STRENGTHENING ORGANIC SYSTEMS, LLC

Organic fraud prevention and supply chain integrity

September 30, 2024

National Organic Standards Board
Compliance, Accreditation, and Certification Subcommittee
USDA-AMS-NOP

Docket: # AMS-NOP- 24-0023

RE: Discussion on "Oversight to Deter Fraud: Residue Testing for Global Supply Chain" Compliance, Accreditation, and Certification Subcommittee

Dear NOSB Compliance, Accreditation, and Certification Subcommittee (CACS),

Residue testing plays a critical role in organic certification by providing a means for monitoring compliance and discouraging the mislabeling of agricultural products. Given the development of the organic market, the organic regulations, and the advancements in testing technology in the past ten years, SOS believes updates to the National Organic Program's (NOP) periodic residue testing program are necessary.

Who is SOS?

Strengthening Organic Systems (SOS), LLC was founded to strengthen the resilience and overall integrity of organic systems and global organic supply chains. Our goal is to assure authenticity of organic products, protect organic businesses from organic fraud, and maintain consumer confidence in the USDA organic seal. Our essential offerings support compliance with the USDA strengthening organic enforcement (SOE) regulations by providing unparalleled insights into fraud vulnerabilities and step-by-step assistance with supply chain mapping, complaint submissions, the development of organic fraud prevention plans, organic training, organic regulatory readiness, and organic fraud reporting. We have extensive experience in providing services and training tailored to meet the needs of individual businesses.

As long-time leaders and regulatory experts in the organic space, SOS is excited to continue to support NOSB in its purpose to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

Why does SOS support NOSB's work on residue testing?

Risk-based and periodic residue testing of organic products is necessary to maintain the integrity of the organic certification label and the credibility of the organic sector. Residue testing, when conducted consistently and expeditiously (especially at farms and at ports for high-risk imported products), helps compliance verification for organic regulations and sends a serious message to fraudsters that they will get caught. Testing can act as a powerful fraud deterrent, as criminals are less likely to engage in fraudulent activities when they believe there is a high probability of being caught. Additionally, the presence of a robust testing program puts the marketplace on notice and signals a commitment to quality and integrity, further discouraging fraudulent behavior.

An updated and more rigorous testing program will augment the ability for both accredited certifying agents (ACAs) and certified operations to verify compliance, deter fraud and prevent contaminated/fraudulent products from entering organic supply chains. The landscape of analytical tools available to the food and non-food industry is quickly evolving. Testing methodologies are becoming more precise, and businesses have options of testing products at various stages of the supply chain. Today, for many brand owners and organic ingredient buyers, it is

company policy and best practice to require testing to authenticate an ingredient or product prior to purchasing or receiving. With updated and expanded testing instruction from USDA, industry will be provided with greater incentive and opportunity to review internal testing programs alongside Organic Fraud Prevention Plans, and further implement testing as a critical mitigation and monitoring tool to address fraud vulnerabilities and high-risk ingredients. Further, certifier instruction, training and expertise in sampling, investigations, and defensible decisions in compliance and enforcement will increase the public confidence in the USDA National Organic Program Seal.

FALL 2024 DISCUSSION DOCUMENT

SOS suggested several improvements to NOP's testing program and NOP Handbook Instruction in our Spring 2024 comments **(See Appendix A**). We encourage review of those comments in conjunction with our feedback below on the Fall 2024 Discussion Document.

NOP 2610: Sample Procedure for Residue Sampling

SOS agrees with the need to perform updates and changes to NOP 2610. We are particularly supportive of including a list of minimum equipment and inspector competencies required to take a sample, identifying and developing inspector training and competencies, and improving instructions for ensuring chain of custody integrity. Dedicating funding and resources to training inspectors, certifiers and labs will be an important and key investment.

SOS encourages the careful examination of existing resources and standardized processes for training, sampling, and equipment. Many expert resources and training or procedures exist, with some examples offered here for reference:

- EPA Soil Sampling
- NEPIS Sampling Guide
- California Guidelines for Collecting Field Samples

With respect to sample collection diversity and sample amounts, SOS strongly supports specific sampling procedures for produce in the field (pre-harvest) along with non-crop and non-harvested crop samples (soil, water, tissue, inputs, seeds) for targeted and risk-based purposes. The SOE Rule places great emphasis on fraud detection and prevention where products change ownership and physical possession within the supply chain. We agree that these are critical points where the risk of fraud or loss of organic integrity is heightened. However, the intentional application of a prohibited substance (aka organic fertilizer fraud), starts on the farm, in a field, prior to the crop being harvested. Fraud detection on the farm requires an inspector that is competent and trained on a combination of risk analysis, field testing and modern enforcement tools. A successful SOE will not happen if our efforts (and testing instruction) do not start on the farm and begin with pre-harvest testing.

NOP 2611: Instruction Laboratory Selection Criteria for Pesticide Residue Testing.

Selecting a lab that is competent and reliable in meeting organic testing needs is crucial. It is important that the organic sector invites partnerships with labs that are very familiar with the organic regulations, understand the unique challenges of testing, and want to provide services to the organic farmers, handlers and certifiers.

SOS strongly agrees that guidance is needed for laboratory selection to include prohibited materials inputs (such as prohibited materials in fertilizers) and other (non-pesticide) substances prohibited in organic production. There is a long history of detected and prosecuted fertilizer fraud with no clear indication that the practice has stopped. One

might say that substituting cheaper, inorganic nitrogen compounds for organic nitrogen sources is the oldest trick in the book, for a good reason – it is cheap, easy, and historically not tested for. The history of fertilizer fraud and the need for increased scrutiny of inputs (opportunity to commit the act) underscores the importance of robust oversight, testing, and enforcement to protect the integrity of organic products. Expanding residue testing beyond pesticides to include a wider range of prohibited substances, such as synthetic nitrogen compounds would go a long way. This would help detect fraudulent adulteration and ensure the integrity of organic fertilizers.

SOS agrees with the specific redline corrections, with a special shout-out to revising the language from "should" to "must in last paragraph, which states, "If certifying agents suspect a prohibited substance was used that is not included on the NOP "target" list, they should initiate sampling/testing and investigation."

NOP 2611-1 Prohibited Pesticides for NOP Residue Testing

NOP 2611-1 is referred to as the "NOP Profile" or "NOP Panel" for residue testing. This list should be expanded and modernized, and SOS supports the comments and suggested changes in the Discussion Document. Adherence to NOP instruction is audited during NOP Accreditation audits, which by default increases the likelihood that certifiers will focus most of the sampling analysis on this profile. Of particular importance is to expand residue testing panel or metabolite testing to include materials beyond pesticides and capture products beyond crop production. Providing explanation of testing panels and application opportunities would be beneficial to targeted application of instruction to investigation needs.

NOP 2613: Instruction Responding to Results from Pesticide Residue Testing

In the Discussion Document, the CACS states:

> "NOP 2613 only outlines how to respond to positive results of pesticide residues. It does not provide direction on responding to positive results of other prohibited substances. NOSB acknowledges that the current regulations only exclude organic sale provisions when residues are detected above the FDA action level or above 5% of the EPA tolerance. However, certifiers need a roadmap for responding to positive results from tests for residual prohibited solvents, heavy metals, and other prohibited substance screens. Without a roadmap for responding to positive results, there will likely be hesitancy in collecting samples for non-pesticide residue sampling, and it will be challenging to ensure consistency among certifiers in responding to these results."

SOS agrees and *strongly emphasizes* the need to *prioritize* updated NOP Instruction that will strengthen the application standard to overcome challenges identified by organic stakeholders relating to unintentional contamination (UREC, drift) and concentration factors. This includes a clear process for responding to positive results for any prohibited substance, with or without an established tolerance or action level. Although we don't have a perfect answer or solution in all cases, we agree with the sub-committee's suggestions on what needs to be developed by NOP to address positive residue detection for crops without tolerance levels (minor crops and non-food crops) as well as guidance to address drift or inadvertent contamination. We offer the following additional comments on policy solution options:

What are the problems we are solving for?

Unintentional contamination (UREC, drift): NOP's Instruction sets a default .01 ppm "de-certification" threshold for products with detected residues without tolerance/action levels, even in cases of drift or other unintentional presence of pesticide residues. EPA tolerances only exist for certain pesticides on certain edible crops and does not cover non-food crops (e.g. cotton), minor crops (e.g. quinoa), and crops that are drifted on from pesticides that do not have an EPA tolerance for that crop.

Concentration factors: When a specific tolerance does not exist for a processed commodity, NOP's Instruction asks certifiers to use tolerance for the raw commodity. Using the same protocols for fresh and dehydrated/extracted/concentrated plant material does not account for dry-down or extraction factors.

Policy Solutions:

Develop criteria for assessing minor crops & non-food crops under established EPA tolerances for broader crop groups.

- *Background*: EPA establishes tolerances for crop groups, which are broader groups of crops that share similar qualities. The crop groups are detailed at 40 CFR 180.41. Pesticide tolerances are established for crop groups so that manufacturers do not have to show evidence for all types of crops included in the crop group in order to have established tolerances for those commodities.
- *NOSB Action/Proposal*: We support a recommendation to NOP to develop criteria for certifiers to determine tolerance levels for minor crops under established EPA tolerances for broader crop groups, and for non-food crops under established EPA tolerances for the edible portion of the crop. The criteria and a procedure for using the criteria would then be incorporated into NOP 2613.
- *Strengths:*
    - Addresses non-food crops, especially important for cotton (non-food crop with documented history of fraud)
    - Utilizes existing EPA tolerance information
- *Challenges/Outstanding Issues we believe are best addressed by NOP*:
    - Involves interagency cooperation between NOP & EPA to co-develop criteria
    - May encounter EPA resistance to extending tolerances beyond crops explicitly listed within a crop group

Clarify the procedure for utilizing EPA tolerances for Indirect or Inadvertent Residues

- *Background:* NOP Instruction doesn't give detail on how to handle the different types of thresholds covered by 40 CFR 180. Without a procedure otherwise, certifiers are currently taking 5% of the inadvertent tolerance values. Applying a 5% limit on values that are already at "drift level" values puts organic growers at a disadvantage.
- *NOSB Action/Proposal*: We support a recommendation from NOSB for NOP to explore the following policy solution option:
    - Recognize the values in (d) *Indirect or inadvertent residues* as equivalent to 5% of EPA Tolerance for the purpose of responding to residue tests (e.g. do not take 5% given that these are already at inadvertent levels; evaluate compliance directly against values as they appear in (d)).
        - Incorporate policy into NOP 2613.
    - Develop a new procedure with EPA for establishing tolerance in paragraph (d) in cases when organic operations detect inadvertent residues.
        - Incorporate procedure with NOP operations for initiating tolerance establishment with EPA.

- *Strengths:*
  - Utilizes existing EPA tolerance information

- *Challenges/Outstanding Issues we believe are best addressed by NOP:*
  - Need better understanding of when/how these tolerances are established.
  - Could be resource intensive if approached crop by crop. See example at 40 CFR 180.685 where there is Paragraph D value is for "all other commodities" instead of by individual crop type.

Addressing Dehydrated, Extracted, or Concentrated Organic Products

- *NOSB Action:* We support a NOSB recommendation to NOP to develop a specific section in NOP 2613 related to responding to positive results for dehydrated, extracted, or concentrated products.
  - We support looking at the adoption of USP 561 as a guideline for establishing thresholds for dried/extracted products (e.g. dried herbs and spices; botanical extracts used in dietary supplements) that account for differences in water content between dried versus fresh product. This would provide a value from which certifiers can apply the 5% threshold, instead of defaulting to .01 ppm for extracted or dried products.
  - We also support looking at the EU model and the factor used to convert fresh to concentrated.
- *Strengths*
  - Addresses concentration factors
  - Already used by FDA for over-the-counter drugs
  - International harmonization (EU)
- *Challenges/Outstanding Issues we believe are best addressed by NOP*
  - Complex intersection between FDA, EPA and USDA regarding oversight of residues in NOP-certified food and supplements
  - Need clarity on the legal authority and implications for FDA
  - Need to clarify terminology and implementation (NOP does not set tolerances; How do these values get incorporated into NOP 2613)

<u>Exclusion from Organic Sale - Distinguishing between intentional (fraud) and unintentional application of a prohibited substance</u>

SOS recommends an amendment to the regulations to clarify that an intentional application of a prohibited substance results in the removal of the organic label (aka exclusion from sale as organic), regardless of whether a tolerance level is established or not. An amendment would bring the regulation in line with the language in OFPA 6511, SEC 2112.

- *Issue:* The Discussion Document indicates there may be confusion and/or a lack of clarity on whether the detection of direct prohibited material application (intentional, regardless of where or when) can or should be excluded from sale as organic. To the best of our understanding (and reading of the law), any crop or product to which prohibited materials have been intentionally (directly) applied shall not be sold, labeled, or represented as organically produced. This is the case *regardless* of whether the residue detected is below 5% of the EPA tolerance level or the FDA action level.

- *Background / Regulatory References:*
  - **What does the law (OFPA) say?**
    Under 6511 / SEC. 2112:
    (c)(2) Compliance Review - Removal of organic label
    If, as determined by the Secretary, the applicable governing State official, or the certifying agent, the investigation conducted under paragraph (1) indicates that the residue is—
    (A) the result of intentional application of a prohibited substance; or
    (B) present at levels that are greater than unavoidable residual environmental contamination as prescribed by the Secretary or the applicable governing State official in consultation with the appropriate environmental regulatory agencies; such agricultural product shall not be sold or labeled as organic under this title.

  - **What does the regulation say?**
    § 205.671 Exclusion from organic sale. When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

  - **What does the Preamble say in response to commenters?**
    (3) *Exclusion from Organic Sale*. Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: "Any crop or product to which prohibited materials have been directly applied shall not be sold, labeled, or represented as organically produced."

    NOP Response: We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been purposefully/directly applied.

    The presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through means of drift or intentional application. If the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than $10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing is not a means of qualifying a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations set forth in the Act and in this part.

- **What do the EU regulations say?**
  *Articles 28 and 29 of EU 2018/8*48
  Article 29 (2) "The product concerned shall not be marketed as organic if the official investigation concludes that an operator has used non-authorized products or substances, has not taken the appropriate precautionary measures to avoid the risk of contamination, or has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

  SEE REFERENCE: A Vade Mecum on Official Investigation in Organic Products (2024) – Good Implementation Practices for Articles 28 and 29 of Regulation (EU) 2018/848. It can be downloaded for free here.
  - This document offers a testing toolbox and structured methodology to facilitate the implementation of the EU organic regulation around testing.

SOS RECOMMENDED ACTION ON EXCLUSION FROM SALE AS ORGANIC:
OFPA is clear on the matter. We agree with early preamble commenters that the regulation at §205.671 could be misinterpreted, and it appears that it is. SOS recommends an amendment to § 205.671 of the regulations (or where most appropriate) to reflect the letter of the law. The regulation should be amended to clearly state that the result of intentional application of a prohibited substance is removal of the organic label (aka exclusion from sale as organic). We also recommend an update to Instruction 2613 to clearly spell out the response process for the detection of a prohibited substance without an established EPA or FDA tolerance level and the consequence (exclusion from organic sale) should the findings of the investigation reveal an intentional application of a prohibited substance.

Decision Tree Suggestion: Sampling Procedure and Planning

The opportunity to develop a decision tree to support investigation approach is a suggested addition to guidance or instruction. Utilizing several expert working groups based on matrix and scope will support development of robust resources and equip certifying agents and the marketplace with the tools to identify, prevent, and deter fraud and contamination of the organic supply chain.

1) Operation Selection Criteria: Considerations for type of sample approach.
   a. Random
      i. Identify scope of products and potential contaminants
      ii. Identify potential sampling locations (storage, field, past buffer, representative at field or farm level) and preferred commodities based on risk.
      iii. Outline sample size, format
      iv. Identify auditor or sampler, and timing required for sampling (before harvest, march testing for pre-emergent, etc.)
      v. Any special instructions (examples provided)
         1. Feed: Sample each constituent ingredient, if a combined feed product is sampled.
         2. Sample the North field along the organic field against the buffer subject to noncompliance in 2023. Identify field sample locations in sample report. Send in for NOP Profile and Glyphosate testing.
         3. Obtain tissue from the last slaughtered animal for residue analysis and send to lab XXBBYY via cooler. Test request form to include << >> residue tests
         4. Obtain a hair sample for residue testing at << Lab>> for <<residues to test for>>

b. Risk or Investigation
    i. Operation's increased risk categories identified for auditor/ sampler
    ii. Scope qualification for sampling confirmed
    iii. Considerations for entry: ensure auditor has adequate instruction for entry, notification, and issuance of sampling receipt. In the event that sampling is declined, process for notifying the office and issuance of notice of noncompliance is clear.
        1. Unannounced Inspection Notice
        2. Management contact for operation
        3. Safety consideration for auditor: Local law enforcement notified?
        4. Pre-audit review of approach and considerations for sampling and audit performed.
        5. Any records gathering and evidence needs identified.
    iv. Identify probable contaminants for risk category and testing/ samples needed.
        1. Confirm Lab needs confirmed for specialty or uncommon products
    v. Timing considerations for sampling outlined
    vi. Identify scope of products and potential contaminants
    vii. Identify potential sampling locations (storage, field, past buffer, representative) and preferred commodities based on risk.
    viii. Outline sample size, format
    ix. Special testing instructions (targeted materials, if in addition or in lieu of the NOP Profile)
    x. Special Handling considerations (cooler, equipment, lab requirements)

In closing, SOS strongly supports residue testing as a critical monitoring and verification tool that can be used to evaluate the efficacy of contamination and fraud prevention measures, demonstrate compliance with regulatory requirements, and maintain integrity of organic global supply chains. We support the steps NOSB and NOP are taking to update the NOP Handbook to ensure clarity and consistency in testing and response practices.

We thank NOSB for its volunteer service and everyone's commitment to work on this important topic.

Respectfully submitted,

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Appendices:

- **A –** SOS Spring 2024 Comments

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