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Sept 30, 2024

Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP 1400 Independence Ave. SW
Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268

Re: Docket # AMS-NOP-24-0023

Re:

- Risk-based Certification Discussion Document
- Consistency in Organic Seed Use Discussion Document

Dear Ms. Arsenault:

IOIA is the leading worldwide training and networking organization for organic inspectors. Though a United-States based nonprofit 501(c)(3), IOIA operates globally with nearly 250 inspector members in over a dozen countries. Our members are the “boots on the ground” at the annual inspections of certified operators. The inspector is often the first representative in-person at the operation and sometimes the only one. We see first-hand successes and failures of the many administrative and technical innovations which are implemented in the name of ensuring organic integrity.

Risk-based Certification Discussion Document

IOIA would like to express our deep gratitude to Kyla Smith and the NOSB for bringing a critical discussion to the forefront of conversation in the organic industry.

Questions to stakeholders:

1. How does your organization define risk?

Though IOIA is not a certifier and therefore does not officially define risk, for a good inspector, the foundation of our job is risk assessment. IOIA strongly recommends the following focal points:

- Risk of human exposure to pesticides and herbicides and other prohibited inputs.
- Agroecological impacts from the use of prohibited substances and other non-compliant practices adversely impacting the environment.
- Split operations in parallel production and handling with the means, motive, and opportunity to commingle and contaminate organic products.
- Long, complex, and/or non-transparent supply chains, especially if they do not allow for traceability.
- Imported products, especially feed and unprocessed produce and herbs
- Non-compliances pertaining to organic integrity, with a lesser emphasis put on clerical errors
- Certified organic operations with a larger market footprint inherently pose a higher risk than smaller local or regional operations, primarily due to the greater volume of products entering the marketplace. A single large operation has the potential to accidentally or intentionally introduce exponentially more non-compliant products.

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?

IOIA is uncertain if there is a need to change the regulations and can see both positive and negative elements to this approach. Defining risk-based oversight might be helpful, but to define risk, risk management, and vulnerability seems unnecessary.

Pros

- A regulation change will force the industry to move forward
- Additional input will be provided by all stakeholders

Cons

- The time required to implement a regulation change is notable, often years or even decades from the time the NOSB makes a recommendation. Risk based certification is needed **now**. The industry cannot wait.

Regardless of whether the NOSB votes on a recommendation to change the rules, there are ways to establish an industry standard much sooner.

- IOIA strongly supports the creation of a working group. The ACA did a fantastic job of providing some excellent resources for risk determination for SOE. Now that the industry has had some time to see the results of implementation, our experience can be used to continue the conversation.
- IOIA strongly encourages the NOP to create a guidance document in the handbook and OILC courses that provide information and clarification on risk.

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?

It is critical that the entire industry use the same *general* risk criteria. The reason is simple, the industry needs a consistent matrix to certify and accredit to. It will not work if an agency is creating a policy that is not in line with the NOP, an inspector is assessing risk outside the parameters of compliance, and reviewers are issuing a wide range of corrective actions based on their own individual understanding of risk.

Though the industry needs to be consistent in risk management, it is important to remember that organic production occurs around the world, and even within the US, some regional or production specific variation will be required for a sound and sensible approach. The public-private partnership should also allow for certifiers to be innovative within the parameters of compliance to the regulations

The discussion document states “ 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.” This is understandable, however, the NOP has codified risk-based as a concept within the regulations. This indicates that the NOP recognizes risk as a pivotal aspect with which to focus regulatory scrutiny. Additional resources, such as a guidance document and/or OILC training, would further clarify how certifiers should approach risk and ensure consistency in both certification and accreditation.

Again, IOIA strongly supports a working group of certification professionals be established. We see immense value not just in starting to create the definitions noted in the discussion document, but also in collaborating in what we’ve learned about OSP questions, policies, and inspection reports. Communication and clear agreements on risk are key to the effective implementation of a risk-based certification process, particularly given the vast diversity of organic production across the globe.

A uniform approach to general risk guidelines can also mitigate certifier shopping. A high-level, unified approach with independent certifier variation based on the public/private partnership allows for certifiers to implement oversight efficiencies for their clients. Also, doing so in a level playing field will not attract clients shopping for an 'easy' certifier if all use a uniform risk based approach to deliver their certification services.

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?

Other industries have done an excellent job in creating high quality, yet efficient risk-based oversight and evaluation. ISO 3100, HACCP, and the food safety industry are a few examples. This is also an opportunity to develop training tailored to the organic industry.

Heartland Health Resource Alliance's comment states "For most consumers, the true value of the voluminous, detailed NOP rule, and all the effort invested in organic farming system plans and annual inspections, is reducing risks to people and the environment." IOIA agrees and applauds their good work in developing The ORG-Tracker database. The resource is an ingenious way for the industry to evaluate health risks stemming from contamination and better assess intentional and unintentional applications. This is an invaluable resource for the industry to better understand one of the most critical areas of compliance.

3/4. What are the unintended consequences that could arise from using a risk-based oversight approach?/ What other ways are there to reduce burdens on low-risk operations?

If done well, there may be very few unintended consequences in a risk-based approach. Strengthening Organic Systems, LLC training on Fraud Prevention Plan notes “Vulnerability is not the same as risk. “Vulnerability” is the weakness, gap. Risk is the likelihood of it mattering”. IOIA agrees and encourages the industry to prioritize time and resources on areas that matter most to the consumer and the planet.

IOIA would like to emphasize the importance of risk-based certification rooted in practice. Discrimination has put the BIPOC population at an extreme disadvantage for generations and agriculture is no exception. Within any type of regulatory change or best practice, we need to ensure that higher risk has no association with race, ethnicity, gender, or sexual preference. IOIA also encourages organic professionals to educate themselves with DEI trainings.

Our general observation is that low risk operations are often evaluated with a significantly higher degree of scrutiny than many of the larger and more complex operations. For example, a small 20 cow dairy may take the same inspection time as an operation handling 15 million dollars in imported products. Though the livestock regulations are inarguably more complex, that is not the only factor that drives why such practices have been normalized. From the beginning, it was recognized that the time and cost needed to comprehensively assess the volume of records at a large and/or complex operation would likely constitute a significant regulatory impediment for that operation. The result was a risk-based systems approach applied as a time management tool. Records are spot checked. Traceability and mass balance audits are used to verify the organic system plan and many components of recordkeeping. Focusing on high-risk ingredients and products when verifying suppliers is the standard approach. Historically, simply due to the information available, all or most records on a small dairy or crop operation could be reviewed and verified within a reasonable amount of time. In general, most large, complex inspections are 3-5 times the length of small and simple operations, yet the large operations may have 100 to 1,000 times

the output. With the introduction of SOE and the shortage of human capital for regulatory oversight, it may be time to reassess how risk-based inspections are designed.

To reduce the burden on low-risk operations, IOIA recommends implementing a tiered inspection approach. Low-risk operations with demonstrated and consistent compliance could benefit from inspection plans that include an alternating focus on different areas over several years, with more in-depth inspections occurring every 3-5 years. This cyclical approach would allow for a more strategic allocation of resources while verifying compliance and meeting the annual renewal mandate. Of course, high complexity, high risk operations and those with a history of significant non-conformances would receive comprehensive inspections at least annually.

One of the primary problems inspectors face is the regulatory requirement that operations provide perfect records, which is not an expectation attainable for most small entities. Adopting a matrix approach to inspections could prioritize the review of critical compliance factors (such as the application of prohibited inputs or use of noncompliant ingredients), over less significant clerical errors (such as an unchecked box or mathematical error on an OSP form). This would streamline the inspection process and provide more efficient regulatory oversight. For example, a small, diversified vegetable operation may have 100 harvest events. The operator may forget to document 3. That's still a 97%, an A+ without the curve. How does it serve the intent of the rule if a farmer is cited with an issue of concern, often resulting in a non-compliance for a 97%? Add to that the time & cost of responding to the issue, and the anxiety associated with a non-compliance citation, especially when other records, such as settlement statements, market sales, yield analysis, and feed rations are often available to support the organic integrity of the operation. What often results is intense frustration from the operator and a regulatory disincentive to continue as a certified entity. However, there should be no "graded compliance" when, for example, a farmer is found intentionally using prohibited inputs or a handler is commingling organic and non-organic ingredients.

What has been happening is that smaller operations are scrutinized minutely because they can be, and larger operations often are disproportionately, by any measure (value, complexity, volume) given comparatively cursory review due to a predisposition to manage inspection times.

If market footprint is included in risk factors as IOIA would recommend, the impact on consumers would likely be a net positive. If human capital is distributed based on risk and market impact, less fraudulent and non-compliant products will be introduced into the marketplace. With a more sound and sensible approach to certification for small, low risk operations, more operations will transition to organic and stay certified. Overall, this is the formula the industry needs to increase availability of products true to the organic seal.

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

An email and hotline would likely suffice. IOIA suggests that TOPP money be used to educate farmers and consumers on how to file a complaint and where to find the information.

Consistency in Organic Seed Use Discussion Document

Discussion & Questions:

1. Is there still support for the 2018 and 2019 recommendations?

Yes, with improvements based on Risk and Commercial Availability requirements, as noted below.

2. How burdensome is it for producers to demonstrate compliance with the commercial availability requirement for seed?

Commercial availability is burdensome for all producers. Removal of the commercial availability clause and the use of some other measurement of achieving 100% organic seed use would be ideal.

Because the rules and recommendations currently apply to all producers, it is burdensome for the small local/regional, direct to consumer producers, who are locally the face of organic production. These producers are usually small mixed vegetable/herb producers searching for a wide variety of seeds. Supplying documentation of a search for 'each' variety is extremely burdensome, as opposed to a large commodity producer selling one crop to third party handlers, importers, exporters or co-packers.

The type and size of the producer's operation and their risk to the organic supply chain should be a consideration in defining seed search requirements for the operation. Small local/regional producers with local markets not selling as organic to handlers are a minimal risk. The time and effort it takes an inspector to verify recordkeeping for seed searches at these operations is not a productive use of inspection time. Operations in National/International markets; especially importers, exporters, third party handlers and co-packers, are a major risk to the integrity of the organic supply chain and should bear the burden of increasing organic seed use within the industry.

3. In general, how available is organic seed, and is untreated seed significantly easier to find than organic seed?

Organic seed options do not appear to be a growing sector. Untreated seed is much easier to locate and normally cheaper than organic varieties. This is even more true for developing countries where commercial availability of organic seed is almost nonexistent for some crops. Some tropical countries may not have the agro-climatic conditions (day length, temperature, etc.) to produce seeds for some vegetables, or seed patentors do not focus on these small markets.

4. Are there some crops for which organic seed is available? Are there any crops for which lack of organic seed supply is notable?

There is a wide range of answers to that question. Yes, organic seed is available in many forms, however, it does not always meet the needs of the farmers. For example, does the seed meet the disease resistance needed to reduce use of inputs. Is organic short day corn available in regions with high silage demands, but short growing seasons? Is the seed company reputable or know for cross-pollination issues and low germination rates. These are the factors that make the clauses in commercial availability important.

When organic seed is available, we still see confusion in practice. For example, some producers look for organic seed late in the season when organic is no longer available, which would indicate limited availability. Very little organic, open-pollinated grain, and pulse crop seed is available or used in regions where lots of organic open-pollinated grain and pulse crops are produced. Very little to no organic white and blue corn seed is available compared to organic acres planted and organic white/blue corn products available to consumers. These are examples that indicate that that overall, the commercial availability clause is not an effective way to mandate organic seed use if the operation does not have some buy in beyond the regulatory requirement.

IOIA recommends that commercial availability of organic seed should mean that seed is available for an entire growing season to meet the needs of the supply chain.

Planting stock for vegetatively reproduced crops and for hybrid varieties are less available than heirloom, open pollinated crops. Farmers should be asked if they save their own seed/planting stock and if not, why. However, commercial availability includes in its definition “quality”. In general, a crop producer is not necessarily capable of raising seed or planting stock, as growing the crop vs growing the planting stock may be two very different businesses and require different growing practices. In some crops, reproduced through vegetative planting stock, the presence of tissue transported viruses or other pathogens may be a problem. Meristem tissue culture is one of the best ways to free planting material from viruses. Tissue culture is also the best way to prevent infestation of nematodes in new fields, i.e. banana production. 205.206(a) REQUIRES (not optional) that growers MUST prevent phytosanitary problems. In some situations, using self saved seed may not be the wisest option from a plant protection and preventive phytosanitary management point of view.

5. Is current organic seed research meeting industry needs? Which crops/varieties are the most promising avenues for organic seed research?

Organic seed research is lagging significantly behind industry needs. This might be due in part to the lack of market demand. As long as the commercial availability clause creates the current loophole for producers, there is less incentive for organic seed research. Organic seed research should focus on requirements of an organic production system rather than a large scale commercial production system:

- Identify traits requested by stakeholders in the supply chain – flavor, storability, milling quality, maximize production in low-input environments, etc
- Variety trials (per harvest zone), to identify varieties with disease resistance, weed compatibility, positive effects of companion plantings.

- Hybrid Seed Production – for disease resistance, weed compatibility, etc.

Organic producers should not be required to do variety testing. This is the role of both private and public research organizations, especially USDA.

6. How can the NOP address the handler role in seed choice, beyond the updates to Guidance 5029 that the NOSB previously recommended? Should the regulations be amended to apply the commercial availability requirements in 7 CFR § 205.204 to handling operations? Should handler Organic System Plans address seed choice? If so, how?

Seed companies are where organic producers or their third-party handlers go to purchase their seed. Most seed companies are parallel handlers and provide both organic and non-organic seed often of the same variety. However, there would be significant time required by inspectors to verify that there may be organic seed commercially available for each variety in their catalog/inventory. It would be easier and more effective to be able to verify a company's written SOP's for growing, purchasing, contracting and researching the growth of their organic offerings as well as focus on expanding their organic offerings. Many seed companies have their own research plots. They should be asked as part of their SOP how they incorporate organic seed research in their trials and what are the results of this research/comparisons.

Inspectors of crop operations frequently see contracts with buyers of organic crops that specify the use of a specific variety/source of seed that is "not commercially available". In these cases, the producers do not look for additional sources of seed. The handler might provide the planting seed and, at the same time, provide a letter that says 'organic seed is not commercially available'. There might be a more positive impact on organic seed usage if organic buyers were required in contracts to make organic seed available to their growers, especially of open and self-pollinated non-hybrid varieties.

Handlers will choose their variety based on their profile as ingredient, not based on its performance at the field level. Handlers are interested in size, brix, flavor, etc, not in nutrient demand or resistance to pests. Asking commercial availability to food processors so they justify why some specific cultivars are in demand will be too restrictive and often completely out of perspective on how the food business works. Handlers should be free to request whatever they need, that is what creates demand. Handlers should provide producers with seed search documentation as well as a letter for non-commercially available of the organic seed.

Seed commercial availability SHOULD NOT BE EXTENDED to handlers, which would in reality move a crop production requirement outside its scope to another scope.

7. What additional information do certifiers and inspectors need to effectively enforce the commercial availability requirement (i.e. how would a certifier or inspector know that an organic option is available and must be used)?

Certifiers should have risk-based policies and procedures based on a producer's supply chain risk. Inspector's should understand each certifier's policy and procedure and the reporting expectations based on a producer's supply chain risk.

We feel that requiring all certifiers to maintain a list of seeds not commercially available is redundant and a waste of certifiers' already limited time.

8. How could the NOP (or other entity) make information about commercial availability available publicly? What additional factors could be used to determine that a seed must be used? How could the EU's seed expert panel model inform the U.S. approach?

We suggest NOP or some other competent entity create and maintain a list of crops and crop varieties that are commercially available. This group could also be tasked with listing/prioritizing organic seed/seed varieties for research and development.

9. Who could/should build/maintain a U.S. commercial availability database for seed? What attributes should be listed/made available?

The NOP or an assigned entity with adequate funding should be responsible for building a list of crops and varieties that are commercially available and who can also be tasked with prioritizing the crops/varieties in need of research/production to make them commercially available.

In conclusion, the Consistency in Organic Seed Use proposal, as written, applies to all producers across all markets. The proposal should be re-thought and based on a producer's risk to the organic supply chain and markets. The idea of 100% organic seed use by each producer is laudable but smaller lower risk producers should not be required to increase their organic seed use any faster than seed researchers and handlers are expanding the organic seed/planting stock market availability.

Thank you again for your vision and your work on these issues.

Sincerely,

A handwritten signature in cursive script that reads "Margaret Scoles".

Margaret Scoles, on behalf of the IOIA Board of Directors
Executive Director