



CALIFORNIA DEPARTMENT OF  
FOOD & AGRICULTURE

A. G. Kawamura, Secretary

**SENT VIA EMAIL AND  
HARDCOPY**

March 4, 2010

Mr. Mark Bradley, Director  
Accreditation, Auditing and Training Division  
National Organic Program, USDA, AMS  
1400 Independence Avenue, S.W.  
Room 2646-S, Ag Stop 0268  
Washington, D.C. 20250-0268

Dear Mr. Bradley:

On December 14, 2009, the National Organic Program (NOP) initiated an onsite review of the California Department of Food and Agriculture's (CDFA's) State Organic Program (SOP). This letter serves as a formal response to the NOP's Final Report of Findings received via email on February 5, 2010. The SOP welcomes this opportunity to improve its operations and maximize its value to both organic consumers and the organic industry.

The SOP has taken progressive steps to significantly improve its business operations. First, a complete Quality Systems Manual was developed to provide guidance to SOP staff and county agricultural commissioners contracting with the SOP. Second, the SOP has revised existing organic registration forms and letters to better meet statutory mandates and industry expectations, while making the registration forms more user-friendly for the organic industry.

Third, the SOP recently completed drafting regulations designed to improve SOP business functions and enforce the mandates of the California Organic Products Act of 2003 (COPA) and NOP regulations. The SOP conducted three listening sessions from February 9, 2010 until March 3, 2010 in order to receive input and guidance on its proposed regulatory package. The regulations are designed to revise and improve SOP's registration, spot inspection, complaint handling, and sampling procedures. Additionally, the proposed regulations will align SOP and NOP regulations. The proposed regulations will be presented to the California Organic Products Advisory Committee (COPAC) on April 30, 2010. CDFA expects these regulations to be promulgated by the summer of 2010.

Fourth, the SOP has revised its processes, procedures, and timelines for complaint intake and processing. An updated complaint form is available on SOP's website and revised tracking logs have been implemented to allow the program to monitor



complaints received and document all cases that are dismissed, assigned, or referred for investigation. Finally, an improved appeal process was developed which includes tracking and monitoring forms and logs to maintain accountability and follow timelines established for the appeal process.

## **FINDINGS AND RESPONSES**

*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.*

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.

*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.*

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.

*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.*

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]."

*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.*

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.**

*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.*

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.

*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 action 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 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.

*Finding 7. Section 3.6.4 of the SOP procedures [Quality Systems Manual] indicates that procedures for records management will be developed, but none exist at this time.*

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.

*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.*

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.

## **CONCLUSIONS AND RECOMMENDATIONS**

*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.*

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 enter 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 non-compliance 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.

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

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.**

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.

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.**



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*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.*

Please feel free to contact me at the number listed below if you have any questions or concerns.

Sincerely, 

David Carlson, Senior Special Investigator  
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Inspection and Compliance  
Inspection Services Division

Enclosure

