National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee
National Organic Program Accreditation Peer Review Process
January 7, 2015

I. INTRODUCTION

The National Organic Program (NOP) is establishing a repeatable and transparent peer review process to respond to previous recommendations of the National Organic Standards Board (NOSB). The NOSB has made three recommendations (2001, 2005, and 2009) concerning Peer Review Panels (PRP) under section 7 U.S.C. 6516 of the Organic Foods Production Act (OFPA). In a memorandum dated November 19, 2014, the NOP asked the NOSB's Certification, Accreditation and Compliance Subcommittee (CACS) to review a 'Peer Review of National Organic Program (NOP) Accreditation' process provided with the memorandum and provide feedback on NOP's process. Furthermore, the NOP requested that the (CACS) provide feedback to the NOSB during the spring 2015 NOSB meeting and that the feedback be in the form of a proposal, which might include (1) support for the NOP's peer review process and/or (2) any recommendations for how the process should be changed to be successful, and/or (3) any suggestions the NOP should consider in its implementation.

II. BACKGROUND & RELEVANT AREAS OF THE RULE

There are three prior NOSB recommendations concerning PRPs. The 2001 recommendation is, in one sense, the most relevant; it speaks to the operating procedures and selection criteria for the PRP, though it uses slightly different terminology. The 2005 recommendation is essentially an assessment of the 2003 ANSI audit and speaks little to the current request of the NOP, *per se*. The 2009 recommendation is a very brief recap of the history of the subject and suggestion for regular American National Standards Institute (ANSI) and OIG audits with a mandatory NOSB review. No part of the prior NOSB recommendations runs counter to the intention and general concepts expressed in the present NOP request for input. In the past there has been various and regular, albeit infrequent, public comment supporting the establishment of a formal PRP as described in the process recently provided by the NOP.

Section 205.509 of the USDA organic regulations requires the USDA Agricultural Marketing Service (AMS) Administrator to establish a panel pursuant to the Federal Advisory Committee Act (FACA) to conduct peer reviews of the NOP's accreditation process and decisions. To satisfy the requirements of §205.509, the NOP has previously contracted with third-party auditing organizations to conduct peer reviews. The NOP contracted with the American National Standards Institute (ANSI) in 2005 and 2014 and the National Institute of Standards and Technology (NIST) in 2010. During the last few years, foreign governments have also conducted peer reviews of the NOP: the European Commission in 2010, the Canadian Food Inspection Agency in 2011 and 2013, and both South Korea and the European Commission in 2014.

A 2010 Office of the Inspector General (OIG) audit of the NOP found that using third-party review organizations to conduct peer reviews does not satisfy the requirement for a peer review panel described in §205.509 of the regulations. The OIG recommended that the NOP either form a peer review panel in accordance with the regulations or change the regulations.

III. DISCUSSION

The CACS discussed the NOP's request and supports: 1) the concept and practice of a formal Peer Review Panel process and 2) the general direction of the process outlined by the NOP and provided with the recent memorandum; with some modifications as provided in the following section. In general, the suggested changes concern the number, composition, and experience of the PRP members. The CACS feels that three members cannot provide adequate breadth of experience to adequately approach the issues involved. In suggesting the inclusion of a standing NOSB member, the CACS intends that it be either the Vice-Chair or Chair of the CACS as they are both experienced and positioned to provide a coherent lens for the Board as a whole and their Board workloads will generally allow for this additional responsibility. Lastly, we suggest giving priority to PRP members with inspection, certification, *and* accreditation experience; these valuable experiences provide for a comprehensive view of the Peer Review Process. The CACS left the majority of the NOP's draft process unchanged and finds it appropriate and necessary.
The CACS recommends – outside the scope of this proposal – that the NOP pursue a rule change to §205.509 removing the FACA reference and allow the hiring of contractors as an independent assessment body, in a manner consistent with the OIG findings.

IV. PROPOSAL

The CACS proposes the following process for the National Organic Program Accreditation Peer Review Process:

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 which are not employees of the 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 the NOSB may be selected to augment the PRP in an *ex oficio* capacity, if and when the member is free

from conflicts of interest as defined by the Secretary, to function as a conduit to the 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 the 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 site. A USDA Organic Insider notice will announce the availability of the report.

Motion to accept the Peer Review Proposal

Motion by: John Foster

Seconded by: Jean Richardson

Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion passed

Approved by Carmela beck, Subcommittee Chair, to transmit to NOSB January 17, 2015