National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee
Risk-based Certification Discussion Document
August 6, 2024

Discussion:

Overview of Risk-based Oversight and Risk Assessment of Certified Operations

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. As the organic supply chain and businesses engaged in the organic industry get more complex, organic certification is becoming less "one size fits all". It is becoming more important for organizations to use a risk-based approach in order to optimize their activities (i.e. focus their attention on the areas of highest risk to their organization). Certified operations and certifiers can both apply risk-based oversight to themselves and their activities; or as an evaluation process to determine the risk of another organization they do business with. This could be a certified operation evaluating a supplier or a certifier evaluating one of their certified operations.

Additionally, the Strengthening Organic Enforcement (SOE) final rule now codifies that certifiers must evaluate and identify high risk operations and products. Specifically, §205.504(b)(7), 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 concept of risk-based certification or decision-making frameworks has been in existence within the organic certification process for some time. Organic inspectors and reviewers proficient in risk-based decision making are more effective and efficient in their work than inspectors and reviewers that are challenged by this concept. Many certifiers have been evaluating the risk of their certified operations for years but for others, evaluating risk is new. Due to SOE as well as the continued pressure on staffing resources within the organic certification community, risk-based oversight and the evaluation of risk is taking a more prominent place in organization's strategies. And while there are some resources, this document aims to determine if these resources are effective or if additional resources are required for certified operations and certifiers to fully adopt and become proficient at risk-based oversight.

These different components of risk evaluation have different purposes and objectives.

Risk-based Oversight and Evaluation Activity	Purpose/Objective
Certifier Performing Risk Evaluation Process on Itself and its Own Activities	• Be proactive and not reactive to addressing potential risks • Develop controls, policies and procedures for the areas of the organization with the most risk
Certifier Performing Risk Evaluation Process on Operations it Certifies per §205.504(b)(7)	• Comply with accreditation requirements (§§ 205.504(b)(7) and 205.501(a)(21)) • Increase oversight of operations identified as high risk in order to identify operations that are engaged in fraudulent activities
Certifier utilizing a risk-based oversight approach	• Incorporates the risk evaluation of oneself and the operations it certifies to set organizational strategies and annual work plans to maximize resources and streamline processes
Certified Operation Performing Risk Evaluation Process on Itself and its Own Activities	• Be proactive and not reactive to addressing potential risks • Develop controls, policies and procedures for the areas of the organization with the most risk
Certified Operation Performing Risk Evaluation Process on Operations it does business with	• Comply with certification requirements (organic fraud prevention plan in 205.201(a)(3)) • Increase oversight of operations doing business with order to avoid doing business with operations that are engaged in fraudulent activities
Certified Operation utilizing a risk-based decision-making approach	• Incorporates the risk evaluation of oneself and the operations it does business with to set organizational strategies and ensure longevity of business due to maximizing organic integrity within one's business and who one does business with

Overview of Current Resources

As previously stated, §205.504(b)(7) requires that certifiers submit to the NOP a copy of the criteria they will use to identify high-risk operations and agricultural products for supply chain traceability audits; and procedures to conduct risk-based supply chain traceability audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator. 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. Again, fraud risk is important however, there are other risks that an operation should be

evaluating and mitigating against in order to maintain organic integrity and compliance on their operation.

Beyond the regulatory text, there are some resources that are focused on the topic of risk-based oversight as it specifically pertains to the organic certification industry.

First, we can look to the preamble to the SOE Final Rule which includes 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, the Accredited Certifiers Association (ACA) has a few best practice documents:

1. ACA Best Practice for Risk Assessment and Follow-up *(November 2019)*
2. ACA Best Practice for Certifier-to-Certifier Information Sharing and Supply Chain Traceability Audits (SCTA) *(April 2024)*
3. ACA SCTA Risk Score Card Template (*April 2024)*
4. ACA SCTA Info Request Form (*April 2024)*

The first document was published in November 2019 as a tool to "help assure sensible allocation of resources and should increase the likelihood of uncovering fraudulent activity or other non-compliant actions that jeopardize the integrity of the organic label." This best practice document breaks out risk criteria by scope (e.g. all scopes/general, crops, livestock, handling) and includes criteria such as compliance history, split or parallel production and complexity of the operation, just to name a few. This best practice document is available to ACA members only.

Subsequently, due to SOE and as part of the cooperative agreement between the ACA and NOP, the ACA developed the latter three documents. These are available to the public through a request to ACA staff. ACA members may access when logged into their member portal.

The SCTA Risk Score Card is the 2.0 version of the previous 2019 version. It includes similar criteria as the 2019 version. In addition, it breaks the risk evaluation into two parts: general risk of an operation and risk criteria related to fraud that would make the operation a good candidate for a SCTA.

Certifiers are not required to use these criteria to comply with §205.504(b)(7).

The Organic Integrity Learning Center is another great resource for certifiers and certified operations. There are a few courses that address the concept of risk:

1. NOP-230: Risk-based Oversight. This course is largely focused on fraud as a risk. However, it does provide an overview that would help an organization apply the risk-based oversight to other risks (other than fraud).
2. NOP-100: Organic Fraud and the Criminal Mind. This course is aimed at providing insight into how fraudsters think so that operations can help deter fraud.

3. NOP-110: Preventing the Organic Fraud Opportunity. This course provides an in-depth review of the fundamental supply chain risk management concepts that can reduce the organic fraud opportunity

Overview of potential issues/gaps

Risk-based oversight was brought up several times during the spring 2024 NOSB meeting in regard to not overburdening smaller, low risk farm operations by the SOE rulemaking. This concept also continues to be a priority of many certifiers that are looking to focus their time and efforts on the certification activities/operations that present the greatest threat to organic integrity due to limited resources (e.g. staff time).

In evaluating the above identified resources, it appears the following could be potential gaps and opportunities for continued improvement:

1. **Definitions:** The topic of risk is multi-faceted and includes an approach (risk-based oversight) as well as two risk evaluation concepts (risk of fraud and risk maintaining organic integrity). Due to this it may be valuable to codify some definitions to assure that the term risk is being used uniformly. Within the OILC courses there are several terms that are defined:
    a. Risk-based oversight
    b. Risk management
    c. Risk
    d. Vulnerability

2. **Evaluation Criteria:** As previously stated, certifiers must establish criteria to evaluate and identify high-risk operations and agricultural products for supply chain traceability audits. Resources exist currently for certifiers to evaluate an operation's risk of fraud (making them a good candidate for an SCTA) as well as an operation's more general organic compliance risk. Risk criteria are not specified in the regulations so there isn't a consistent set of criteria used by all certifiers. Additionally, there currently isn't a defined mechanism for how industry can provide information and data to NOP and certifiers outside of the complaint process which doesn't apply in all situations. Industry may have more general information regarding commodities from certain countries or regions that should be evaluated as risks. Developing a pathway to engage with industry to proactively obtain this information, along with developing processes by which certifiers can evaluate their risk criteria and add and remove criteria. How can we take an agile approach to risk criteria so that we are considering acute risks?

3. **Risk-based decision-making framework:** The idea of risk-based oversight is more of a best practice. In the OILC course NOP-230 it is stated that when risks stemming from vulnerabilities (e.g. financial stressors, limited staff or resources, supply chain changes, regulatory updates, human error, and negligence) are not addressed it can lead to the following:

    a. For certifiers:
        i. Loss of business
        ii. Increases in costly mediation and settlement agreements
        iii. Suspension or revocation of noncompliant operations
        iv. NOP enforcement action
        v. Loss of accreditation

b. For certified operations:
   i. Product recalls
   ii. Fraudulent organic sales
   iii. Loss of organic integrity
   iv. Suspension or revocation of organic certification

In addition, CACS believes that loss of certified operations following the rules (e.g. voluntary surrender) may occur when other certified operations do not address their vulnerabilities.

It just makes good business sense to evaluate risk and vulnerabilities to one's business. Also, the likelihood of addressing all the risks simultaneously does not seem feasible, especially when a business is navigating finite resources (e.g. money and staff time). Therefore, implementing a risk-based approach to identify the highest compliance risks to one's organization and prioritizing the mitigation strategy again just makes good business sense. In organic certification, certifiers can and should use this approach to prioritize and target high-risk operations and activities. However, this is a skill. Some people are naturally better at this type of decision making but it certainly can be learned. There isn't currently in the resources identified above a preferred framework that businesses should use when utilizing a risk-based oversight approach. Obviously, each business's risk factors will be different and how they choose to prioritize them and mitigate against them will be different. In organic certification, is a shared or consistent risk-based decision-making framework important so that certifiers are utilizing the same model on themselves and on the operations, they certify in order to arrive at similar decisions on where and how to spend their time (i.e. prioritizing certification oversight on operations that present greater risk)?

4. **"One size fits all (most)" Certification:** As continuously stated throughout this document, with the advancement of the organic industry we've seemingly outgrown the "one size fits all (most)" model. A low-risk operation's certification process should likely not be the "same" as a higher risk operation. In some ways, it can be easier to fall back to this way of thinking as it takes some of the decision making out of it. It is easier for certifiers to have one organic system plan with the same questions and leave it up to the operation to determine if it applies to them and based on their activities how complex their answer needs to be. It is easier for inspectors to do the same number of audits (for example) on all types of operations versus needing to decide on the number of audits to conduct based on the risk of an operation. It is easier for review staff to answer the same set of questions in evaluating an inspection report and making a final certification decision. Certifiers are likely also concerned with ensuring they are meeting accreditation requirements. Certifiers may feel they are at risk of a noncompliance if they are taking a risk-based approach and are streamlining the certification process in certain ways for low-risk operations.

   However, the easefulness created for certifiers in continuing this "one size fits all (most)" certification is resulting in an additional burden to lower risk operations.

   This is part of how a certifier could be using risk-based oversight. Meaning that if a certifier was using a risk-based oversight approach the result could be that certification requirements look different for lower-risk operations than higher risk operations, such as reduced paperwork, reduced audits, reduced inspection time and/or focus areas, recalibration of focus on areas of an operation where the likelihood of fraud to be detected increases (e.g. yield and sales verification). Some certifiers are likely already doing this; however, it is likely that many are not. Certifiers may need to consider where they are applying resources and adjust accordingly. It is

likely that certifiers don't have a full enough picture of an operation and its risk until after an Organic System Plan (OSP) is submitted. One way to reduce burden is to reduce paperwork. However, in order to do so a certifier would need to have an idea of the operations potential risk prior to the submission of its OSP, which means frontloading resources. The idea is that in the end the resource burden is less on operations and certifier staff later in the certification process. Again, these are new concepts for some so understanding the possibilities for compliant ways to reduce the burden on low-risk operations that are not too resource-heavy on certifiers will help certifiers feel comfortable in adopting this approach.

Conclusion:

Risk evaluation is an important tool and is now required by certifiers to evaluate high risk operations and by certified operations in the form of an organic fraud prevention plan. Risk evaluation is a factor in risk-based oversight or decision making. The result of which is spending more time on higher risk areas of an operation or on higher risk operations and less time on lower risk activities of an operation or lower risk operations.

While these concepts are not new, there seems to be a renewed focus on them due to SOE and continued limitation on resources. The board seeks to understand what resources are serving the organic community well and what additional resources exist so that we may continue to grow the organic sector while maintaining a high level of organic integrity and reducing fraud.

Questions to stakeholders:

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 certifier operations? Why or why not?
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?
3. What are the unintended consequences that could arise from using a risk-based oversight approach?
4. What other ways are there to reduce burdens on low-risk operations?
5. How can the community provide information to NOP and/or certifiers on acute risks?
6. Certifiers:
    a. Have you adopted or base your risk assessment criteria on the ACA Best Practices documents?
    b. When operations are identified as low risk, what actions are you taking to streamline and make these operations' certification less burdensome?

Subcommittee Vote:

Motion to accept the discussion document on risk-based certification
Motion by: Kyla Smith
Second by: Nate Lewis
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1