National Organic Standards Board Certification, Accreditation, and Compliance Subcommittee Residue Testing for a Global Supply Chain Discussion Document July 9, 2024

Note: The Certification, Accreditation, and Compliance Subcommittee (CACS) is working on many fronts regarding residue testing. This document discusses several topics, including updates to Guidance Documents NOP 2610, NOP 2611, NOP 2611-1, and NOP 2613.

Executive Summary of Changes to Existing Guidance Documents:

This table outlines the changes proposed to each of the current guidance documents in the National Organic Program (NOP) Program Handbook, which are discussed in more detail throughout this discussion document. Also summarized are recommendations for additional guidance documents.

NOP 2610 – Sample Procedures for Residue Sampling	 Sampling Equipment Inspector Training and Competencies Duplicate Sampling and Sample Retention Chain of Custody Integrity Sample Collection Diversity & Sample Amounts Time is of the essence Specific Redline Corrections
NOP 2611 – Laboratory Selection Criteria	Expand Testing Guidance Specific Redline Corrections
NOP 2611-1 – Prohibited Pesticides for NOP Residue Testing	 Information Layout Regional and Crop Specific Information Expand What to Test Test for Metabolites Companion Testing Update Frequently
NOP 2613 – Responding to Results	Detection without Tolerance Level Dehydrated, Extracted, or Concentrated Above EPA Tolerance / FDA Action Level Specific Redline Corrections
Additional Guidance Documents	 Residue Sampling Decision Tree Residue Sampling of Non-Crop and Non-Harvested Crop Products Validation and Verification Guidance for 205.273(d) Additional Instruction Considerations

Introduction:

The Certification, Accreditation, & Compliance Subcommittee (CACS) presented discussion documents at the <u>Fall 2023</u> and Spring <u>2024 NOSB</u> meetings on Residue Testing for a Global Supply Chain (RTGSC). Many commenters supported continuous improvement in testing to ensure integrity, considering the size of the organic marketplace and the program's global reach.

Residue testing is an essential tool for ensuring compliance with organic regulations. Residue testing does not substitute for the certification process and verification of compliance through an organic system plan review and annual inspection. However, it can support this process with objective results related to the presence of prohibited substances or the use of excluded methods.

The RTGSC series aims to work with the community to provide a recommendation that ensures testing remains a relevant and effective tool for compliance verification in the organic global supply. At the Fall 2023 NOSB meeting, a commenter wrote, "An updated and more rigorous testing program will augment the ability for both certifiers and certified operations to verify compliance, deter fraud, and prevent contaminated/fraudulent products from entering organic supply chains."

Foundational Focus and Timing:

Foundational work is needed first. Therefore, the CACS aims to update the foundational elements in the respective related guidance and instruction documents with this document. As one commenter stated, "...ensure there can be clarity and consistency in the testing and response practices."

During the spring 2024 NOSB meeting, the CACS asked the community for feedback on modernizing the guidance documents corresponding to residue testing. The common theme was that the guidance scope needed to encompass prohibited substances beyond residues of pesticides (e.g., synthetic solvents, heavy metals, and other prohibited substances) in addition to expanding guidance to address samples beyond the harvested crop / raw ag commodity (e.g., soil, water, plant tissue, livestock products, processed products, etc.). Also, there was a consensus that pesticide residue tests must be expanded based on known domestic and international risks (e.g., herbicides and fumigants) and common farming practices for the region based on agronomics. A public commenter from the certifying community noted, "Broadening the list to include solvents, fumigants (particularly those used at the borders), conventional fertilizers, herbicides, and other prohibited substances used in conventional food production would give us more useful tools without increasing the burden of testing."

Updates to the guidance documents on these topics are necessary to support the work of certifiers and their inspectors, who collect samples and analyze results. The guidance documents must provide certifiers and inspectors with the resources and information to collect samples confidently, ensure the appropriate type of test is ordered, and consistently respond when samples test positive for prohibited substances.

The goal is to aid the NOP in updating guidance documents so residue sampling can remain a critical verification tool in the certification process. We also encourage the organic community, certifiers, scientists, farmers, inspectors, and NOP to share experiences of potential threats and determine best

practices through testing to verify the integrity and authenticity of organic products. Below is a summary of public comments and NOSB analysis related to the various guidance documents on residue sampling.

Proposed Updates to NOP Guidance

Sampling Procedures for Residue Sampling (NOP 2610)

 NOP 2610's primary focus is to outline sampling procedures. NOSB requests that the belowmentioned updates be incorporated into revised instructions for sampling procedures for residue testing.

a. Sampling Equipment

- i. Sampling equipment can pose a risk of contamination of sampled products. To create a consistent sampling regime across all certifiers globally, NOP should update this guidance with a list of minimum equipment and inspector competencies required to take a sample; specific tests have different requirements.
 - Equipment: Shipping cooler, ice packs, gloves, bags, sample collection reports, grain probe (for sampling grain bins), other specialized sampling tools, and proper cleaning methodology.

b. Inspector Training and Competencies

- i. Competencies: What training do all inspectors need to qualify to consistently take samples on organic operations?
 - This training should also be developed for more complicated sampling demands on higher-risk operations.
 - a. I.e., Imports, investigations, etc.
- ii. Note: Coupling sampling and annual inspections can compress inspectors into a rushed sampling procedure.

c. Duplicate Sampling and Sample Retention

- i. When sample results are positive for residues, many quality assurance programs retain a duplicate sample to retest. However, it is not currently best practice to take a duplicate sample when inspectors take samples per §205.670. NOP 2610 could be updated to outline when this action is relevant and what steps inspectors should take to ensure the validity of results from duplicate samples.
 - 1. We need to determine how and where these duplicates are retained.

d. Chain of Custody Integrity

i. A residue sample chain of custody is essential in obtaining actionable sample results. If there is any breakdown in this chain of custody, the validity of the results can be questioned, and certifiers may not be able to take action if a positive outcome is found. The current guidance outlines the best practices for sealing bags, tamper-evident tape, and ensuring that shipping labels demonstrate a chain of custody. However, the updated guidance could include instructions for adequately identifying samples, ensuring integrity, and documenting the chain of custody. A clear set of procedures would assist certifiers with their staff training and potentially develop agreements with 3rd parties other than inspectors to conduct residue sampling activities.

e. Sample Collection Diversity and Sample Amounts

- i. NOP 2610 clearly describes the sample size necessary for obtaining valid pesticide residue results based on the commodity type. It provides some narrative guidance on what part of the plant should be sampled if sampling occurs in the field or how to document a composite sample if several samples from different bulk containers are used to create a single composite sample. However, the instructions must clarify how samples are collected in various situations and include pre-collection preparatory information such as purging or best practices for avoiding sample site contamination. For example, collecting a grain sample in the field would dramatically differ from collecting a grain sample in a bulk ship. As we look to expand the handbook documents beyond prohibited pesticides, the guidance should include specific processes for collecting samples in inspectors' various situations. Hence, inspectors and certifiers have the confidence to take samples in many situations. At a minimum, NOSB would like to see specific sampling procedures for the following commodities and situations:
 - 1. Produce in the field.
 - 2. Produce in packed boxes.
 - 3. Grain and oilseed in the field
 - 4. Grain and oilseed in storage (bins, tanks, covered piles)
 - 5. Grain and oilseed in transit (rail cars, containers, bulk ships)
 - 6. Liquid processed products
 - a. Oils
 - b. Juice and other extracts
 - c. Milk
 - 7. Herbs and spices
 - Non-crop and non-harvested crop samples (soil, water, tissue, inputs, seeds)
 - 9. All other crops appropriate to their condition

f. Time is of the Essence

- Sample collection and preparation must be thorough and expedient to minimize sample decay, pesticide losses, and contamination of products entering the chain of commerce.
 - Include best practices for sample holding and timeframes for submission.

g. Specific Redline Corrections:

- i. Update section 4.4: Certifiers are called upon to record the variety of a crop and the brand name. However, circumstances may arise in which this information is unavailable to the individual collecting the sample. We recommend changing to "recording information when available."
- ii. Evaluate that reference material is current and that reference links are functional.
 - 1. Codex Alimentarius Commission links are broken in the reference section.
 - 2. Reference links should be expanded to reflect best practices in sampling.

Laboratory Selection Criteria (NOP 2611)

NOP 2611 primarily focuses on ensuring the laboratories used for residue analysis are accredited
to conduct multi-residue pesticide screens. As NOP expands guidance related to testing for
other types of pesticides and prohibited substances, the laboratories conducting these analyses
must be competent and consistent. Therefore, NOSB requests that additional specific
requirements for laboratory selection accompany any additional types of tests described in
handbook updates.

a. **Expand Testing Guidance:**

- i. Identify labs that can test for specific risks across all organic scopes: crops, livestock, wild crops, and handlers.
 - Crops Scope—Guidance is needed for laboratory selection to include prohibited materials in inputs, synthetic herbicides, fertilizers, and other substances prohibited in organic production.
 - a. Additional items to test outside pesticide residue must be included.
 - i. For example, testing oilseed meal for prohibited synthetic solvents requires laboratory competencies in oil chemistry, and certifiers will need to determine if the laboratories they currently use for multi-residue pesticide screens have the necessary competency and accreditation to conduct these additional tests.
 - 2. Identify Current best practices for a broader set of needed test methods, matrices, and sample methodologies.

- a. Testing within the agricultural and food industry is routine and well-researched.
 - Benchmarks with ISO, GAFTA, FOSFA International, Regulation EC No 619/201, and other respected institutions may be consulted as resources to help inform what type of lab accreditation and testing methods are needed across the NOP Scopes.
 - ii. Benchmark with the USDA / AMS laboratories that conduct PDP testing for quality control and verification of procedures.

b. Specific Redline Corrections:

- i. Expand Scope and Rename Document: The Title of 2611 focuses solely on pesticide residue testing, and the instruction concentrates mainly on the QueEChERS (Quick, Easy, Cheap, Effective, Rugged, Safe) method. With the recommended scope expansion changes suggested above, the title of this document will need to change to reflect the updated content.
 - 1. The QueEChERS, method is an analytical approach that vastly simplifies the analysis of multiple pesticide residues in fruit, vegetables, cereals, and processed products.
- ii. **Update Section 4.1:** revise the language from "should" to "must" in the 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."
 - 1. If testing is not conducted, an explanation as to why a test was conducted should occur.
- iii. **Update Section 4.2.1:** revise the Laboratory Selection Criteria to require "a current copy of the lab's accreditation certificate on file" versus the need to have "lab accreditation certificates attached to each lab test."
- iv. **Update Section 4.2.2**: revise the language from "certifiers should maintain the lab's current proficiency test and resolution of corrective action" instead of relying on these documents to "be available from the laboratory."

Note: Industry and regulatory collaboration must exist to ensure the current methodology is approved promptly.

Prohibited Pesticides for NOP Residue Testing (NOP 2611-1)

1. NOP 2611-1 provides certifiers with a list of prohibited pesticides commonly included in multi-residue pesticide screens. The list offers a baseline multi-residue screen so that certifiers implementing pesticide residue sampling as a compliance tool request the most comprehensive list of substances possible from the laboratory. However, this guidance document must be expanded to reflect the breadth of prohibited substance residue testing conducted by certifiers. NOSB received substantial comments from stakeholders with suggestions for additional substances that could be tested for and types of tests that could be performed.

Stakeholders would like to see this guidance become more practical. NOSB believes updating the structure to include specific testing methodologies for particular substances and the rationale for electing a specific test will accomplish this need. Also, indicating the connection between chemical name, pesticide function, and the registered crop could assist certifiers with investigations. Therefore, NOSB would like NOP to consider the following tips in revising this guidance document to be more beneficial for certifiers engaged in broader residue sampling activities.

a. Information Layout:

i. Example 1 below includes the type of test first and the specific substances second.

Test Type	Specific Analyte Tested
Multi-residue pesticide screen (ex. QuEChERS)	1-Naphthol, 3-hydroxy carbofuran, 5- Hydroxythiabendazole, Acephate, Acetamipridetc.
Single Analyte Herbicide Screen	Glyphosate, 2,4-D, Dicamba
Residual Solvent Panel	Hexane, Acetone, Methanol, etc.
Heavy Metals	Cadmium, Arsenic, Lead,etc.

ii. Example 2 below also considers adding best practices or rationale for electing a particular type of residue screen:

Test Type	Specific Analyte Tested	Rationale for Selecting Test
Multi-residue pesticide screen (ex. QuEChERS)	1-Naphthol, 3-hydroxy carbofuran, 5- Hydroxythiabendazole, Acephate, Acetamipridetc.	Choose this screen when testing the efficacy of buffers on specialty crops grown near conventional production.

		When ordering and designing multi-residue screens, consider the product's origin. Tests should focus on the pesticides typically used in the country of origin.
Single Analyte Herbicide Screen	Glyphosate (with AMPA and Glyphosine), 2,4-D, Dicamba	Choose this screen when inspectors observe herbicides or when sampling a crop (e.g., wheat) where herbicides are routinely used but other pesticides are not. Note: this is not a panel screen
Residual Solvent Panel	Hexane, Acetone, Methanol, Di-Chloroethane, etc.	Choose this screen when sampling oilseed meals in transit or at handling facilities. Consider adding the fat content percentage to provide insight into whether the seed meal was expelleror solvent-extracted.

- b. Regional and Crop-Specific Information: Understanding the region and what pesticides or processing aids are commonly used on conventional farms can provide insight into what to test for to identify the presence of residues. Some pesticides are illegal in the U.S. but still permitted in certain countries. One stakeholder mentioned, "We recommend using pesticide use data to develop a list of prohibited substances that are the most likely to be used for a specific crop in a production region."
- c. Expand What to Test: Currently, the target list found in 2611-1, also referred to in the industry as the "NOP panel," lists fewer residues than a standard or EU panel. One commenter mentioned, "We believe that the list of prohibited substances provided is incomplete, and including it as guidance could lead to the mistaken impression that it is comprehensive. Analyses should be based on the most likely pesticides found on the crop in the region where it is grown."

- A multi-residue single-panel screen is suitable for use in some scenarios; however, the target list is limited, and pesticides often do not appear on the crop's harvested portion.
 - Foliar and soil tests are valuable; for example, if a producer sprays corn
 with fungicide before the ear has set, the grain may not contain the
 fungicide.
- ii. The NOP is expanding guidance on the types of tests that certifiers can perform to address broader contamination and fraud concerns.
- iii. For example, solvents are ubiquitous in conventional production. Consider testing organic soybean meal for solvents. Guidance for testing livestock products (milk, eggs, fiber), livestock tissue, processed products, agricultural inputs, etc. needs to be considered
- iv. Expand target list (NOP Panel) to include other prohibited substances, including glyphosate, 2, 4-D, dicamba, co-formulants, adjuvants, antibiotics (specifically streptomycin, oxytetracycline, and natamycin), GMOs, livestock drugs (hormones, antibiotics, or synthetics), etc., keeping continuous improvement in mind and updating the suggested list at a frequency similar to the PDP program updates.
- d. **Testing for Metabolites:** Testing for metabolites can also have value. One commenter stated, "The metabolites aminomethylphosphonic acid (AMPA) and glyphosine should also be included. These degradants are more likely to persist in the soil and would be strong evidence that glyphosate had been applied recently on a given field."
- e. **Companion Tests:** As the table states above when examining a solvent test to identify the illegal use of a processing aid for soybean processing into soybean meal, a fat % test could provide an additional indication of fraud.
- f. **Update Frequently:** A list can be helpful for reference; however, it must be reviewed at a set frequency to ensure that it is current for domestic and international substances.

Note: Several commenters mentioned the power of a multi-screen residue test and its limitations. One commenter stated, "The QuEChERS method and variations on it have several advantages in conjunction with multi-residue analytical methods; it is not necessarily the best approach in every case nor the sole approach that should be utilized."

A commenter stated, "The prescriptive nature of this list creates an overtly focused emphasis on screening for pesticides instead of testing for any or all likely present prohibited substances. Testing needs to be targeted to the likely risk to a specific type of operation or the potential contamination observed on site."

Responding to Results (NOP 2613)

NOP 2613 provides excellent guidance to certifiers when responding to results from multi-residue pesticide screens on raw agricultural commodities. It does not support the needs of certifiers when faced with positive results for pesticides not registered for the crop on which it is found, for other prohibited substances that are not pesticides (e.g., solvents or heavy metals), or for residues of any kind found in dehydrated, extracted or concentrated plant material. We expand on the issues and propose some solutions below:

- 1. 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.
 - a. Detection without Tolerance Level: When detected pesticides are not registered for the crop on which they are found at any level above 0.01 ppm, the guidance indicates that certifiers should exclude the crop from the organic marketplace and alert the appropriate authorities, including the EPA and FDA. This approach assumes that any detection of a prohibited pesticide when there is no established tolerance indicates that the product no longer qualifies for organic status and that there is a human health and safety concern.
 - i. **Minor Crops:** However, this situation can occur when testing minor crops for which tolerances have yet to be established for many pesticides (e.g., aronia berries and Jerusalem artichokes). Therefore, NOP should develop alternative corrective action approaches or tolerance levels when residues of pesticides not registered for the crop are detected on "minor crops" (EPA defines minor crops as crops grown on fewer than 300,000 acres).
 - ii. **Non-Food Crops:** Criteria should also be developed to determine tolerance levels for non-food crops, such as cotton seed meal
 - 1. Resource Examples for Creating Paths Forward
 - a. EPA has established tolerances for the edible portion of the crop.
 - iii. **Drift or Inadvertent Contamination:** Guidance is needed to determine drift or inadvertent contamination events versus fraudulent activities
 - 1. Resource Examples for Creating Paths Forward
 - a. Review EPA Tolerances for Indirect or Inadvertent Residues
 - b. Limits could be determined by levels of that material that might be used in conventional products.
 - Generally, if it is drift or inadvertent contamination, the residue levels should be about a tenth of what would be found in a conventional product.

- b. Dehydrated, Extracted, or Concentrated Organic Products: When sampling dehydrated, extracted, or concentrated organic products, positive results can be amplified and misconstrue the raw agricultural commodity's contamination level. For example, a fresh hop sample may indicate no pesticide residue detection. However, that same hop sample dehydrated and concentrated may reveal positive results. EPA tolerance is established for various agricultural commodities, typically specific to the form (e.g., fresh, dried, etc.). However, this system only sometimes supports taking action on a positive sample result. NOSB recommends NOP develop a specific section in NOP 2613 related to responding to positive results for dehydrated, extracted, or concentrated products.
 - i. Resource Examples for Creating Paths Forward
 - 1. <u>United States Pharmacopeia (USP) 561</u> has limits for botanical/supplements / concentrated products.
 - 2. The European Union uses a factor to convert fresh to concentrated.
- c. **Above EPA Tolerance / FDA Action Level:** Guidance should be explicit regarding how certifiers should exclude products from the organic marketplace and how other agencies should be alerted when residues are detected above the EPA tolerance / FDA action level.

d. Specific Redline Corrections

- i. Update 5.3.2.b to clarify if it should also include detections "<u>at or</u> above" the FDA action level
- ii. Update 5.3.3. am to clarify if it should also include detections "at or above" 0.01 parts per million
- iii. Update 5.3.3 to clarify how to respond to positive results for materials that are not pesticides.

Suggestions for New Guidance Documents:

- 1. The discussion around residue testing as a compliance verification tool has identified some gaps in guidance. In the sections above, we provided suggestions for improving the existing guidance. Below, we give some ideas and context for new guidance documents that could assist certifiers in deploying residue testing more effectively in the organic marketplace.
- 2. We welcome additional stakeholder comments on additional aspects that should be included in guidance on residue sampling of prohibited residues in organic operations.
 - a. Residue Sampling Decision Tree

- i. Overall, stakeholders commented that it would be tremendously helpful to certifiers if NOP developed a decision tree that could assist certifiers in determining when to sample, what to sample, where to sample, what types of tests to run, and how to respond to positive results from each situation. Guidance might not capture the nuance of every situation, but having a decision tree could support certifiers in understanding how to apply residue testing in a supply chain most effectively. We welcome stakeholder comments on how such a decision tree would be organized and how it could be presented to be readily understood and integrated into certifiers' residue sampling programs.
 - 1. Three samples from our stakeholder community are found in the appendix.
 - a. Risk-Based Decision Tree
 - Critical Aspect of Selecting the Product to Sample
 - high-value crops, large shipments, country of origin, market footprint, and split or parallel production are target areas for testing.
 - ii. Multi-ingredient processed products
 - iii. Residue Test Result Decision Tree based on Current Instruction
 - iv. Notice of Detection and Next StepsDecision Tree

b. Residue Sampling of Non-Crop and Non-Harvested Crop Products in organic operations

- i. Certifiers need to sample inputs, such as soil, water, tissue, etc.
 This guidance should encompass the following relevant areas:
 - 1. Proper sampling techniques and testing methodology
 - 2. Unavoidable Residual Environmental Contamination
 - 3. Enforcement of positive results

c. Validation and Verification Guidance for 205.273(d)

i. The Strengthening Organic Enforcement rule now requires importers to have a prohibited substance prevention plan. For certifiers to validate and verify the efficacy of these plans, they must have some guidance related to how residue testing can support these validation and verification efforts. We welcome stakeholder comments on essential elements to guide validating and verifying importers' prohibited substance prevention plans.

d. Additional Instruction Considerations

- i. Residue Sampling and Testing Instructions for all scopes: Handling, Livestock, Crops
- ii. Residue Sampling for Multi-Ingredient Products / Finished Products
- iii. Initiation Sequencing for a Stop Sale Action.
 - Fraud has resulted in significant quantities of contaminated or illegitimate products being placed into the stream of commerce.

In addition to guidance document updates, other comments from the public centered around:

- Collecting and Aggregating Positive Test Result Information: Testing results must be
 aggregated and disseminated to certifiers. Some commenters pointed to a unified
 reporting format and a centralized point for posting positive residue test information.
 This would help transparency and inform the certifier's risk assessments and decisions
 on what to sample.
- 2. **Costs as a barrier to testing:** Extensive testing, companion testing, duplicate testing, etc., can be cost-prohibitive or ultimately impact certification fees.
 - a. Some solutions provided included certifiers who could collectively approach ISO-accredited labs to request a group discount for cost savings.
- 3. Working Group: Several members of the stakeholder community mentioned the value of a cross-functional working group consisting of inspectors, certifiers, laboratory personnel, and specialists in the field to identify and outline the industry's best practices and certifier policy for sampling and testing specific to the matrix sample and the test required.
- 4. **Appropriate Compensation**: Although out of the NOSB scope, several stakeholders mentioned testing can be expensive. It is essential to ensure that costs are not a limiting factor in leveraging testing as a tool.

Conclusion:

Testing, as a tool, has played a crucial role in the organic program since the implementation of the Strengthening Organic Enforcement (SOE) Rule. It not only assists certifiers in validating compliance but also provides the ability to rapidly detect evidence of commingling/contamination in operations deemed to be high risk, thereby enhancing the program's proactive nature.

Modern-day threats do not just come from pesticide residues. A one-size-fits-all test is only sometimes the correct tool for the job. Threats can also come from fumigants and conventional processing aids, such as solvents.

In the spirit of continuous improvement, CACS believes that a full review of existing guidance and regulations regarding prohibited substance residue testing protects the integrity, unlocks the power to assist in compliance verification, and helps create consistent enforcement decisions. We appreciate all stakeholder comments as we look to make recommendations for final updates to residue testing instruction documents at the NOSB Spring 2025 Meeting.

Questions:

The CACS has an extensive series of questions to inform continued discussion regarding the regulations surrounding testing.

A. Guidance Document Questions

1. NOP 2610 -

- a. What training do all inspectors need to take to qualify to take samples on an operation?
- b. To increase bandwidth, should certifiers outsource sampling to a third party?
- c. What additional changes or corrections would you recommend?

2. NOP 2611 -

a. What additional changes or corrections would you recommend?

3. NOP 2611-1 -

- a. What additional changes or corrections would you recommend?
- b. What is the best method to ensure the target list of prohibited substances provided is updated, maintains relevancy, and isn't restrictive?

4. NOP 2613 -

- a. How should a certifier select a reference EPA tolerance when the commodity or group is not listed with an established tolerance?
- b. How should a certifier review metabolite detection?
- c. What should a certifier do when results come from third-party operations with unknown sampling methodology?
- d. How should a certifier interpret samples of a multi-ingredient product or a tested lot composed of several lots from suppliers?
- e. What should a certifier do with multiple tests for a single lot, but the test results conflict?
- f. How should a certifier interpret and respond to results from foliage versus commodity tests?
- g. How should a certifier address tests conducted outside the U.S. for materials not on the "NOP panel" multi-residue screen panel?
- h. How can instruction be improved to supply guidelines for prohibited material applications before harvest (intentional and unintentional) since EPA and FDA tolerances are established based on the consumption of the harvested commodity and what existing tools and resources are needed or available to inform the scenarios below:
 - i. Identify what might have been applied when concerns exist so that appropriate testing can be conducted

- ii. Evaluate the concentration of the material on commodities that aren't at the harvest stage so investigations can determine whether an application intentionally or unintentionally occurred.
- iii. Determine whether crop or field status should or should not be impacted
- i. What additional changes or corrections would you recommend?

5. Suggestions for new guidance docs

- a. What essential elements guide validating and verifying importers' prohibited substance prevention plans?
- b. How should a decision tree be organized, and how could it be presented to be readily understood and integrated into certifiers' residue sampling programs?
- c. What additional guidance documents should be created to assist in residue testing

B. How to Enhance Testings' Effectiveness Questions

- 1. Given the limited number of samples, how can certifiers maximize the information gathered? Specifically, how can certifiers coordinate and strategize to take samples that represent the most significant risk to the organic supply chain?
- 2. How can certifiers see testing as a solid tool to detect and react to fraudulent activities? What would change about the program for certifiers to elevate how they test?
- 3. What technical assistance is needed for certifiers to leverage testing to initiate adverse action?
- 4. What training resources are needed to prepare inspectors to be sufficiently proficient in sampling so the test results cannot be challenged based on testing protocol?
- 5. Does testing 5% of operations annually provide a sufficient survey of the organic supply chain to deter fraudulent actors? If cost were not a factor, what is the best testing rate to understand the entire supply chain and the risks for contamination?

C. 7 CFR 205.671 - Exclusion from organic sale

Background: The Organic Foods Production Act at 7 USC 6511(c)(2)(A-B) outlines the authority conveyed to the Secretary for "removal of the organic label" should a prohibited substance be detected on an organic agricultural product. It is determined that the residue is either "the result of an intentional application of a prohibited substance or present at levels greater than unavoidable residual environmental contamination as prescribed by the Secretary...in consultation with the appropriate environmental regulatory agencies." It appears that Congress intended the Secretary to establish exclusions from organic sale mechanisms for intentional applications of prohibited substances and unintentional contamination detections when levels exceeded UREC levels. It did not limit the authority to only pesticides regulated by EPA or FDA. CACS recognizes that the initial regulation, 205.671, focused on pesticides, as the respective regulatory agencies established thresholds to draw. However, as the

organic marketplace matures and our compliance verification mechanisms become more sophisticated, it necessitates a review of the regulations that enable certifiers to take direct action in excluding contaminated organic products from the marketplace.

It is in this light that CACS asks the following questions of stakeholders:

- Should certifiers have more flexibility/cause to exclude organic products from the marketplace?
 Detection of what types of prohibited substances warrant exclusion from the market? How
 should NOP establish thresholds for substances that do not have tolerances or action levels
 determined by other regulatory agencies? Please provide comments on the following
 hypothetical situations and present your own experiences.
 - a. Positive residues of EPA-registered pesticides detected on immature crops (e.g., corn plant before tasseling) through tissue testing rather than testing of the crop itself. In these cases, since the crop is not what was tested but is the only part of the plant for which an EPA tolerance is established, certifiers do not have the authority to exclude the crop from the organic marketplace without a subsequent test of the crop.
 - b. Positive residues of prohibited substances that are not pesticides (e.g., hexane in soybean meal). When prohibited substances other than pesticides are detected, the current regulation has no regulatory mechanism to exclude that product from the organic marketplace.
 - c. Positive tests of non-harvested crop products. Should certifiers have the authority to exclude products from the organic marketplace when residues are detected in the soil, water, inputs, tissues, etc., but not the organic products themselves?
- 2. How can we strengthen partnerships with other agencies to improve our ability to exclude contaminated products from the organic marketplace?

Subcommittee Vote:

Motion to accept the discussion document on Residue Testing for a Global Supply Chain

Motion by: Amy Bruch Seconded by: Nate Lewis

Yes: 6 No: 0 Abstain: 2 Recuse: 0 Absent: 0

Decision Tree Example #1: Risk-Based Decision Tree

Testing Criteria Process Flow

Guidance

 A guidance document is published that addresses when and why to test that outlines risk, investigations, supply chain audits and on-site observations for a wider, more broad selection of prohibited inputs.

Best Practice and Policies

- NOP, certifiers, inspectors, and testing/sampling experts create a best practice for the specific tests, matrices, and methodologies.
- Certifiers develop policies and procedures for their own individual agencies.

Training Qualifications

- Funding is made available to create trainings to equip certifiers, reviewers, and inspectors.
- Training and experience are part of what determines the qualifications for the scope and complexity of assignments for reviewers and inspectors.

On Site Instruction

- The inspector may use the guidance document and agency policy to collect samples when they make observations that suggest contamination and/or fraud.
- Detailed instructions and matrices will be provided to the inspector by the certifier for fraud and risk based testing.

Decision Tree Example #2: Residue Test Result Decision Tree Based on Current Instruction

- A. Residue Detected
 - a. No
 - i. Notify the certified operation of the test results and indicate that the product may be sold as organic.
 - b. Yes
 - i. Residues Detected at less than 0.01 ppm
 - 1. Notify the certified operation of the test results and indicate that the product may be sold as organic. Asses Why the residue is present and follow up with the operation as appropriate
 - ii. Residues Detected at or above 0.01 ppm
 - 1. EPA tolerance is established
 - a. Yes
 - If residue is detected at or below 5% of the EPA tolerance
 - Notify the certified operation of the test results. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272. If residues are not a result of the application of prohibited pesticides, the product may be sold as organic.
 - ii. If residue is detected above 5% of the EPA tolerance but not above the EPA tolerance level
 - Immediately Notify the certified operation of the test results and indicate that the product may not be sold as organic. Assess why the residue is present. Issue a notice of noncompliance for the violation of 7 CFR 205.671. Additional violations may include a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.
 - iii. If residue is detected above the EPA tolerance level
 - 1. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. Assess why the residue is present. Issue a notice of noncompliance for the violation of 7 CFR 205.671. Additional violations may include a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.
 - b. No
 - i. FDA Action Level Exists?
 - 1. Yes
 - a. If residue is detected below the FDA action level
 - Notify the certified operation of the test results. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the

following violations: 205.202(b), 205.202(c), 205.272. If residues are not a result of the intentional or direct application of prohibited pesticides, the product may be sold as organic.

- b. If residue is detected at the FDA action level
 - i. (needs defined as requested above)
- c. If residue is detected above the FDA action level
 - Immediately notify the certified i. operation of the test results and that the product may not be sold as organic. The FDA or a foreign equivalent may provide guidance on addressing these products. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272

2. No

- a. If residue is detected at 0.01ppm
 - . (needs to be defined as requested above)
- b. If testing detects a residue of prohibited pesticides above 0.01ppm
 - i. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.

Example #3 Decision Tree: Notice of Detection and Next Steps Decision Tree

- 1. Receive a notice of detection.
- 2. Verify lab results, methods, date of test, and authorized signature to determine how actionable the residue testing may be
- 3. Review the material and brand name association products, comparing the affected crop type.
- 4. Confirm if the crop is allowed in organic production
- 5. Confirm the EPA tolerance level and the amount of detected material
- 6. Initiate a trace to determine the grower, ranch, lot, facility, and shipping locations
- 7. Place the product on hold as applicable
- 8. Review the grower application records to determine the source and whether the material is permitted in the affected crop.