National Organic Standards Board Certification, Accreditation, and Compliance Subcommittee Residue Testing for a Global Supply Chain: Regulation Review § 205.671 Proposal Fall 2025

Executive Summary

The Fall 2024 and Spring 2025 discussion documents on Residue Testing for a Global Supply Chain generated strong conversation leading into this proposal, suggesting a revision to the regulations at § 205.671. Several additional areas are still in the discussion phase (see separate Discussion Document regarding UREC and drift, downstream communication, and sampling).

Exclusion from organic sale (§ 205.671):

Challenge: 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 per § 205.671 Exclusion from organic sale.

Solution: CACS proposes revising § 205.671 of the UDSA Organic Regulations to require exclusion from organic sales due to the intentional application of a prohibited substance, aligning the regulations with Section 6511 of the Organic Foods Production Act (OFPA).

Discussion

Exclusion from organic sale (§ 205.671)

The organic program has experienced exponential growth since the Periodic Residue Testing Final Rule took effect in 2013, and threats to integrity remain ever present. When the pesticide rule was being discussed, commenters stated that the regulation at § 205.671 could be misinterpreted to allow products to be sold as organic when prohibited substances were applied, if the tests showed levels of the prohibited substance less than 5% of the EPA tolerance. Intentional or direct application of prohibited substances to a crop or product, regardless of whether the residue detected is below 5% of the EPA tolerance or FDA action level, should not be sold, labeled, or represented as organically produced. Clarity is needed to reconcile the regulatory text with the Organic Foods Production Act (OFPA).

Background/Regulatory References

1. OFPA Section 6511 OFPA states:

(c)(2) 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 the intentional application of a prohibited substance; or
- (B) present at levels 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.

2. USDA Organic Regulations (7 CFR Part 205) states:

§ 205.671 Exclusion from organic sale. When residue testing detects prohibited substances at levels 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 investigate the certified operation to determine the cause of the prohibited substance.

One public commenter further confirmed support, stating, "Exclusion from Organic Sale—NOP regulations do not fully reflect OFPA requirements. Due to the word 'or' used as the conjunction between sections (A) and (B) of OFPA § 6511.c.2, OFPA requires removal of an organic label under two conditions, first, if residues of prohibited materials are present either through intentional application or, second, if they are present at levels described in Subsection (B): (A) the result of the intentional application of a prohibited substance or (B) present at levels 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 products shall not be sold or labeled as organic under this title. Therefore, § 205.671 of the NOP regulation must be revised to clarify that an intentional application of a prohibited substance or excluded method is grounds for removal of the organic label, regardless of whether the material has an established EPA tolerance level."

- 3. Periodic Residue Testing Final Rule (77 FR 67239) Preamble Response to comments states:
- (3) Exclusion from Organic Sale. Commenters expressed that § 205.671(a) could be easily misinterpreted. They said that § 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 § 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 drift or intentional application. Suppose the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application. In that case, 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 sell[s] the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing does not qualify 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 outlined in the Act and this part.

4. EU Regulations Articles 28 and 29 of EU 2018/848

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

Compliance Process Overview

Regarding prohibited substances, there are two compliance pathways a certifier can take:

- 1. Exclusion from organic sale (§ 205.671)
- 2. Noncompliance procedure for certified operations (§ 205.662)

Exclusion from organic sale currently only applies to products that contain pesticide residues greater than FDA action levels or 5% of EPA tolerances. This means that certifiers can immediately exclude contaminated products from the organic marketplace. Additionally, certifiers may also follow the procedures outlined in § 205.662, depending on the determination of why the residue is present.

Certifiers must follow the applicable compliance procedures for all other prohibited substances (not pesticides). The immediate exclusion from organic sale under § 205.671 does not apply. The product ultimately may be excluded from sale if the operation's organic certification is suspended or revoked.

Section Summary

NOSB has reviewed the possibility of amending § 205.671 of the regulations to clarify that an intentional application of a prohibited substance or excluded method removes the organic label (a.k.a. exclusion from sale as organic), regardless of whether a tolerance level is established. The overwhelming majority of stakeholders agreed that adding language about intentional applications would help to clarify matters.

Public Comment Summary

During the Fall 2024 and Spring 2025 meetings, the NOSB asked a series of questions about § 205.671. The responses are summarized below and assisted in the formation of the discussion above.

In general, commenters favored achieving alignment for exclusion of sale, especially when an intentional application earlier in the season yields an "above threshold" result on a test based on EPA tolerances or FDA action levels. In addition, it clarifies the intentional application of other prohibited substances (outside of pesticides) and excluded methods.

General Comments on § 205.671:

- 1. Broad support for aligning clarity on the immediate exclusion of sale with intentional application of prohibited substances, even when residues are below EPA/FDA thresholds.
- 2. Many advocate expanding beyond pesticide focus—residues from solvents, fertilizers, and other inputs need to qualify for exclusion if willful intent is found not to limit scope.
- 3. Certifiers seek clear authority to sample and test non-harvested plant parts or related materials (e.g., leaves, stems, soil) when there are concerns about organic integrity. EU Regulation 2018/848 can serve as a benchmark, as it permits testing at any stage of production when contamination is suspected.
- 4. Commenters call for mechanisms to eliminate noncompliant materials proactively, including temporary holds to bolster consumer confidence.
- 5. Need distinct differentiation between "natural residues" or UREC (e.g., arsenic in rice) and prohibited inputs.

- 6. Enforcement tools (e.g., § 205.662(d), Handbook document NOP 4002) exist, and the proposed updates to NOP 2613 will help, but are not always effective for non-pesticide substances and could take more time to get to the same spot.
- 7. There is concern about the difficulty in distinguishing between willful and non-willful contamination and the delays in enforcement.

Spring 2025 Questions & Comments

Q1: Are existing certifier tools sufficient for willful violations involving non-pesticide substances (solvents, excluded methods, fertilizers)?

- 1. **Willful Intent Trumps Residue Level Detection**: *If the application is intentional, exclusion from sale should occur regardless of the presence or absence of residue.*
 - Special Note: Willful violations do not always result in residues on food. For example, many herbicides will not be taken up by the crop and will be undetected in food, unless they are used as a preharvest desiccant (*think about grain crops harvested in hot, humid conditions...).
- 2. **Lack of Guidance**: Certifiers report inadequate guidance for non-pesticide cases; more support and instruction are needed on non-willful applications.
- 3. **Threshold Challenges**: The 0.01 ppm default threshold is problematic. Many crops tested (e.g., hay, silage) lack EPA limits, causing confusion and inconsistent enforcement.
- 4. **Need Upstream Focus**: Testing further up the supply chain can be critical for root cause analysis.
- 5. **Timing & Resources**: Complex investigations are slow; certifiers need more time, tools, and clarity. This needs to be a focus area because when non-compliant products are detected in advance, much harm is done to the certified operations doing everything right and the consumers who are paying a premium for authentic, high integrity certified organic products.
- 6. **Testing Limitations**: Focusing on edible portions limits actionability. Inedible parts lack tolerance levels and test interpretation guidance. The current regulations do not prevent certifiers from performing these tests; however, a lack of familiarity or uncertainty about how to interpret the results could be a barrier to testing.

Q2: Is it necessary to expand § 205.671 to cover intentional applications, or do other regulations already allow exclusion?

The majority of stakeholder commenters agreed on proceeding forward with a technical correction for alignment, clarity, and an expedited pathway to exclude fraudulent products resulting from a willful act.

Summary of Responses:

- 1. **Broad Support for Amendment**: Stakeholders favor clarifying that intentional use of prohibited substances leads to exclusion from organic sale, regardless of residue or tolerance levels.
 - a. With 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.
 - b. A Certifier mentioned that "Clarification would be a major improvement to address cases of fraud."
 - c. Clarification is needed because several responders still pointed to the need for established EPA or FDA tolerances.

- 2. **Codifying Stop Sale**: Adding a clear "stop sale" authority under § 205.671 would support enforcement and improve consumer confidence.
 - a. An additional commenter mentioned, "This would strengthen enforcement capabilities without relying solely on residue thresholds. At the same time, existing regulatory provisions (§ 205.662) already allow certifiers to remove products from the market that are not produced in compliance, even without exceeding residue thresholds. Codifying this into § 205.671 with a general principle of "stop sale" notices would enhance clarity and consumer confidence. Note: Willful applications circumvent whatever level is present.
- 3. **Timeliness is Key**: Current procedures (e.g., § 205.272, noncompliance notices) are slow. A more precise and faster pathway is needed.
 - a. A stakeholder mentioned, "would allow timely control of noncompliant products that is not possible through the existing noncompliance and adverse action procedure."
 - b. A stakeholder mentioned that "expansion is necessary. While § 205.105 spells out what substances are prohibited, the due process involved before denial of certification often results in fraudulent products being sold to consumers. Producers outside the U.S. that market products as USDA Organic are subject to a widely varying set of regulations regarding inputs and farming practices. The mechanisms in place to enforce these regulations can also be vastly different over both space and time."
- 4. **Global Harmonization**: Aligning with EU organic standards was recommended for consistency and better international oversight.
 - a. One stakeholder mentioned "EU rules on production and labeling of organic products require that certifiers downgrade a product to nonorganic status when the certifier determines it was not produced in accordance with the applicable regulations."
- 5. **Alternative Risk-Based Approach**: One suggestion proposed setting lower thresholds based on EPA's chronic reference doses (cRfD), not just current tolerance levels.

Note: A few stakeholders suggested alternative approaches that could lead to the same outcome, such as § 205.272 and a Notice of Noncompliance. However, the timeliness of these pathways, particularly when a known willful application is introduced, may pose an issue.

Continuous improvement to address the realities of "stop sale" timing:

- 1. Stop Sale Measure not included in § 205.671 Challenge:
 - Existing "exclusion from organic sale" measures often come too late—products already reach the market or are "released into the stream of commerce."
 - Suspended products remain available for organic sale until the point of suspension, which may occur long after the sale.
- 2. HOLD System Addition?
 - One commenter mentioned that a potential challenge is balancing a prompt response and exclusion from sale with the necessity of ensuring there is due process in investigating positive residue findings or excluded method presence.
 - Suggested Solution: A hold on product for which a positive residue or excluded method use
 is detected would allow for an investigation to be completed and also presents the
 opportunity for downstream notification of the supply chain, another potential
 requirement explored by the Board. Note: Clarification is needed on who bears
 costs/responsibility for held products.

Q3: There have been cases where questionable products have been received. Still, testing is avoided to confirm compliance due to the significant financial risk of knowing the product could be non-compliant (e.g., an imported product received that is already paid for). What are the solutions here?

Selective testing concerns:

- 1. Financial risk could deter testing even when concerns arise.
- 2. Testing may flag negligible or unknown substances without clear thresholds, leading to disproportionate penalties (e.g., loss of organic status for entire crops).
- 3. Certifiers face ethical challenges in enforcing regulations based on technicalities rather than real contamination.
- 4. Arbitrary enforcement causes frustration and discourages thorough testing.
- 5. Since the organic program is a "process-based system," testing isn't a requirement for certified operations receiving, handling, or processing certified organic products; therefore, testing can be deployed selectively or even "strategically..."

Several examples were provided, including:

- Example 1: There is no question that incomplete instruction, or overly burdensome consequences in specific areas of the supply chain (such as dehydrated products being subject to fresh product thresholds), incentivize a careful approach to selective testing only when a compliance concern has been identified. Note: Based on the NOSB Spring 2025 proposal on NOP 2613 updates, this issue should hopefully be resolved.
- Example 2: Testing sometimes yields inconclusive or minimal findings due to residues found without a threshold established that still trigger significant consequences, such as multi-year losses, raising fairness concerns due to guidance follow-up action.
- Example 3: Testing an imported product after it is received and paid for can lead to devastating financial risks if the product is non-compliant.

Suggested Solutions:

- 1. Fraud Prevention Plan Recommendations
 - a. Provide guidance on developing internal sampling programs to verify incoming organic products that are certified in certain high-risk regions.
 - b. Encourage proactive supplier verification and risk-based testing, especially for imports.
 - c. Share testing responsibility across the supply chain.
- 2. Contractual Considerations
 - a. Contracts should include testing requirements before payment.
 - b. Reimbursement clauses can protect buyers if products fail to meet organic standards.
 - c. Shifting expectations around testing could prevent fraudulent or contaminated product sales.
- 3. Benchmarking, Global Harmonization & Next Steps
 - a. EU models offer strong examples for risk-based testing and accountability.
 - b. Encourage port-of-entry or exporter-level testing for imports to strengthen oversight.
 - c. Implement options provided in the Spring 2025 NOSB Proposal:
 - Testing for a Global Supply Chain Guidance Document Review that was unanimously voted on to provide additional guidance on NOP 2613 - responding to results and implementing solutions to handle crops without testing thresholds.

Proposal Conclusion

The regulations governing residue testing have remained largely unchanged since 2013, while specific provisions, such as UREC, have been in place for even longer. However, the organic industry has evolved

dramatically since then. It is both wise and essential—rooted in the very principles of organic production and certification—to consistently assess and enhance our practices to ensure we thrive in a dynamic marketplace. Now is the time to revisit and refine these regulations, celebrating the practical elements and courageously reimagining those that no longer serve our vibrant industry.

Despite the NOP's assertion that residue testing is not used to qualify products treated with prohibited substances purposely or directly applied, and that intentional applications already trigger investigation and penalties, the current regulatory language in § 205.671 lacks the clarity and immediacy needed to effectively enforce this provision of the exclusion from sale outside of a test result. Public comments, including many comments from the certifier community, overwhelmingly indicate that ambiguity in this section leads to inconsistent interpretation and enforcement. This is particularly true when residues fall below existing EPA or FDA thresholds, when no thresholds exist, when the sampling event is conducted on a non-edible portion of the crop (e.g., leaf or other plant material) or when there is additional evidence other than a test result. Stakeholders emphasize that residue detection is not always possible—especially with non-pesticide substances—and that certifiers need clearer authority to exclude products from sale based on willful application alone, regardless of residue presence. Aligning § 205.671 with OFPA § 6511 would ensure that intentional applications automatically disqualify a product from organic sale, reinforce the integrity of the organic label, and provide certifiers with the tools they need to act swiftly and decisively.

Specifically, CACS proposes revising § 205.671 of the regulations to require exclusion from organic sales due to the intentional application of a prohibited substance, aligning the regulations with OFPA (Section 6511).

Additional points supporting the need for revision:

- Codifying Enforcement Tools Enhances Consistency and Confidence: Clear inclusion of intentional
 application as grounds for exclusion helps ensure consistent and timely enforcement, bolstering
 consumer and market confidence.
- 2. **Global Harmonization is Key to a Resilient Organic Market**: Aligning with EU standards improves international oversight and prevents exploitation of regulatory inconsistencies across international borders.
- 3. **Protecting Ethical Operators and Leveling the Playing Field**: Clarifying the rule safeguards compliant operators from being undercut by fraudulent competition.
- 4. **Clarification Supports Preventive Action, Not Just Reaction**: Encouraging internal sampling, stronger contracts, and supplier verification reduces the chance of prohibited substances entering the organic supply chain.
- 5. **Residue-Based Thresholds Alone are Inadequate**: Intentional application should result in exclusion regardless of residue presence, staying true to the principles of organic production.
- 6. **Regulatory Clarity Reduces Ethical Conflicts for Certifiers**: Certifiers need straightforward rules to act decisively and fairly, without facing professional or ethical dilemmas.

Subcommittee Vote:

Motion to accept the proposal on Residue Testing for a Global Supply Chain: Regulation Review of § 205.671

Motion by: Amy Bruch Seconded by: Kyla Smith

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1