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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STRENGTHENING ORGANIC SYSTEMS, LLC

Organic fraud prevention and supply chain integrity

April 3, 2024

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

Docket: # AMS-NOP-23-0075

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 an important 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. An updated and more rigorous testing program will augment the ability for both ACAs and certified operations to verify compliance, deter fraud and prevent contaminated/fraudulent products from entering organic supply chains.

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 and investigations, 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 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?

SOS believes that required periodic residue testing of organically produced agricultural products on a regular and random basis is necessary to maintain the integrity of the organic certification label and the credibility of the organic sector. Requiring accredited certifying agents to annually conduct residue sampling and testing on **at least** a minimum of five percent of the operations they certify is necessary to monitor organic food and fiber production and handling operations and provide a safeguard to help keep contaminated or fraudulent organically labeled food products from entering the marketplace.

Under 7 U.S.C. 6506 accredited certifying agents are required by law to conduct annual periodic residue testing of organically produced agriculture products on a regular and random basis to determine if certified agricultural products contain any pesticides, other nonorganic residue, or natural toxicants. As the regulatory overseer of the nation's organic certification system and the USDA agency responsible for assuring compliance with the OFPA's

legal and regulatory requirements, the AMS has legal responsibility to ensure that the NOP has **adequate** regulatory standards, enforcement guidelines, and residue testing procedures in place to implement a reasonable and effective monitoring and residue testing system.

SOS believes that while NOP's residue testing program is a good program, the associated guidance and instruction on what to test for and how to respond to results has become outdated. The landscape of analytical tools available to the 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. Developing and implementing an effective residue testing program must rely on science-based information and product-specific attributes, and the program should be designed to meet the needs of certifying agents and certified operations and updated to stay consistent with industry standard testing practices and expectations. Strategies for reducing fraud and contamination risks must be considered at each step of the supply chain and for each product type and product form and consistent testing methodologies must be used across the labs used by certifiers.

In short, given the implementation of SOE, the importance of testing as a critical compliance monitoring tool, and the outdated status of the NOP's testing guidance/instruction, SOS believes NOP's residue testing program needs improvements to be considered "adequate." NOSB's work in this area is not only important, but it is well justified since providing NOP with a recommendation on residue testing falls directly under the specific responsibilities of NOSB outlined in OFPA starting at section 2119(k):

> 5. PRODUCT RESIDUE TESTING. —The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

Updating NOP's residue testing program will strengthen testing as a tool for detecting fraud and it will help to produce data that can then be used to inform targeted risk assessment and aid greater efficacy in fraud detection. This work is timely for NOSB, NOP and organic stakeholders that are committed to SOE and optimizing effective implementation and fraud prevention.

What updates are needed to NOP's residue testing program?

NOP 2610: Instruction Sampling Procedures for Residue Testing

1. Does this document instruction provide adequate information for certifiers and inspectors to collect samples in the field?
2. Are there areas pertaining to sample collection (sample size, when to collect samples, sample selection, etc.) that need to be developed or improved? Please provide suggestions.
3. How can additional instruction or guidance on sample collection support the voracity of testing results so that adverse actions are more defendable?

SOS Response:

NOP 2610 provides some valuable information for pulling samples in the field, but improved resources would benefit the integrity of the supply chain. Specifically, the guide provides limited or no resource guidance for minimum training and qualification, sampling techniques, pulling appropriate sample by product type, sample size, and selection. Further clarification is supplied for these recommendations here:

1) Beyond the recent updates to reflect changes under the SOE final rule, the guide should reflect the breadth of the organic supply chain, not only commodities produced in crop production. This includes livestock products (milk, eggs, fiber) and livestock tissue, processed products, agricultural inputs, and sampling best practices that support production compliance verification, including foliar sampling and resources for consistent enforcement decisions beyond the consumed or harvested commodity.

2) Resources exist for best practices in sample pulling, sample integrity, and sample training. A comprehensive instruction pointing to EPA, FDA, and other recognized and established sampling practices would support accredited certifying agent activities, reduce variation in approach, and increase deterrents to fraud.

3) The instruction does not outline minimum qualification or equipment criteria for sampling, and establishing minimum training requirements for conducting field sampling, including specific qualification or expertise based on type of sample pulled would be beneficial.

4) Purge or best practices for avoiding sample site contamination are absent from the instruction. While the instruction indicates that a sample should be pulled from a single location in a field, bin, or pallet, this does not align with best practices and actual activities may not meet minimum established standards for collection. The instruction should outline that the auditor or certifier representative must collect the sample, and supportive instruction to indicate appropriate purge, collection scenario based on lot, origin, and commingling of multiple lots or sources. Sweeping up a sample from a bin, collecting off the top of a bulk tub, having the operator collect the sample, collecting from carryover crop storage of a crop already sold, or failure to adequately clean equipment prior to sampling may result in inaccurate results or results without compliance value to the program or to the operation, cost time and resources, and fail to support effective compliance decisions and defensible results.

5) Best practices for sample holding and timeframes for submittal to a lab are absent. Samples may take extended time to be submitted to the lab, may not be held or shipped in appropriate conditions based on the product type- resulting in spoilage, breakdown of chemical compounds or sample degradation.

6) Instruction relating to the complexity of mixed product sampling would be useful also. In the event a product sampled is comprised of multiple ingredients, positive results must be traced through each ingredient in the supply chain. Instruction for appropriate sample procedure when sampling a mixed product (including collection of each contributing ingredient) could be useful.

7) The instruction should continue to contain chain of custody, sample documentation, and resources, and the links should be updated and expanded to reflect best practices in sampling.

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

1. Section 4.1 describes one type of residue screen that can be used for testing. What additional tests should be included in this section (e.g., heavy metals, synthetic solvents, fumigants, National Organic Standards Board (NOSB) Proposals and Discussion Documents April 2024 175 of 267
herbicides, etc.)? What should be the threshold for validating additional testing methodologies in this section to ensure results are actionable?
2. Sections 4.2 and 4.3 describe laboratory selection criteria and suggested laboratory practices. Do either of these sections need to be updated to align with current best practices?

3. How can additional instruction or guidance on laboratory selection criteria and testing methodology support the voracity of testing results so that adverse actions are more defensible?

SOS Response:

NOP 2611 should be updated to reflect sample requirements under USDA National Organic Program. The title of this document references pesticides, a finite category of materials in crop production. The instruction should be updated to reflect laboratory selection to include testing beyond pesticide residues, including herbicides and other synthetic or prohibited materials for all scopes of USDA NOP certification, including wild crop, livestock, and handling activities. SOS recommends a working group of experts be established to develop recommendations for expanding this instruction beyond pesticide residue laboratory selection, including prohibited materials in inputs, synthetic herbicides, fertilizers, and other substances that are prohibited in organic production.

NOP 2611-1 Prohibited Pesticides for NOP Residue Testing:

1. Does this list of prohibited substances provide value to certifiers in evaluating organic compliance?
2. How can this document be improved?
3. Would certifiers find value in developing a decision tree to determine which tests should be conducted depending on the commodity, geographical location, and position within the supply chain? Please describe how a decision tree could assist certifiers with testing and compliance verification.

SOS Response:

Consistent with the comments by the Organic Trade Association from 2023, NOP's Guidance on Residue Testing 2611-1 (Prohibited Pesticides for NOP Residue Testing) should be updated to reflect substances and methods currently in use. We agree that an efficient process by which to update the list should be explored so that the list can keep up with new and emerging technologies, substances, and their uses. SOS encourages NOSB to work with testing labs, accredited certifiers, and other stakeholders to update the list contained in NOP-2611-1 and identify where focused evaluation can be expanded.

Updates are needed to address the challenges around positive test results for which EPA has not established a tolerance, and FDA has not established an action level. Further, when a specific tolerance does not exist for a processed commodity, NOP's Instruction asks certifiers to use the tolerance for the raw commodity.

NOP 2613: Instruction Responding to Results from Pesticide Residue Testing

1. Section 5.3.3 describes how to respond to positive results when there is no EPA tolerance or FDA action level. Please describe experiences attempting to respond to results in this type of situation. How can this section be improved to facilitate and support sampling and testing for prohibited substances that do not have EPA tolerances or FDA action levels (e.g., synthetic solvents)?
2. Are additional sections within this instruction needing updating or improvement? Please provide suggestions.

SOS Response:

Several opportunities exist to improve NOP 2613. A benefit of the instruction 2613 is that there is clear guidance over the threshold for positive residue results and explanation for certifier activity relating to residue results. The

following comments outline opportunities to improve and modernize 2613 to support a robust and effective sampling system:

1) This guidance is limited in scope to only established tolerances by EPA and FDA, and not all commodities or products have established thresholds. For products without established threshold, 0.01 ppm becomes the default threshold, which results in restrictive decisions for products that have not been considered in other regulations.

2) Using the same protocols for fresh and dehydrated, extracted, or concentrated plant material does not account for dry-down or extraction concentration. This results in overly restrictive decisions for the organic spice and herb sector, as the fresh tolerance is applied to a dried product. SOS recommends polling of experts to determine a reasonable concentration factor for these types of products.

3) There are field application limitations to use of strictly EPA or FDA tolerances established for harvested commodities or the more restrictive instruction for decisions where a tolerance is not established. For example, if an auditor observes evidence of spray in a field or a certifier receives a complaint that a field has been treated with a preemergent early in crop development, NOP Guidance does not provide enforcement instruction to support evaluating leaf or soil residues prior to crop maturation or guidelines for evaluating environmental contamination and half-life of materials to remove penalty for unavoidable pre-existing environmental contamination. Where instruction is not clear, enforcement activities may become less prevalent, including sampling despite risk being present.

4) Identification of resources for evaluating half-life and defensible decisions based on results that account for developing crop, soil, and livestock products would support improved program integrity and provide a deterrent to fraud.

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 you are taking to update the foundational elements found in 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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