



April 7, 2015

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-15-0002

RE: Certification, Accreditation, and Compliance Subcommittee (CACS) – National Organic Program Accreditation Peer Review Process

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the CACS Proposal on the National Organic Program's Peer Review Process. In response to the National Organic Program (NOP), CACS is providing recommendations on how the process may be improved. Consistent with the Office of Inspector General (OIG) Audit of 2010, CACS is also recommending, outside the scope of this proposal, that NOP pursue a rule change to §205.509 removing the Federal Advisory Committee Act (FACA) reference and allowing the hiring of contractors as an independent assessment body.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

Consistent with the Subcommittee recommendation, OTA supports: 1) the concept and practice of a formal Peer Review Panel (PRP) process and 2) the general direction of the process outlined by NOP (See Appendix A) with the subcommittee proposed modifications. This panel is critical to consumer confidence in the certification process and the organic integrity of the organic label.

A critical part of NOP's work is to accredit and oversee the work of third-party accredited certifying agents. NOP's accreditation program is the foundation of a sound functioning organic regulatory structure. Regular systematic audits, performed by qualified auditors, form the basis for the continued quality of this regulatory system.

OTA strongly supports continuous review and improvement to the NOP accreditation system, and we continue to support the required review of accreditation procedures compliant with ISO/IEC 17011 (formerly named ISO Guide 61). Using ISO 17011 as the basis for evaluation of an accreditation program not only provides a framework for analysis of all aspects of the system, it also results in



increased acceptance of the accreditation program by regulatory authorities in other countries due to the ISO 17011's international use.

With respect to the composition of the PRP and the inclusion of a standing NOSB member, OTA agrees with the subcommittee's recommendation to give preference to an NOSB member who is either Vice Chair or Chair of CACS. We also support the recommendation that priority be given to PRP members who have experience with inspection, certification and accreditation.

On behalf of our members across the supply chain and the country, OTA thanks NOSB for the opportunity to comment and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Senior Director of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A – CACS Subcommittee Proposal

- 1) Contract with assessment body. AMS will contract with a peer assessment body to coordinate and manage the peer review panel, once established.
- 2) Select peer review panel. The peer assessment body, in consultation with the NOP Deputy Administrator, will select the peer review panel for each peer review assessment effort.
 - a) The panel will include at least five individuals, the majority of who are not employees of USDA.
 - b) All members must have knowledge or experience with ISO/IEC 17011 or conformity assessment activities.
 - c) All members of the panel must sign a confidentiality statement to not copy, disclose, or distribute any documents they review while participating on the panel.
 - d) At least three members must have expertise in organic production and handling methods, pursuant to the OFPA, specifically in the areas of organic certification and inspection.
 - e) At the discretion of the NOP Deputy Administrator, a current member of NOSB may be selected to augment the PRP in an *ex officio* capacity, if and when the member is free from conflicts of interest as defined by the Secretary, to function as a conduit to NOSB about PRP activities.
 - f) A staff member of the NOP Accreditation and International Activities (AIA) Division will provide support for the panel. This person will be responsible for selecting, redacting, copying, assembling, and distributing copies of documents for panel review.
- 3) Select a representative sample of accreditation decisions. The panel will select at least three, but not more than five, samples from final accreditation decisions rendered by NOP.
 - a) The decisions subject to sampling will be those signed during the 12 months immediately preceding the date of the panel's first organizational meeting.
 - b) The date of the accreditation decisions to be considered for sampling will be the date on which the NOP Deputy Administrator signed the decision.

- c) The samples may be selected randomly or as individual items of interest at the discretion of the peer review panel. If only three or fewer decisions were issued during the prior 12 months, then all the decisions will be selected for review.
 - d) If possible, panel members should select accreditation decisions for at least one large, one medium, and one small certifier for review. This is not, however, a mandatory requirement. The selection of sample decisions is at the panel's complete discretion.
 - e) In addition to the above files, select additional files will be reviewed if necessary to ensure that each of the following type of file is sampled (if such activities were conducted during the sampling period):
 - i) Initial accreditation of a certifier;
 - ii) Renewal of accreditation of a certifier;
 - iii) Surveillance (routine or directed) of a certifier;
 - iv) Suspension of accreditation of a certifier;
 - v) Revocation (withdrawal) of accreditation of a certifier;
 - vi) Amendment of scope of accreditation of a certifier;
 - vii) Appeal of proposed adverse action(s) against a certifier; and
 - viii) Audits and resulting decisions in response to formal complaints filed against a certifier.
 - f) Files with allegations of wrongdoing by a certifier that may be the subject of investigations beyond the scope of the NOP accreditation process should not be selected.
- 4) Prepare NOP accreditation process documents for review by the panel. A staff member of the AIA Division will assemble all relevant NOP AIA procedural documents for review by the panel, including findings and corrective actions from past peer reviews. These may be saved as files, or as links to public documents that are already available on the NOP Web site, as applicable.
- 5) Prepare certifier documents for review. The staff member of the AIA Division will provide the following documents for each certifier selected for review:
- a) Application for accreditation or renewal, including all attachments;
 - b) AIA document review summary sheet;
 - c) NOP audit plan;
 - d) NOP audit report;
 - e) Letters and any Notices sent to the certifier;
 - f) Proposed corrective action from the applicant;
 - g) Notes and decision summary from accreditation committee meeting;
 - h) Signed agreement from the certifier;
 - i) Decision letter from the Deputy Administrator; and
 - j) Certificate of accreditation.
- 6) Review accreditation procedures. Each member of the review panel will review the NOP accreditation procedural documents for the following criteria:
- a) Compliance with the accreditation procedures in Subpart F of the USDA organic regulations (7 C.F.R. §§ 205.500 - 205.510); and
 - b) Compliance with ISO/IEC 17011.
- 7) Review accreditation decision documents in preparation for meeting. Each member of the peer review panel will review the accreditation decision documents provided. Panel members should consider whether the NOP and/or AIA Division followed established NOP procedures for accrediting certifiers, or renewing their accreditations.
- 8) Prepare individual opinions. Each member of the panel will complete a peer review report form for the review of the accreditation procedures and for each of the decision files. Reports will identify:
- a) Any elements of the NOP accreditation procedures that are not aligned with Subpart F of the regulations or ISO/IEC 17011;
 - b) Any instances where records indicate AMS personnel or committees did not adhere to established NOP procedures for accrediting certifiers or renewing their accreditations; and
 - c) Completeness and effectiveness of corrective actions from past reviews.

- 9) Prepare draft consensus report. The peer review assessment body will consolidate the reports into a single narrative summary report. The draft report, along with copies of individual reports, will be circulated to the peer review panel.
- 10) Peer review panel meeting. After reviewing the report, the peer review panel will meet by conference call to discuss their findings and the draft report. The panel will provide comments to the peer review assessment body and agree on language for the final report.
- 11) Peer review panel report. The peer review assessment body will consider the comments and prepare a final report. The final report will be sent to the NOP Deputy Administrator with copies to the peer review panel.
- 12) Presentation. The peer review panel report, along with any NOP response, will be presented at the next NOSB public meeting.
- 13) Publication. After the public meeting, the NOP will post a copy of the peer review panel report and the NOP response, on the NOP Web