures and regulations regarding the SOP. The NOP accepts this proposed course of action and will review its implementation and effectiveness at the next onsite review of the California SOP.

NOP Report Finding 2. The scope of the SOP program submitted by the State of California and previously approved by the NOP does not include the processing of agricultural products.

SOP Response: Finding 2 is related to Conclusion 1; please see Conclusion 1 for additional information.

The COPA mandates the California Department of Public Health (CDPH) to administer SOP functions for processed products. Food and Agricultural Code Section 46013.1 (b) mandates "Every person engaged in this state in the processing or handling of processed products pursuant to Section 110460 of the Health and Safety Code, and pet food pursuant to Section 18653, and cosmetics pursuant to Section 111795 of the Health and Safety Code, including processors of alcoholic beverages, fish and seafood, shall register with the State Director of Health Services."

CDPH is statutorily mandated under Health and Safety Code Section 110812 to "enforce regulations promulgated by the National Organic Program (Section 6517 of the federal Organic

Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq.)), provisions of this article, and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code." The statutes related to the processing of agricultural products are identified as Attachment 1 and are enclosed for your review and approval.

The SOP is in the process of further establishing specific roles and responsibilities for enforcement and compliance activities related to processed organic products. Consequently, the SOP has drafted a memorandum of understanding (MOU) between CDFA and CDPH in order to clarify the state and federal legislative and regulatory responsibilities of the SOP. The MOU will be effective by April 1, 2010. A copy of the draft MOU is enclosed and identified as Attachment 2.

NOP Determination: On April 1, 2010, NOP received the referenced MOU between the CDFA and CDPH for review and approval. The NOP agrees that the referenced statutory language clearly identifies CDPH's responsibilities to enforce the NOP and approves the inclusion of the MOU between CDFA and CDPH as a part of the California SOP program.

NOP Finding 3. COPA and NOP regulations are not aligned under the SOP with regards to issuance of notices of noncompliance prior to proposing adverse actions. Review of records at CDFA revealed that operations were routinely issued notices of proposed adverse action for failure to renew their registration with the State or County prior to being issued a notice of noncompliance.

SOP Response: In response to this clarifying finding, the SOP has aligned its procedures in the Quality Systems Manual with regards to issuance of notices of noncompliance prior to proposing adverse actions. Food and Agricultural Code Section 46001 establishes, in part, that the COPA shall be interpreted in conjunction with ... regulations adopted by the National Organic Program..." In addition, Food and Agricultural Code Section 46002(a) mandates "All organic food or product regulations and any amendments to those regulations adopted pursuant to the federal Organic Foods Production Act of 1990 (7 U.S.C. Sec. 6501 et seq.), that are in effect...or that are adopted ...shall be the organic food and production regulations of [the SOP]."

NOP Determination: NOP accepts this response and will review its effectiveness at the next onsite review of the SOP.

NOP Finding 4: COPA requires that to sell organic products in the State of California, organic producers and handlers, regardless of size, must hold a valid registration with the State. However, the SOP procedures do not require organic certifying agents to include this additional requirement in their review and approval of organic production and handling plans for California operations. As a result, certified operations could be revoked by the County or State for failure to register as an organic operation, but continue to produce and sell products outside the State.

SOP Response: In response to this clarifying finding, the SOP shall formally request the NOP to approve the COPA in its entirety, which includes the SOP's registration activities and mandates. Approving the COPA in its entirety would enable the NOP and SOP to inform certifiers operating in the State of California that they must comply with the requirements of

COPA and would enhance coordination between the SOP, accredited certifying agents, and county agricultural commissioners. A formal request for approval of COPA in its entirety will be sent to the NOP for review and consideration by April 1, 2010.

Upon the NOP's approval of the COPA in its entirety, the SOP shall issue a directive to all accredited certifying agents conducting operations in the State of California shall inform their clients that they must comply with all requirements of the COPA, specifically, Food and Agricultural Code Section 46013.1 (a), which states, in part, that "Every person engaged in this state in the production or handling of raw agricultural products sold as organic, and retailers that are engaged in the production of products sold as organic, and retailers that are engaged in the processing, as defined by the NOP, of products sold as organic, shall register with the agricultural commissioner in the county of principal operation prior to the first sale of the product..." This will ensure that revocation of an operation's registration and certification occurs simultaneously. These revised procedures shall be implemented upon NOP approval of the entirety of COPA.

NOP Determination: On April 1, 2010, the NOP received a request from the CDFA Secretary requesting approval of the State's registration program for organic producers and handlers and the associated fee structure. The NOP has accepted the registration and fee requirements as an additional requirement pursuant to paragraph 205.621 of the NOP regulations. NOP will issue a notice to all NOP accredited certifying agents of this approved requirement and require verification of registration with the State as an organic producer or handler prior to granting certification.

NOP Finding 5. Livestock qualifications. Review of one County office found that there were no persons qualified to inspect livestock operations on staff and available to conduct compliance and enforcement activities in the County.

SOP Response: The Quality Systems Manual contains mechanisms for referring compliance and enforcement activities to appropriate and qualified individuals. In the event that the SOP or county agricultural commissioner receives a complaint in regard to a certified organic livestock operation, the Quality Systems Manual stipulates that the complaint would be referred to the operation's accredited certifying agent. The SOP assigns complaints to accredited certifying agents under the following conditions:

- Practices of operations by certified producers.
- Alleged violations at a certified retailer or handler.
- Alleged violations of raw agricultural products involving certified operations.

If a county does not have individuals qualified to inspect livestock operations on staff and available to conduct compliance and enforcement activities, SOP staff would serve as the lead compliance and enforcement authority. The SOP would conduct compliance and enforcement activities utilizing technical expertise from CDFA's Animal Health and Food Safety Services Division and CDFA's Feed Fertilizer, Livestock Drugs, and Egg Regulatory Services.

NOP Determination: The NOP accepts this response and will determine the effectiveness of this policy at its next onsite review of the SOP.

NOP Finding 6: The SOP procedures do not provide for proper administrative processes under the NOP. Review of one adverse action file selected during the County review found that while the proposed adverse action allowed 30 days to appeal before the adverse action was to take place, a final adverse action was initiated only 24 days later. In addition, there had been no notice of noncompliance issued prior to issuing the proposed revocation. Further review of 5 files at the State office indicated that while the failure to allow adequate time for appeal was an isolated incident, the SOP had consistently omitted the required notice of noncompliance when issuing proposed adverse actions for non-renewal of registration. A review of the SOP procedures revealed that the procedures do not clearly require a notice of noncompliance be issued prior to proposing adverse actions for other than uncorrectable or willful violations. In addition, while the revised procedures have numerous templates, there was no template for issuance of notices of noncompliance or proposed adverse actions.

SOP Response: SOP has revised its Quality Systems Manual to clearly require a notice of noncompliance to be issued prior to proposing adverse actions for other than uncorrectable or willful violations. In addition, the SOP has developed a template for issuance of notices of noncompliance and proposed adverse actions and has included the templates in the Quality Systems Manual. Please refer to the response for Finding 3 for additional information.

NOP Determination: ~~The NOP accepts this response and will review the implementation and effectiveness of these revisions during its next onsite review of the SOP.~~

NOP Finding 7: Section 3.6.4 of the SOP procedures indicates that procedures for records management will be developed, but none exist at this time.

SOP Response: The SOP identified, established, and maintains documented procedures for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of all records relating to the provision of the SOP under Section 3:6.4 of the Quality Systems Manual. All controlled copies are numbered or lettered and updated by the Branch Chief whenever changes are made. Recipients of controlled copies of the Quality Systems Manual are issued a list of amendments or modifications to the Quality Systems Manual as they occur. It is the responsibility of the SOP Program Supervisor to ensure that the most current Quality Systems Manual is issued and ensure that all SOP and CAC staff follow it. The SOP Program Supervisor maintains a list of the names, control numbers, and location of all controlled copies. Controlled copies are filed at SOP headquarters.

NOP Determination: The NOP accepts this response and will review the effectiveness of this system during its next onsite review of the SOP.

NOP Finding 8: The NOP needs to inform certifiers operating in the State of California that they must comply with the requirements of COPA in compliance with the approved SOP. State and Counties need to coordinate/communicate with certifiers with regards to NOP and SOP requirements to ensure consistent application of the standards. A review of one file revealed that while the State officials worked with one producer with regards to a noncompliance, there is no documentation to indicate that the certifier was notified and took the required action.

SOP Response: The SOP welcomes NOP's finding specifying that it will inform certifiers operating in the State of California that they must comply with the requirements of COPA in compliance with the approved SOP.

In response to this finding, the SOP has revised its procedures to ensure that accredited certifying agents are notified of any enforcement action taken against their client by the SOP. In addition, all accredited certifying agents operating in the State of California will be invited to the county training sessions tentatively scheduled for the fall of 2010.

NOP Determination: The NOP accepts these proposed actions and will review their implementation and effectiveness at the next onsite review of the SOP.

CONCLUSIONS AND RECOMMENDATIONS

NOP Conclusion 1. The documented processes presented to the NOP for review and approval as a SOP do not include the compliance of processed organic agricultural products. To remain approved as a SOP, the state must submit documented processes to the NOP describing how the state conducts compliance and enforcement activities regarding processed agricultural products sold as organic in the State of California.

SOP Response: Conclusion 1 is related to Finding 2; please see Finding 2 for additional information. CDPH administers the SOP for processed products. CDPH utilizes its existing complaint system to receive and respond to complaints regarding organic products. Currently, CDPH operates a toll free number for the receipt of complaint information by phone, but also receives complaints and information via fax, e-mail, mail, and referral. CDPH complaint intake staff enters the complaint data into CDPH's Complaint Data Management System and contact the complainant to gather any additional information that is necessary for follow-up.

The Complaint Coordinator refers all organic complaints to the Chief of the Food Safety Inspection Unit for evaluation. Within three days of receipt, the Unit Chief reviews the complaints for alleged violations and refers all complaints with sufficient information for follow-up to the District Supervisor for assignment. If further action is not pursued, the complainant will be notified that the Department will not pursue investigation of their complaint and the reason for such decision.

The District Supervisors receiving the complaint from the Unit Chief are responsible for assigning the complaint to investigative staff and reporting back on any violations discovered during the investigation. Complaint investigations will be completed within 90 days of receipt, unless excessively complex or large in scope. If violations are confirmed, CDPH will issue the firm a Notice of Violation and initiate appropriate noncompliance procedures as set forth in Title 7, Code of Federal Regulations §205.662. CDPH will monitor the firm's corrective action plans to ensure they come into full compliance within the prescribed period of time as set forth by the Department, COPA, and NOP regulations. CDPH provides findings of complaint investigations to the complainant upon completion of an investigation.

A summary of all organic complaint investigations completed is provided to CDFA during its quarterly COPAC meetings.

NOP Determination: The NOP accepts the incorporation of CDPH procedures for ensuring the compliance of processed products into the SOP and the MOU between CDFA and CDPH in response to this Conclusion. The NOP will evaluate the implementation and effectiveness of these processes and the MOU at the time of the next onsite evaluation of the SOP.

NOP Conclusion 2. The SOP should request NOP approval of their registration requirements and fee structure as an additional requirement for certification under the NOP.

SOP Response: Food and Agricultural Code Section 46013.1 et seq. establishes the registration requirements and fee structure for the California State Organic Program (see Attachment 3, pages 6-9 and 25-29). For your convenience, the SOP has attached the California Organic Products Act of 2003 as approved by the Governor of the State of California on September 13, 2002.

The SOP is in the process of formulating a formal request for sections of the California Organic Products Act of 2003 that may have been not been approved during the initial certification of the California State Organic Program pursuant to Title 7, Sections 205.620 and 205.621 et seq. Code of Federal Regulations. This formal request shall be submitted by April 1, 2010.

NOP Determination: On April 1, 2010, the NOP received a formal request from CDFA to approve NOP approval of the registration requirements and fee structure (Food Agricultural Code (F AC) Section 46013 et seq. and Health and Safety Code Section 110875 et seq.) and authority to conduct spot inspections (FAC Section 46018.1), contained in the California Organic Products Act of 2003 (COPA), consistent with Sections 205.620 and 205.621 et seq., Title 7, Code of Federal Regulations.

NOP has approved the registration and fee structures as requested as additional requirements under the NOP. Further, NOP approves the spot inspection program as an amendment to the California SOP.

NOP accepts this response to Conclusion 2.

NOP Conclusion 3. The SOP should review county offices to ensure that documented procedures are fully implemented, activities are being performed as required, and that personnel are trained and qualified to conduct activities required under the SOP.

SOP Response: Upon promulgation of the proposed regulations, the Department will begin conducting county training sessions for all counties involved with SOP functions. During the training sessions, counties contracting with the SOP will be audited to ensure that documented procedures are fully implemented, activities are being performed as required, and that personnel are trained and qualified to conduct activities required under the SOP. This is expected to commence in the fall of 2010 and be completed by October 1, 2010.

are trained and qualified to conduct activities required under the SOP. This is expected to commence in the fall of 2010 and be completed by October 1, 2010.

NOP Determination: The proposed activities satisfactorily respond to Conclusion 3 of the onsite review. NOP officials will review the effectiveness of the proposed audits and training activities at the time of our next review of the SOP.

NOP Conclusion 4. The SOP should prepare formal responses and any proposed corrective actions with regard to the findings and recommendations of this report within 30 days of receipt of the final report.

SOP Response: In response to the findings and recommendations of the onsite review of the SOP issued February 5, 2010, CDEFA presented NOP with responses and proposed corrective actions dated March 4, 2010, with accessory documents provided on April 1, 2010.

NOP Determination: The responses satisfactorily address Conclusion 4 of the onsite review report.

CLOSEOUT OF AUDIT FINDINGS AND CONCLUSIONS

The proposed corrective actions include ~~proposed dates for completion~~. In order to allow the California SOP time to accumulate sufficient records to form the basis for a review of the effectiveness of proposed corrective actions, NOP will conduct a follow-up review later this year to verify implementation of the proposed corrective actions and to close the audit findings.

Again, thank you for your response to the findings and conclusions of this review. We look forward to continuing to work with the California SOP in our partnership to ensure the compliance of organic agricultural products produced and sold in the State of California. If you have any questions, please do not hesitate to contact me or Mark Bradley by email or at (202) 720-3252.

Sincerely,



Miles V. McEvoy
Deputy Administrator
National Organic Program

CC: A.G. Kawamura
Patrick Kennelly
Rayne Pegg
AMS Compliance and Analysis