National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Risk-based Certification Proposal
February 4, 2025

Introduction:

Risk-based oversight as a model for decision-making and compliance prevention strategy is an approach used by certified operations and certifiers in organic certification. These concepts are not new. An increase in fraudulent organic activities over the past decade by a few unscrupulous operations (relative to the number of compliant organic operations) has the organic community taking another look at the concept of risk-based certification. Due to an increase in organic fraud, we saw the implementation of the Strengthening Organic Enforcement (SOE) final rule, which codified the evaluation of an organic operation's risk of organic fraud as well as many other provisions aimed to make it harder for an operation to engage in fraudulent activities (e.g. requiring more operations to become certified, increasing labeling requirements, codifying audit requirements, etc.). While these more robust provisions were well-intentioned, the result is that low-risk operations (not the intended target) were caught in the crosshairs. As such, we have the opportunity to reflect on what we've learned over the past year and reexamine the idea of risk-based certification; i.e., where and how can we focus on high-risk operations and reevaluate the certification process for low-risk operations?

Background:

While the SOE final rule was intended to prevent fraud, it had unintended consequences such as increased costs or operational complexity for all operators, including those that are legitimate and/or low-risk. It also created potential additional barriers to entry for legitimate operators, even if they don't engage in fraudulent practices. So, while being well-intentioned, the result may have felt like an "over-correction."

Enter risk-based certification. The National Organic Standards Board (NOSB) requested this as a work agenda item in 2024 on the heels of the SOE final rule implementation. It became apparent, through comments to NOSB and reports from the National Organic Program (NOP), that while this rule was not intended to have major impacts to low risk (e.g. small producers) operations, unfortunately that was what was happening in practice. This was largely due to revisions to certifiers' organic system plan (OSP) templates that impacted all organic operations.

At the Fall 2024 NOSB meeting, NOP Deputy Administrator Dr. Jennifer Tucker introduced the idea of reconceptualizing "Sound and Sensible" to "Continuous Improvement." The NOP has further communicated this idea to certifiers, indicating that this will be an ongoing and collaborative effort to innovate our systems. The Certification, Accreditation, and Compliance Subcommittee (CACS) hopes this proposal will aid in this collaboration to rethink the structure of the certification process in order to preserve its sustainability for the long term, while also ensuring organic integrity throughout the marketplace.

Relevant areas in the organic regulations and OFPA:

Since the inception of organic certification as a federal program, risk-based certification has existed. OPFA and the organic regulations at 7 CFR Part 205 allow certified operations and certifiers to use

systems that are relevant to one's structure, production model/type, site specificity, etc. while developing their OSP and certification policies and procedures. As discussed in the Fall 2024 NOSB discussion document, the concept of risk-based certification is not new. However, due to several final rules published in the past few years, this topic is of the utmost importance in order to maintain and grow the organic industry while continuing to uphold organic integrity.

The SOE final rule included specific provisions for certified operations and certifiers to evaluate risk. Section 205.504(b)(7) now requires that certifiers develop policies and procedures in order to perform supply chain traceability audits (SCTA) on operations identified as high risk. Supply chain traceability audits may be smaller in scale (e.g. cross check of a smaller number of transactions between two entities); this is often referred to by certifiers as a routine SCTA. SCTAs may also be conducted as part of an investigation. The scope and scale of this type of SCTA may be expanded to cover more transactions or to go further up or down along the supply chain. The preamble to the SOE Final Rule included the following criteria as potential risk criteria (to be used to evaluate a certified operation's risk):

- Products for which there is a relatively high demand, low supply, and high organic premium;
- Products which may be subject to treatment with prohibited substances after production;
- Unpackaged products which are not enclosed in final retail containers;
- Products with multiple handlers in the supply chain;
- Products from a supplier that lacks a record of compliance;
- A sudden increase in the available supply of an organic product or commodity;
- Operations which change certifying agents frequently; and
- Operations which are certified by more than one certifying agent.

In addition, per §205.201(a)(3), a certified operation must include in their organic system plan a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud as appropriate to the certified operation's activities, scope, and complexity. In order for an operation to successfully create an organic fraud prevention plan, they need to evaluate the risks and vulnerabilities their operation is subject to.

Discussion:
This proposal aims to provide additional support to certifiers and inspectors on how to cultivate critical thinking as a core competency and effectively manage time as a resource in order to make sound and sensible decisions that best protect the marketplace and prevent fraud.

This proposal focuses on the fundamental building blocks certifiers and inspectors use in evaluating an operation's risk (fraud and/or compliance related) and picking the best verification tool possible. Specifically, the proposal suggests a common set of definitions, baseline risk assessment criteria, the development of a process and matrix certifiers can use to determine the best certification approach to use per operation, and additional training and resource development. See the Summary of Proposal section for more details.

Public Comment:

During the Fall 2024 NOSB meeting, the CACS received several comments on this topic. Most were in

favor of the concept of risk-based certification, acknowledging that the certification process can be burdensome and overly complex for low-risk operations as well as certifiers. That said, commenters thought it of the utmost importance to proceed cautiously as to mitigate against unintended consequences and not to lean so far into this concept that organic integrity is rendered meaningless.

CACS asked a series of questions and received thoughtful answers from our stakeholder community. These are summarized below:

1. How does your organization define risk?
   a. Would it be valuable for the definitions listed above (Risk-based oversight, Risk management, Risk, Vulnerability) to be included at §205.2 Terms Defined?
   b. Are there other definitions that would be beneficial to include at §205.2 Terms Defined besides those listed above? Is it important that all certifiers use the same risk criteria to evaluate certified operations? Why or why not?

Response summary: Most, if not all, commenters agreed having shared definitions was important. Some commenters thought these should be in the regulations, while others thought this could be elsewhere such as in Accredited Certifiers Association (ACA) best practice documents and/or the NOP Organic Integrity Learning Center (OILC). Commenters also thought that when evaluating an operation's risk, certifiers should use the same general risk criteria while being able to remain adaptable and flexible.

2. What other resources (e.g. trainings, models, certifications/credentialing program) are currently available that would help an organization become more proficient at risk-based oversight and/or risk evaluation?

Response summary: There were several resources identified including OILC courses, ACA best practice documents, OTA's Organic Fraud Prevention Guide, Dr. John Spink's website "Food Fraud Think Tank," the Cressey Fraud triangle, and ORG-Tracker.

Additionally, the idea of an interactive training or a certification/credentialing program focused specifically on risk-based decision-making was also mentioned by a few commenters. One commenter stated, "a comprehensive, mandatory program could ensure uniform adoption across the certifying community."

Lastly commenters suggested the following models could be consulted:
- HACCP and the food safety industry
- EU's approach to risk assessment
- ISO 31000 Risk Management Framework, which provides comprehensive guidelines for managing risk effectively across various sectors

3. What are the unintended consequences that could arise from using a risk-based oversight approach?

Response summary: Commenters stated the following as possible unintended consequences:
- smaller, low-risk operations feeling overlooked or undervalued in the certification process and/or losing connection with their certifier
- risks being missed, especially if new risks emerge

- too little attention paid to low-risk operations, resulting in impacts to organic integrity or losing the deterrent benefit of comprehensive oversight
- operations trying to game the system purposefully to position themselves as low-risk to get the benefits that may come along with that designation
- operations getting complacent in certain compliance verification points (e.g. record keeping)

However, commenters also noted that the risk of not using a risk-based approach is continuing to overburden our smaller, low risk operations, resulting in increasing attrition or operations not entering into organic certification. Additionally continuing to tax an already fragile certifier and inspector community by expecting more and more leads to burnout.

4. What other ways are there to reduce burdens on low-risk operations?

Response summary: Commenters suggested the following ideas to reduce burdens on low-risk operations:
- Inspection related items:
  - Inspection focused only on a specific element of organic compliance, rather than a full-scale inspection every year (with full inspections every other year or every third year)
  - Reduce the frequency of on-site inspections
  - Remote/virtual inspections for certain types of low-risk operations (e.g. no physical handling of organic product)
  - Simplified/reduced audits (e.g. mass balance and/or traceback) at inspection
- Reducing/simplifying the paperwork (e.g. OSPs, recordkeeping)
- Streamlined review processes related to certain types of materials or ingredient supplier changes

5. How can the community provide information to NOP and/or certifiers on acute risks?

Response summary: Some ideas from comments include reporting directly to NOP or the certifier through the current complaint system, email or a hotline. There was also mention of establishing a forum, which could be through the NOSB. Commenters also stated that NOP should communicate to certifiers, at the annual certifier training, identified areas of high-risk taken from the various data sources they have available to them.

6. Certifiers:
   a. Have you adopted or based your risk assessment criteria on the ACA Best Practices (ACA BP) documents?
   b. When operations are identified as low-risk, what actions are you taking to streamline and make these operations' certification less burdensome?

Response summary: Most certifiers indicated that they used the criteria from the ACA BP and that their criteria were based from that BP so there was a lot of alignment. There was one certifier that stated they did not use the ACA BP, but their criteria had some overlap with the ACA BP.

Certifiers stated they incorporated the following in order to reduce a low-risk operations' certification burden:
- Allowing for simplified recordkeeping systems (e.g. herd lists for closed herd operations). Records must still be auditable.

- Streamlined review processes (products and ingredient suppliers, certain types of materials, fast tracked initial review for operations with no changes from year to year)
- Hourly inspection rates
- Relative to high-risk operations, low-risk operations will not be subject to SCTAs and less likely to have a routine unannounced inspection or residue sampling

Summary of proposal: *Brief summary of what the subcommittee is proposing.*

1. **Definitions:** CACS proposes that all stakeholders use a common set of definitions. Some of these currently live in the OILC course NOP-230: Risk-based Oversight. CACS proposes the following definitions be revised in the OILC course. Additionally, CACS proposes that other stakeholders utilize these definitions in their resources (e.g. ACA best practice documents, individual certifier policies and procedures, industry white papers, other training resources, etc.). CACS is not recommending these be added to §205.2 Terms Defined at this time. Inclusion into the regulatory text may be reevaluated as a necessity at a later time. Strikethrough text is proposed to be deleted. Underlined, red text is proposed to be added.

   a. **Risk-based oversight** is a systemic, cyclical approach to considering risk. This approach involves the process of identifying and prioritizing risks (via a vulnerability assessment and risk assessment including all potential risks such as fraud risks and compliance risks), and planning and scheduling mitigation measures, with a goal of reducing and managing risks. Risk assessment and past performance inform the planning process. ~~Risk management is the execution of the planned and scheduled tasks that contribute to the overall goal.~~

   b. **Risk management** is the actionable step of the risk-based oversight approach. Risk management is the execution of the planned and scheduled tasks and processes that contribute to the overall goal of the prevention, reduction or minimization of risks, including mitigation strategies, preventive measures, and implementation. ~~consists of coordinated tasks and processes.~~ Risk management is only one component of the overall risk-based oversight approach.

   c. **Risk** is the potential exposure to deceptive, dishonest or noncompliant actions, resulting in financial losses, reputational damage, certification status changes and/or legal consequences. Risks on organic operations can be categorized as risk of noncompliances (in broader terms), or more specially, as risk of fraud ~~effect of uncertainty on objectives (ISO 22380), such as quality objectives or compliance objectives.~~

   d. **Vulnerability Assessment** is the step aimed at reviewing and assessing various factors that create vulnerabilities in a supply chain (i.e. weak points where fraud and/or noncompliances have the greatest chances to occur) ~~a deficiency or weakness that creates opportunities for exploitation or susceptibility to a given hazard.~~

   e. **Risk Assessment** is a systematic process of evaluating the potential risks (likelihood vs. severity) that may be involved in an activity or relationship. This may include the assessment of fraud and/or more board compliance related risks of an operation.

   f. **Risk Evaluation** is the process of making a judgement or determination about the amount or degree of risk identified (e.g. low, medium or high) in a risk assessment.

2. **Risk Criteria:** CACS proposes that certifiers use a baseline of common risk criteria while allowing certifiers flexibility to adjust based on their specific operation portfolio. CACS recognizes that many certifiers use the criteria in the "ACA SCTA Risk Score Card Template" and propose that this serve as the baseline criteria. Additionally, CACS proposes that certifiers, in collaboration with NOP, ACA and any additional stakeholders deemed necessary. identify a common objective/goal of performing risk assessments on organic operations for the purposes of

complying with the requirements at §205.504(b)(7). Lastly, CACS proposes that NOP communicate acute risks to certifiers at the annual certifier training. The predictable, annual communication is utilized by other schemes and will allow certifiers to better plan and maximize their resources. Currently, NOP utilizes issuing directives to certifiers. These are unpredictable and do not allow for certifiers to proactively and effectively allocate resources. This is not to say that directives will be entirely eliminated. They may still be required based on information that arises later in the year. However, communicating known risks on an annual basis will hopefully result in the reduction of directives being issued, again which will allow certifiers to more effectively manage resources, as well as comply with the requirements regarding performance of SCTAs in a more consistent manner across certifiers.

3. **Oversight Activities Process and Matrix:** CACS proposes that NOP, in coordination with ACA, develop a process by which certifiers can evaluate the regulatory text and use critical thinking to determine the opportunities to approach the certification of operations with different risk level differently. Furthermore, it is proposed that using this process that ACA develops a matrix of activities to add to a high-risk operation's certification and options to reduce a low-risk operation's certification burden. CACS acknowledges that certifiers need different tools to evaluate different types of operations. This process and matrix will help certifiers more consistently pick the right tool depending on an operation's risk evaluation. This process and matrix are, by no means, intended to convey that low-risk operations are being held to a lower standard. Once complete, CACS proposes that ACA inform NOP in order for NOP to conduct training of accreditation and audit team personnel. This will ensure that NOP staff and certifier staff are operating under the same expectations regarding risk-based certification and continuous improvement. The following are examples provided by commenters in response to the Fall 2024 Discussion Document on this topic:
   a. Examples of increased oversight activities that may be utilized for high-risk operations: unannounced inspections, residue testing, supply chain traceability audit, additional audits during annual inspection.
   b. Examples of reduced oversight activities:
      i. Inspection related suggestions: focused inspections in some years with full inspection every other or every third year; remote/virtual inspection for certain types of operations; fewer traceback and mass balance audits (compared to high-risk operations)
      ii. Minimize/reduce recordkeeping/paperwork requirements; common OSP
      iii. Cost structure to incentivize low-risk operations

4. **Training and Resources:** CACS proposes that NOP and ACA develop and revise resources and training materials to support certifiers in conducting risk-based certification (i.e. finding the right set of tools/activities for the specific operation based on their profile - organic activities and risk evaluation).
   a. Revise and/or create ACA Best Practice Documents to:
      i. Incorporate the definitions in this proposal
      ii. Explain the process to be used by certifiers to evaluate the regulatory text and use critical thinking to determine the opportunities to approach the certification of operations with different risk level differently
      iii. Communicate the oversight activities matrix to certifiers
   b. Revise NOP-230 in the OILC to:
      i. Incorporate the definitions in this proposal
      ii. Provide more interactive modules/activities pertaining to both risk of fraud and risk of noncompliance

      c.   Continue to include risk-based certification as a topic at annual NOP Certifier Training/ACA Professional Conference

Subcommittee Vote
Motion to accept the proposal on risk-based certification
Motion by: Kyla Smith
Second by: Amy Bruch
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1