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Written Comments on the NOSB Discussion Document "Residue Testing for the Global Supply Chain"

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These comments are submitted to the National Organic Standards Board (NOSB) on behalf of the ORG-Tracker team which we lead, and the Heartland Health Research Alliance (HHRA). ORG-Tracker is a project of HHRA, a non-profit working on how to promote human and environmental health through farming system change. Please refer, as well, to our previous comments presented at the Spring 2024 NOSB meeting.

Summary and Key Points

Organic farmers and ranchers invest considerable time, money, and resources in complying with USDA's organic regulations. The rest of the supply chain—including certifiers—also put substantial effort and resources into maintaining organic integrity. Consumers ultimately bear these costs. Multiple consumer surveys over many years have reported consistently that a major reason, and often the primary reason, that individuals are willing to pay more for organic food is to reduce pesticide dietary exposures and risk.

We conclude that there is good news and bad. There are many organic farmers and ranchers in the U.S. and abroad that adhere to NOP rules and requirements. But too many increasingly struggle to turn a profit in the wake of cheaper, often bogus "organic" food from farming operations and/or businesses more skilled at gaming the system at scale than refining the art and science of organic farming.

Our key points address NOP-required residue testing currently undertaken as a tool supporting organic certification and enforcement:

- The current level of organic industry investment in pesticide residue sampling and testing, and related compliance and enforcement activities, ***can and should deliver more substantial benefits to both consumers and the organic community***.
- The USDA and its accredited certification agents can make better use of the data from testing for prohibited substances and excluded methods through a platform such as ORG-Tracker that compiles the data from all certifiers, rapidly analyze it, and report back to certifiers in real time.

- The NOP, NOSB, certifiers, and organic community should strive more systematically to achieve the full range of positive human health and environmental outcomes that will flow from wider adoption of organic farming systems and compliance with organic production and handling standards.
- Guidance Documents need to be updated to reflect advances in science and desired outcomes, with focus on: (1) identifying Unavoidable Residual Environmental Contamination (UREC) residues in contrast to residues more likely to arise from instances of non-compliance, negligence, or fraud, and (2) distinguishing between residues that pose low levels of human and environmental risk and residues posing higher and possibly worrisome risks.
- Residue and other testing can be made more cost-effective and valuable via improved targeting, data compilation, and data analysis designed to extract operational insights to support continuous improvement.
- Product should be excluded from organic sale based on a more precautionary and health-based standard (e.g. a pesticide active ingredient's chronic Reference Dose [cRfD]), rather than a percent of EPA's tolerance for a given crop-pesticide combination.
- Amendments to OFPA would provide guidance and impetus to assist the NOSB and USDA in enabling certifiers to more quickly detect and more decisively deter fraud and negligence, thereby shielding legitimate organic businesses from unfair competition and delivering on the promises embedded in the organic label.

We understand that under current law and policy, the NOSB and USDA are limited in what they can do to achieve what many people consider the most important reason for having an organic program and buying organic food: promoting positive public health and environmental outcomes. Our comments on the NOSB's residue testing discussion document offer suggestions for concrete steps that can be taken in the near term to expand the benefits arising from the organic community's investment in residue testing.

Residue Testing Must Address Human Health and Environmental Outcomes

We have also submitted comments on the risk-based certification discussion document and further elaborate upon them in these residue testing comments. We applaud the work of the NOP and NOSB on the topic of risk-based certification (RBC). To summarize our comments, we propose that organic certification and enforcement take into account and prioritize the risks to human health and the environment related to organic food. While organic is a process-based standard, the process leads to certain predictable, evidence-based outcomes regarding pesticide dietary risk, biodiversity, climate change, farmer and farmworker health, soil biological activity and carbon sequestration, and other parameters related to food and occupational safety and ecological integrity.

Our comments on risk-based certification explain the need for a more nuanced and comprehensive definition and use of the term "risk" as used relative to the certification process

and outcomes and in the mitigation of toxic chemical risks and threats to the environment. We have also submitted comments on the inerts discussion document.

Taken together, these three sets of comments outline a path forward for the modernization of the authorities, concepts, responsibilities, and goals pursued through the provisions in the OFPA and the regulations and guidance documents issued pursuant to the NOP rule.

Our comments here focus on how certifiers and the NOP can more effectively use residue testing to drive down the already very low level of pesticide dietary risks stemming from consumption of organic food. The key is to detect and respond to emerging pesticide "hot spots" in global organic food chains, and to do so quickly and with precision. Certifiers need new analytical tools to determine whether a prohibited substance found in an organic sample is a UREC-like residue or evidence of a deliberate application.

Certifier Sampling, Testing and Investigation Can Be More Effective and Efficient

The number of instances in which certifier testing will detect a prohibited substance is bound to rise because of the growing diversity of circumstances likely to lead to detectable residues, coupled with steady progress in lowering the limits of detection and expanding the scope of possible compounds that can be found in food.

The organic community, and especially certifiers, need simple, easy-to-apply tools to determine which detections warrant further testing and/or investigatory steps and which do not. To support such decision making, the NOP and NOSB will need to establish threshold levels of human health and/or environmental risk above which additional investigatory activity is required, and below which it is not required, but may be undertaken at the discretion of certifiers. Risk in this context means not just the risk of non-compliance but also the environmental and dietary risks of prohibited pesticide residues entering the organic food supply. We further elaborate on ways to improve effectiveness and efficiency in addressing the NOSB's specific questions in Part B.

ORG-Tracker: Background, Current Status and Aspirations

ORG-Tracker uses the USDA's Pesticide Data Program (PDP) and UK-Food Standards Agency (UK-FSA) pesticide residue data. The system has the capacity to receive and analyze other residue data sets, including certifier pesticide residue data. We have recently published results using the residue data generated by the PDP and UK-FSA on organic samples and are currently working to incorporate certifier data in future analyses.

The ORG-Tracker analytical system is a prototype developed to demonstrate what is now possible in tracking, analyzing, and investigating pesticide levels and relative dietary risks. We believe that a system like ORG-Tracker can help the USDA and its accredited certifiers fulfill the pesticide-reduction goals that are an integral part of OFPA.

Back in the 1980s, we identified the need to obtain high-quality data to quantify the relative pesticide risks of organic and conventional food. By 2002, we had enough data to publish our first paper that provided undeniable evidence that organic farming eliminates high-risk pesticide use and residues and reduces consumer exposure to pesticides, with obvious benefits to human health and environment. Our work to develop better analytical tools has been supported by dozens of colleagues over the years, with funding from foundations and NGOs—especially Consumers Union and Consumer Reports. ORG-Tracker is the culmination of and next logical step in this work.

The Heartland Health Research Alliance is currently the institutional home of the Dietary Risk Index (DRI) system. ORG-Tracker's analytical capabilities depend on the DRI and its underlying datasets and algorithms, hence the need for HHRA to be part of the process of building ORG-Tracker. Several HHRA Board members, scientists, and advisers have deep roots in research on the human-health benefits arising from organic food and farming.

HHRA recognizes it is up to the NOSB, NOP, USDA, certifiers, the ACA, and possibly the Congress, to determine whether and how a system like ORG-Tracker is linked to OFPA implementation, what institutions should be responsible for its operation and maintenance, and how it should be governed and funded. HHRA and the ORG-Tracker team are going to continue building ORG-Tracker and demonstrating its capabilities over at least the next three years as the organic community and appropriate officials work through these issues.

We will prepare several papers for publication in appropriate, peer-reviewed journals documenting the technical and methodological aspects of ORG-Tracker. Additional papers will identify where better data and more advanced statistical and research methods can aid with fraud investigations and support incremental progress in driving down pesticide dietary risks in organic food and beverages. We will also quantify with greater precision than previously possible the differences in the frequency, levels, and distribution of pesticide dietary risks stemming from growing and eating organic versus conventional foods. We are confident that such research will have long-term benefits for the health and safety of organic food, as well as people working within organic food chains. The nuts, bolts, and tactics that make progress possible on organic farms will also surely benefit conventional growers, including many that are managing split operations.

Potential applications and insights from ORG-Tracker output tables will expand as more certifier and other residue data is loaded into the ORG-Tracker dataset. Output tables will show where the highest risk organic samples are coming from. They will show which organic crops and regions both rarely and regularly are found to contain high-risk residues. Certifiers will be able to generate and download tables of valuable data in support of their efforts to identify and remove high-risk lots of organic food from the stream of commerce. System outputs can also be used in court to support forensic evidence when fraud cases result in adverse certification or criminal actions.

Once the system is fully in place, ORG-Tracker output tables that incorporate newly uploaded certifier residue data will be available and disseminated back to certifiers in real time, and often within minutes for several standard output tables. Exceptions may arise when a given residue detection is the part of an on-going investigation. Data associated with investigations will be handled in accord with protocols yet to be crafted, vetted, and agreed upon.

HHRA also believes that ORG-Tracker or a comparable platform needs to be a distributed network that is readily accessible to a diversity of users, including within the organic community, and ideally with some sort of collaboration and support from the NOP/USDA. The NOP could also host such a platform and integrate it into the Organic Integrity Database.

We expect that there will be interest in using such a platform and analytical system for applications beyond certification and enforcement activities in industry, academia, non-profit organizations, and the research community. As a result, HHRA is committed to assuring that no single entity gains control over ORG-Tracker, its evolution, is how it is used. HHRA believes that open access in a non-proprietary system will be the best way to continuously improve the platform's accuracy, scientific credibility, and utility for certifiers, the organic community, government agencies at the state and federal level, the food industry, and the research community.

A. Guidance Document Questions

1. *NOP 2610.*

Our comments are aligned with the previous comments made by the International Organic Inspectors Association and the Accredited Certifiers Association. Sample integrity is needed to protect organic integrity. We believe that the NOP staff should work with PDP staff in the development of sampling procedures that can fulfill the missions of both programs. We also encourage certifiers to use analytical labs for residue testing that utilize the PDP's testing protocols, setting the stage for certifier test results to be readily comparable to results from annual PDP testing.

2. *NOP 2611 and 3. 2611-1*

We are pleased to see our previous comment acknowledged and the list of pesticides to be tested expanded to include glyphosate and its metabolites. We concur that analyses should focus on what is most likely to be in organic food based on empirical evidence and practical experience.

On page 126 of the residue testing discussion document, in subsection b. ii, the issue addressed is what certifiers must do when they "suspect" a prohibited substance was used. Point 1 appears to have a typo. Did the NOSB intend to say: "If testing is not conducted, an explanation as to why a test was not conducted should occur"?

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?*

The discussion document addresses the current guidance when a pesticide is detected in a crop that does not have an EPA tolerance established. The document explains that the current approach assumes that in the absence of a tolerance "...there is a human health and safety concern." This is flawed policy that needs to be changed in our opinion. Most pesticide residues in conventional and organic food that lack a corresponding tolerance pose little or virtually no risk. In most cases, such residues are the result of drift from a neighboring crop and are often beyond the control of organic and conventional farmers. Less than 1% of the positive organic samples in the PDP dataset pose risks worthy of investigation.

We believe that a risk threshold based on a pesticide's cRfD and residue level is preferable to one based on tolerances, even when EPA has established a tolerance. In many cases where drift is the cause of contamination, there will be no established EPA tolerance. But a basis for calculating DRI values almost always will exist. When it does not, it likely means a compound is known to pose little if any toxicological risk to humans, and perhaps has been granted an exemption from the requirement for a tolerance. In such cases, a default cRfD is set in the DRI system based on the best available information.

b) *How should a certifier review metabolite detection?*

Metabolites of prohibited substances may be UREC, or may result from negligence or fraud. Certifiers should handle pesticide metabolites in the same way they are handled in tolerance descriptions put forth by EPA. Any metabolite included in a tolerance expression should be included in setting exposure thresholds by the NOP and certifiers.

c) *What should a certifier do when results come from third-party operations with unknown sampling methodology?*

Such results are insufficient to take adverse action. The results can be considered in producing a written complaint, especially if the third party provides additional evidence of a prohibited substance application. If the documentation is deemed sufficient, an unannounced inspection and/or an independent sample may be warranted. If the results from a sample collected by an organic inspector and submitted to the certifier's lab are consistent, then it will be appropriate to move forward based on the test results and associated information.

d) *How should certifiers interpret samples of a multi-ingredient food or a test lot composed of several lots from suppliers?*

If a residue is detected above the acceptable threshold in any sample, the tested food product should be investigated like any other sample. Data from the PDP will provide clues as to which ingredient in a multi-ingredient food is most likely to be the source of detected residues. But the cost and access to raw ingredients that would be required to track residues to their source is almost certainly beyond the capacity of certifiers.

The PDP has also generated residue data on both composite (5 pound) and individual fruit and vegetable pieces (e.g. an apple, a carrot). These data provide insights into the distribution of residue levels in, for example, the approximate 15 apples in a 5-pound composite sample tested by the PDP. These data could be drawn upon in developing more detailed guidance for what a certifier should do when a residue is found in a composite sample.

e) *What should a certifier do with multiple tests for a single lot, but the test results conflict?*
In such a case, certifiers should consider repeating the test using a separate lab, if the highest reported residue level poses possibly unacceptable risk levels, e.g. a DRI value of over 0.5. We believe that such a conservative approach would be the most protective of both organic integrity and human health.

f) *How should a certifier interpret and respond to results from foliage versus commodity tests?*
It depends on the crop, pesticide, and region. If the certifier has other convincing evidence that a prohibited substance was deliberately applied, then the certifier should issue a notice of non-compliance and begin adverse action against certification. However, if there is no corroborating evidence and the prohibited substance is at a low level, then it is probably an UREC. The presence of essentially UREC residues on foliage will be a common occurrence with potential to siphon off considerable certifier staff time and testing resources. To avoid such an outcome, the NOP would need to establish UREC levels specific to different parts of the growing season, as opposed to those applicable to residues in harvested crops.

Residue dissipation and half-life studies could be drawn upon in setting such foliage-specific UREC levels. We urge the NOP and certifiers to consider alternatives to in-season residue testing for the purpose of assuring compliance with NOP pesticide requirements, especially when looking for evidence of use of pre-emergent herbicides. The cost of deploying residue testing as the primary basis for compliance during the early stages of crop production would likely prove costly and only occasionally effective. Exceptions will exist, such as persistent systemic pesticides, but still, variable and dynamic conditions in a crop field (windy/still, wet/dry, hot/cold), coupled with the physical-chemical properties of the soil, will often make it difficult to definitively link a given prohibited substance residue to an application of the chemical.

g) *How should a certifier address tests conducted outside the U.S. for materials not on the "NOP panel" multi-residue screen panel?*

The best option would be to calculate the DRI value associated with the residue, as done for all other residues, and hold the imported sample to the same risk thresholds as applicable to all other organic samples. For samples posing risks above the acceptable threshold, certification would be revoked for the suspect shipment, future shipments would be candidates for follow-up testing, and other steps could be taken as warranted in the event of reoccurrence.

Methamidophos, acephate, and other high-risk organophosphate insecticides have been detected with increasing regularity by the PDP in imported organic green beans from Mexico since 2016. Such findings have been addressed by Consumer Reports in feature stories. Hence, certifiers and those working along organic produce supply chains spanning the U.S. and Mexico had reason to focus efforts on preventing a reoccurrence of such residues in the future. From our detailed research on residues in organic and conventional samples of the same crop, we conclude that certifiers will benefit from new policies and better tools to identify and mitigate such very high-risk residues and samples, and the quicker the better. (Later in these comments, we explain that preventing the lot containing the single highest-risk sample of organic green beans from entering the organic food supply in the U.S. would have eliminated a significant share of total DRI risk stemming from all prohibited pesticides detected by the PDP in organic food in the last five years).

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:*

The question notes incorrectly that "tolerances are established based on the consumption of the harvested commodity..." Tolerances are set at a level to cover maximum, expected residues in raw agricultural commodities when they leave the farmgate. The PDP prepares samples of food for testing as close as possible to how the food would be eaten—a banana would be peeled and only the flesh would be tested. Across nearly all foods, residue levels decline significantly between the farmgate and consumption.

i. Identify what might have been applied when concerns exist so that appropriate testing can be conducted

This is a complex challenge. Consumers are most concerned about the residues of pesticides they and their families ingest. This is why DRI values based on a serving of food and PDP residue results are an appropriate option to set thresholds, and track compliance with pesticide labels and NOP-pesticide requirements. By basing acceptable residue thresholds in the context of organic compliance on DRI values instead of tolerances, several problems can be fully or largely avoided. However, the next step certifiers should take when a residue is

detected in foliage early in the crop cycle is not among them. For the reasons explained above, we do not recommend routine reliance on residue testing of early-season foliage in assuring compliance with pesticide-related NOP rules and requirements. We suspect other methods will be more likely to successfully detect and deter fraud, such as auditing mass balances of pesticide purchase records and reported applications on split operations.

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.

Many certifiers struggle to find ways to detect and deter fraudulent applications of the herbicide glyphosate. Early season applications are the norm and ubiquitous in all farming areas, and include pre-emergent applications, but glyphosate-based herbicides (GBHs) can be applied in many different ways for different reasons at almost any point of a growing season.

With the exception of pre-harvest crop desiccation uses, GBH applications rarely result in residues in the harvested crop, but residues may show up on other nearby crops that were nearly ready for harvest around the time of a nearby GBH application. But determining whether low levels of glyphosate detected on the foliage in a crop field on an organic farm is from a use of a GBH on that farm, or drift from nearby conventional farms, will often be highly dependent on timing, and possible only with substantial investment of certifier resources and staff time.

At some point, the organic community must come to accept that there will sometimes be low-level residues of prohibited substances on some organic food samples for which the source will likely remain unknown. Law enforcement does not strive to issue speeding tickets to every driver exceeding a posted speed limit by 1 or 2 mph. For similar reasons, certifiers should not be compelled to chase down the source of residues associated with trivial health risks, and should instead target their limited resources to detect and deter higher risk, non-compliant uses of prohibited substances.

iii. Determine whether crop or field status should or should not be impacted.

For a given pesticide-crop combination, a residue in food at harvest at or above the 40th percentile of the distribution of residues in conventional crops is strong evidence of a willful, in-season application of the pesticide. Any residue in an organic sample above that 40th percentile threshold should be treated as evidence of fraud or negligence. If that is the case, the entire operation—not just the crop or field—should be issued a major non-compliance.

Again, for any given pesticide-crop combination, we are confident that a residue present at or below 1/10th of the mean of positive conventional samples likely fits the definition of

UREC. It is harder to make such judgements between 10th and the 40th percentile of the residue distribution. Residues that fall in that range may warrant further investigation and closer scrutiny over time on the relevant pest management provisions in organic farming system plans, possibly coupled with additional residue testing.

But we also believe that additional efforts to track down the sources of such residues are warranted only if the human health and/or environmental risk levels associated with a residue in this range exceeds the applicable "minimal-risk threshold".

Such a "minimal-risk threshold" needs to be set based on a pesticide's chronic dietary toxicity, and not at 5% of the applicable tolerance as currently the case. This key threshold can be established such that a single serving of food would deliver no more than some small percent of the exposure level that EPA regards as "safe" in conventional food (e.g. 1% of EPA's "level of concern" exposure). Replacing the 5% of tolerance threshold with 1% of the level EPA regards as safe would align NOP pesticide-residue policies with the way the EPA quantifies pesticide dietary risk, and it would markedly expand the margins of safety embedded in the organic label, and hence be more precautionary than current policy.

Across federal and state regulatory agencies, minimal risk chemical and heavy-metal thresholds in water, air, and the workplace are set in basically the same way that EPA establishes hopefully "safe" levels of dietary exposure to specific pesticides. In general, when a residue is found in a harvested commodity above the inadvertent residue level, action should be taken to decertify the lot of food from which the sample was collected, and especially if the DRI level associated with the residue is above the pesticide's dietary risk "action threshold" (discussed in depth in our RBC comments, e.g. a DRI somewhere between 0.05 and 0.2).

But we hope it will become widely accepted in and outside the organic community that it makes no sense to truck nutritious organic food to a landfill, or to feed it to animals, when it poses essentially no human health risk. Developing and implementing policies that will allow this sort of risk-level driven outcomes will be an essential component of OFPA and NOP policy upgrades, if and as greater emphasis is placed on achieving favorable public health outcomes.

5. *Suggestions for new guidance docs.*

a) *What essential elements guide validating and verifying importers' prohibited substance prevention plans?*

This is a tough question given how complex global organic food supply chains have become. Current law and policy is clearly deficient in this area. These deficiencies have created a vacuum in which constructive action and innovation in compliance and enforcement procedures in the

U.S. are largely frozen in place. Even after the promulgation and implementation of SOE, we still see ways for unscrupulous exporters to export food to the U.S. that are fraudulently labeled as organic.

Two options warrant consideration in improving compliance and the ability to detect import fraud. First, USDA should enhance focus on pesticide-related compliance in the accreditation of certifiers working abroad, whether U.S. based or working only in countries outside the U.S.

Since certifiers abroad work in some countries in which the rule of law is substantially more elastic than in the U.S. and organic institutions are weak, the motive and opportunities to commit fraud are greater. The consequences when a fraudulent shipment is detected and confirmed also need to be significant enough to deter common tactics now used to simply move pesticide-laden, mislabeled "organic" food shipments around ports-of-call and certifiers until a way is found into the U.S. market. When raw ingredient shipments are turned back, there are options abroad to use them in manufacturing organic, multi-ingredient foods, thereby in effect covering the tracks back to fraudulent raw ingredients.

Second, there also is no practical alternative to heavy reliance on residue testing of imports in assuring compliance with pesticide-related provisions of the OFPA. Over time the results of ongoing, routine residue testing of shipments headed to the U.S. can be drawn upon in adjusting sampling frequency and to identify what pesticides are the highest priority to analyze.

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?

As a practical matter, the decision tree should be built to assure consumers that organic food has fewer pesticide residues and poses far lower pesticide dietary risks than conventional food. The decision tree should incorporate individual sample risk thresholds that certifiers can use to identify and mitigate high risk crops from certain regions. Without being overly prescriptive, the decision to take and test a sample should be driven by data on known or expected pesticide dietary risk levels. Most imported organic food comes from specific countries during certain times of the year. Certifiers should require and verify broad-spectrum residue testing of a sample of shipments of each raw commodity or food from a given country. The number and frequency of sampling should be initially determined by the volume of shipments, coupled with the residue and risk profile of the corresponding conventionally grown crops in the country of origin of imports headed to the U.S. The DRI can and does generate this information.

The decision tree can also identify crops, regions, and types of operations known to be low risk, and therefore of lower priority for sampling. Human-health risk-based criteria should govern the frequency and scope of residue testing. The decision tree should also recognize the limits of pesticide residue testing when verifying compliance. Because many pesticides have relatively short half-lives on foliage or in harvested crops, even rigorous testing will be able to detect only a fraction of the fields treated with such prohibited substances, especially when testing crops near or after harvest. The organic community, the NOP/NOSB, and Congress should be

reminded regularly that over three-quarters of pesticide pounds applied on most crops occur in the first weeks of a crop cycle and rarely, if ever, result in detectable residues at harvest. Pre-emergent herbicides are a particularly vexing problem.

The decision tree should identify the compliance and health-risk factors that should be taken account of when a matrix other than the harvested crop is chosen for testing—such as soil, non-edible parts of the crop, or weeds. Certifiers need to rely on investigative techniques in addition to pesticide residue analysis. The decision tree should include what other evidence is needed to augment data from residue analyses.

c. What additional guidance documents should be created to assist in residue testing?

We believe that the ACA and NOP should issue best practices and guidance documents that demonstrate constructive use of the results from certifier testing. Such guidance should be proactive and pave the way for continuous improvement. Best practices and formal guidance will help certifiers to identify non-compliant high-risk residues in organic supply chains more quickly, accurately, and reliably. The methods used and data relied on will support adverse actions targeting non-compliant operations. Over time, certifiers will benefit from a higher probability of withstanding appeals. This outcome will emerge as certifiers become able to reference substantial pesticide residue data in the same crop that strengthens the evidence pointing to an illegal application as the most likely source of a detected residue.

With perishable products identified as posing high-human health risk, steps should be taken to remove the product from the organic market before necessary investigative steps are completed and before any adverse action is taken against the certification of the operation found to be non-compliant. Currently this can be done only if the product also exceeds 5% of EPA tolerance for that pesticide.

What does the organic community need to achieve this goal?

1) Collect and analyze data on pesticide residues, prohibited substances, and other health risks that are detected in organic food and food ingredients.
2) Key data points include the source of samples tested, number of samples tested, percent positive, and the mean level and distribution of residues or other toxins.
3) Evaluate the levels of pesticides detected in organic food samples for *human health* risk. For pesticide-related risks, this can be done using EPA-set chronic Reference Doses (cRfDs) and typical serving sizes for a given food (e.g. via the health-based metric in the DRI system).
4) In the case of other prohibited substances (GMOs, antibiotics, and solvents), develop methods to collect samples, test them for contamination, and evaluate compliance and health risk levels. Other food safety risks could include heavy metals, PFAS, and other persistent pollutants. These too will likely require establishment of relative risk thresholds that determine whether a detected contaminant is UREC or actionable.

B. Questions Probing How to Enhance the Effectiveness of Testing

We agree with the discussion document that "certifiers need a roadmap" to respond to positive results. Based on empirical evidence from the PDP and other sources of residue data (e.g. the UK-FSA, food companies, certifiers), we urge the NOSB, NOP, and Congress to consider that:

- The diversity and number of detected prohibited substances and possibly risky residues present in organic and conventional food are likely to increase, and faster than certifiers and the organic community can track them all to their sources.
- Most such detections pose very low, if any risk to human health and the environment, especially relative to other documented and known risks.
- Data on expected levels found in conventional food offer the best guide to what might be deliberate, fraudulent applications of prohibited pesticides, and therefore:
- Systematic analysis of the distribution of contaminant levels found in organic and conventional foods can guide certifier decisions to investigate and issue non-compliances.

Only a small share of inadvertent residues will warrant any further efforts to track and mitigate in terms of promoting public health and environmental quality. An even smaller number still will result in successful suspension or revocation of certification. In terms of day-to-day operations, certifiers and their inspectors will need to distinguish possibly fraud cases from incidental contamination, and quickly based on information readily available, coupled with their past experience with an operation or crop/food from a given region.

As stressed throughout these and our other comments, we suggest that certifiers not be required to automatically investigate the source of residues of prohibited substances detected in food if the residue level is both an inadvertent residue ***and*** below a defined, low-human and environmental risk threshold.

"Inadvertent residues" are those that are almost certainly not present in a sample of organic food from deliberate, fraudulent application of the detected prohibited pesticide. Based on our research, setting an "inadvertent" residue level at 1/10th of the mean of the positive samples of the same pesticide found in conventional samples of the same crop would reliably differentiate between UREC and possible fraud or negligence.

Any residue at or above around the 25th percentile level of residues in conventional crops is plausibly a result of a direct application, and less likely to be UREC. Any residue at or above the 40th percentile level in the distribution of residues on conventional crops is almost certainly a result of a deliberate direct application, whether by fraud, negligence, or sabotage.

In the USDA's Pesticide Data Program and other residue datasets, we have seen organic samples that are contaminated with multiple residues. While each of these residues may be below 5% of EPA tolerance, cumulative adverse health effects may and sometimes do pose worrisome risk. Synergistic effects sometimes occur. We also believe that multiple residues above inadvertent residue levels in an organic sample should be considered strong evidence of

deliberate applications. A neighbor may have applied a tank-mix of multiple pesticides, but it is extremely unlikely that drift or volatilization movement onto an organic field would result in above-inadvertent residues of several of the pesticides applied by a neighbor.

Action – and Inaction -- Thresholds are Needed

We recommend the setting of a pesticide dietary risk threshold below which certifiers will not be routinely required to take further steps to investigate the source of the residue. Another threshold is needed above which investigations should always be carried out, unless there is clear evidence of the source of the contamination from outside the organic operation (e.g. PFAS in the soil of a certified organic farm). Action triggered when a residue is found between these two thresholds should be contingent on other factors that certifiers should take into account (history, cost, feasibility of proving fraud from a detected residue, etc). Such cases are often difficult, but based on PDP data, they occur only occasionally in most crops and regions.

Most positives reported by the PDP fall far below likely minimal-risk thresholds, unless such levels are extremely risk-adverse (e.g. 1/1000 of the maximum level EPA regards as safe). Some residues will be indicative of a deliberate application of a prohibited substance. In these and our risk-based certification comments, factors are identified that might be helpful as certifiers decide whether and how to proceed when a prohibited substance is detected.

Instead of specifying a set level for all pesticides as currently the case—such as a residue at 5% of the applicable tolerance or a default level of 0.01 ppm—the threshold should be human-health risk based and vary by the relative toxicity of the substance found. The cRfD of the active ingredient is the best available measure of relative dietary risk, and should be coupled with sample-specific residue levels and typical serving sizes for various foods to calculate dietary risk levels. Reported residue concentrations can also be compared to EPA tolerances, but we urge the organic community to switch to health-impact based metrics, rather than tolerances. ***Recall that tolerances are established to enforce compliance with the use directions on pesticide labels, and are not based on health risks***.

For a residue in any given crop-pesticide combination, current NOP policy sets the certifier "adverse action threshold" at 5% of the applicable tolerance. Instead, we suggest an action level based on, for example, 5% of the maximum, allowed residue level in a single serving of a given food, based on EPA-set "levels of concern" for that crop-pesticide combination. EPA-set "levels of concern" are based on chronic Reference Doses, coupled with residue levels and serving sizes, and are calculated for people of known weight (cRfDs are based on milligrams of pesticide ingested in a day per kilogram of bodyweight, so the heavier a person, the higher the cRfD, and the lower the applicable DRI). But based on stated EPA dietary risk assessment policies, any residue in a single serving of a food that leads to an exposure level at or above the pesticide's chronic RfD in a day for a person exceeds the agency's "level of concern". No ifs ands or buts.

So, a certifier "adverse action threshold" based on DRI values over 0.05 for a given pesticide in a single serving of an organic food would mean that a residue accounting for up to 1/20th of the acceptable daily intake level for the pesticide would not be subject to further assessment.

Most residues reported in organic samples by USDA's Pesticide Data Program fall below this threshold. For many foods, residues corresponding to a DRI value of 0.05 or higher are rare or non-existent. But unfortunately, some foods and samples do pose higher risks, and a few pose unambiguously unacceptable risks by virtue of a DRI value greater than 1.

The ability of certifiers to deal with the very few residues posing possibly worrisome risks in organic samples depends on them NOT being required to chase after extremely low levels of risk stemming from UREC-like residues.

The discussion document goes on to address how certifiers should respond to residues detected in a sample from a certified entity that may or may not be present because of drift or other sources not stemming from a direct application of the pesticide. A very common example are fungicide residues in fresh organic produce picked up as the produce moves through a packing facility that also processes and treats conventional food with post-harvest fungicides.

As described in our comments on risk-based certification, the NOSB should recommend, and NOP should revise the definition of UREC residues to more comprehensively include residues that are inadvertently present in organic food due to circumstance beyond the operator's control. This was OFPA's intent in establishing UREC, and doing so now would lessen the burden of residue testing for certifiers ***and*** organic operations found to be consistently compliant with all NOP requirements.

We welcome the language on page 130, under 1. (a.) (iii) that calls for certifiers to use a threshold similar to our "inadvertent residue" metric in determining whether a residue is present in a sample from drift or a direct application.

The distribution of residue levels in conventional crops can be drawn upon by the NOP, certifiers, and the organic community in setting residue thresholds for prioritizing sample selection, use in fraud investigations, tracking the impacts of organic farming systems, policy analyses, incorporation in epidemiology studies, and for other purposes.

Why adopt action and inaction thresholds? There are vast differences between chemical levels and associated risks in all corners of the environment, as well as in food and water and our bodies. It is not practical to avoid all chemical and heavy metal exposures. As a result, it is logical and beneficial to identify and mitigate the most significant sources of risky chemical exposures, and especially those that can be avoided with relative ease, like pesticides in food compared, e.g., to heavy metals in certain foods. We hope this practical reality will find its way into OFPA, NOP rules, and the day-to-day activities of certifiers, and the sooner the better.

Action and inaction thresholds will allow certifiers to determine whether further investigation and possible adverse action is justified, and what cases can be closed. Without these action

thresholds, certifiers will lack the resources to mitigate high risk residues. ***This is the practical reality the Congress, NOSB, and the NOP must accept and respond to in modernizing the way the organic community deals with prohibited substances, and other inputs and practices that can undermine public and environmental health***.

We offer four generic suggestions in setting minimal risk and action thresholds for use by certifiers:

1. The thresholds should be based on the best estimate available of a substance's cRfD and the hopefully "safe" levels of exposure based upon them.
2. "Minimal-risk thresholds" could be set initially such that the residue leads to exposure in a single serving of food that accounts for some small percent of the total exposure level deemed acceptable by EPA or other regulators.
3. The risk mitigation "action threshold" could be set at a level where the detected residue level, when present in one serving of food, corresponds to 50% or more of the level deemed hopefully "safe" by regulatory authorities. This would correspond to a DRI value of 0.5 or greater.
4. Continuous improvement can then be tracked by incrementally reducing the number of detections that fall above the applicable risk-mitigation action threshold, while also increasing the number that fall below minimal risk thresholds. ***Such progress can be coupled with the ability to periodically lower one or both risk threshold, a clear sign of continuous improvement***.

The ORG-Tracker system that is currently under construction can generate the above thresholds for most foods and pesticides, and all foods regularly tested by the PDP. The table below provides an overview of the 1,496 residues detected in organic samples tested by the PDP from 2016-2022. This analysis utilizes cRfDs adjusted by Consumer Reports (CR) to reflect broader adherence to the added 10-X safety factor called for in the Food Quality Protection Act (FQPA). CR made these adjustments to more assuredly prevent harm to pregnant women, infants, and children from pesticide dietary exposures.

ORG-Tracker uses EPA-cRfDs and chronic Population Adjusted Doses (cPADs) in calculating DRI values. Accordingly, the number of samples in the higher-risk zones in the table below overestimate the actual number by a sizable number.

Even with the more conservative Consumer Report-adjusted cRfDs, only around 6% of the samples with residues pose risks above a DRI value of 0.1 and the majority (76%) fall in the minimal risk zone or category (a DRI less than 0.01).

Number of Positive Organic Food-Pesticide Combinations With a Detectable Residue: Organic Food Tested by the PDP from 2016 to 2022 Based on Consumer Reports DRI Values

DRI Range	Number of Positives	Percent of All Positives
Greater than 2	15	1.0%
1.0 to 2.0	12	0.8%
0.1 to 1.0	60	4.0%
0.01 to 0.1	266	17.8%
Less than 0.01	1,144	76.4%
All Positives	1,497	100.0%

In addition in the CR analysis, the ***single riskiest organic sample*** accounted for around 70% of the total human-health risk associated with the 1,496 residues detected in organic food by the PDP from 2016 through 2022. This sample of organic green beans from Mexico contained an illegal methamidophos residue, and was present by virtue of an application of acephate (methamidophos is a breakdown product of acephate). If that one fraudulent shipment had been prevented from entering the organic food supply, pesticide dietary risks in organic samples tested by the PDP over five years would have been reduced by an amount equal to the aggregate risk from some 1,300 of the 1,496 positives found in all organic food samples.

ORG-Tracker will also provide empirical data to certifiers and the NOP useful in delineating low-risk, UREC residues from possibly fraudulent and/or risky residues that do warrant investigation and possible enforcement actions. Over time, ORG-Tracker tables will summarize the distribution and mean levels of residues detected by certifiers in each crop and crop stage, based on the combined results of all certifier testing. This will give all certifiers, the NOP/NOSB, the food industry, and the public health community a set of baseline levels to determine how common or unusual a given residue is, as well as how risky it is in terms of dietary exposures and public health.

Likewise, detected residues can be compared to estimated “Inadvertent Residue” levels, as well as existing tolerances or action levels. Armed with such data, certifiers can determine whether a given residue:

- Poses a very low, essentially *de minimus* risk,
- Is likely the result of a direct application on the crop, or is instead a residue from a UREC source, and
- Has been detected for the first time in a crop-region, is rare, or is frequently found.

Such information will help certifiers in prioritizing their follow-up actions when a residue is detected in an organic food, or foliage or soil sample. Tracking progress with accepted metrics grounded in the way EPA and other regulators quantify pesticide dietary risks will allow the organic community to credibly analyze pesticide residue frequency and associated risk levels in organic food in order to:

- Make comparisons to conventional food,
- Analyze risk levels in U.S. grown organic versus imports,
- Risk levels by food and production region, and
- Track trends in residue frequency and risk levels by crop, region, pesticide, and circumstance leading to residues in organic food (e.g. packing fruit in a facility that also packs organic).

Knowing where the real risks are will surely help certifiers target and mitigate them.

1. 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?

We support the discussion document in highlighting the value of "...a unified reporting format [for pesticide residues] and a centralized point for posting positive residue test information". Such data should be compiled, made publicly available, but most importantly it should also be analyzed to provide the insights needed to support identification of those samples and residue detections that warrant further investigation, and possibly mitigation, and those that do not.

Certifiers can be given the data and analytical capability to target and prioritize available investigatory and enforcement activities toward those certified operations and crops that are the source of residues that intersect compliance and health risks. The data will also serve as an early-warning system when a new crop-region combination begins to show up as a source of worrisome residues. The data will enhance the speed and accuracy of certifier decisions regarding whether a detected residue is likely inadvertent and should be regarded as UREC.

Rapid and low-cost delineation by certifiers of possibly worrisome from trivial risks will, in our judgement, prove to be the ***linchpin enabling continuous improvement in driving downward pesticide dietary risks in certified organic food***, and thereby promoting organic integrity.

Again, ambiguity in question 1 above over what is meant by "maximize" and "significant risks" must be cleared up in order to consider what steps could and should be taken. Our message is that one of the "significant risks" facing the organic community under current law and policy is

that a significant share of the resources invested in the testing for prohibited substances is unlikely to achieve stated and desirable goals. Even more troublesome is the likelihood that pesticide-related risks in the U.S. organic food supply will likely increase without the sorts of changes in law and policy outlined in these comments and our comments on risk-based certification.

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?

Certifiers can improve pesticide-related compliance and enforcement if they adopt the dual goals to enforce the intent of OFPA and reduce pesticide dietary risks.

3. What technical assistance is needed for certifiers to leverage testing to initiate adverse action?

Certifiers will benefit from NOP-supported and enhanced training for organic inspectors, with focus on how to collect, handle, and submit samples to testing labs (and ideally to labs that can adhere to PDP test protocols). Doing so will be mutually beneficial. The USDA will build a trained and competent independent private sector workforce, and certifiers will benefit from access to well-trained individuals who can help ensure organic integrity.

Compiling the results of all certifier residue tests in a single dataset will enable certifiers to discover more reliable and deeper statistical insights about the presence and levels of pesticides in organic food. Such insights will help certifiers interpret and act upon the results of residue testing, conduct investigations, and withstand appeals of adverse action.

The discussion document addresses a key issue – the high cost of residue testing [p. 133 pt. 4]. We offer two suggestions regarding ways to address the cost of testing. First, test smarter.

The USDA's Agricultural Marketing Service has considerable expertise at its disposal through the PDP. Analysts managing the PDP should be more available to certifiers, and vice versa, to leverage information exchange and hasten the flow of new insights.

Second, share the costs of generating more and better data. The NOSB and NOP should consider recommending that OFPA be amended in the next farm bill to provide for a cost-share agreement between the USDA and certifiers. Such an agreement could cover at least some of the costs of running not-for-cause certifier samples through analytical labs running the PDP protocol. In return, the certifier carrying out the testing and analytical labs would agree to: (1) use the same verified protocol as the PDP program, and (2) allow the results to be added into the annual PDP dataset. Doing so would create a larger, richer residue dataset that will advance the ability to isolate those few samples of organic and conventional foods that contain high-risk residues.

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?

It follows from the answer to (3) above for inspectors to be fully and properly trained to collect samples according to the PDP protocol. This will help fulfill the missions of both the PDP and the NOP.

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?

No, and not even remotely close to what will be required, especially for some imported organic foods, and not just because an inadequate total number of samples is being tested.

The necessary number of samples will be a function of the prohibited substance under consideration, the information accessible on the prevalence of use of the substance in areas where organic fields are grown, and the cost and scope of available analytical methods. If testing is the sole or primary tool, the cost of even modest success will often be prohibitive.

C. 7 CFR 205.670 – Exclusion from Organic Sale

1. Should certifiers have more flexibility/cause to exclude organic products from the marketplace?

Yes, in the case of samples found to contain residues at or above action thresholds that are the result of actions taken by organic farmers (e.g. spraying a prohibited substance).

Detection of what types of prohibited substances warrant exclusion from the market?

Certifiers and enforcement officials should prioritize those that pose the greatest risks to public health and food safety, and secondarily environmental risks and to the extent possible (e.g. to pollinators, soil health, the climate).

How should NOP establish thresholds for substances that do not have tolerances or action levels determined by other regulatory agencies?

Through standard risk-assessment procedures drawing upon available toxicological data. We see doing so is implicit in the UREC mandate in OFPA.

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?

As argued throughout these comments, we urge the NOSB to recommend that the NOP establish benchmarks of dietary risk in organic food samples based on the following criteria:

a. "Inadvertent" and UREC residues.
b. The distribution of residue levels of the same pesticide in other samples of the same organic food.
c. Action and inaction thresholds as discussed herein, modified as needed and appropriate to the substance of concern and the matrix to be tested.

Another advantage of such a policy framework is that certifiers can work to manage all chemicals and sources of food safety risk in a consistent manner that retains the focus on the highest public health and environmental risk residues. Most consumers seek out organic food to reduce exposures to risky residues, irrespective of whether the residue is a prohibited substance, an organically approved biopesticide, an insecticidal toxin in a GMO crop, an animal drug, or a heavy metal or PFAS.

Conclusion

The organic food community is saddled with a growing list of demands. Rising costs and mounting regulatory burdens associated with those demands are undermining the economic viability of organic farms and supporting businesses. Operations cutting corners, or simply ignoring them increasingly threaten the economic viability of some of the country's most experienced and committed organic farmers, and this problem is getting more acute at an alarming rate.

As the 2025 farm bill takes shape, we hope one of the goals will be to develop enhanced organic certification and enforcement tools and authorities for the NOP and certifiers. The rulemaking for Strengthening Organic Enforcement was necessary to address fraud, but our concern is that the increased regulatory burden will add costs on operations that do not need or deserve added scrutiny. Plus, looking harder where there are no risks makes no sense and is unfair.

Creative individuals and sophisticated criminal enterprises, some with virtual state sanction, can find ways to get bogus organic food, or organic food ingredients, into certified organic food products for sale in the U.S. Inevitably with current tools and policy, catching talented and determined cheaters will be difficult, but when it happens, the consequences should be serious

and sufficient to make it difficult for perpetrators to just enhance paperwork while seeking out a more accommodating certifier. Putting in place such a system, and meaningful penalties, will require amendments to the OFPA. Without them, progress will be harder to achieve and sustain.

Hopefully, the U.S. organic food and farming community will be able to make a compelling case to Congress as it writes the next farm bill to amend OFPA in ways that will move toward leveling the economic playing field. Imported organic products of dubious quality should not be allowed to flood supply-sensitive markets and erode profitability for long-established organic farms that rigorously follow the rules. The good news is that many such NOP-compliant farms exist in the U.S. and abroad, but they increasingly struggle to turn a profit in the wake of cheaper, often bogus “organic” food from operations more skilled at gaming the system than refining the art and science of organic farming.

Success will require a multifaceted system with components selected and integrated to match the importance and complexity of ongoing challenges. If the ultimate goal and measure of success is near 100% compliance with all NOP and OFPA requirements and near-zero presence of any and all prohibited substances in certified organic food, the road ahead will prove difficult and costly.

But if the goal is to deliver organic food that is progressively safer and rarely contains worrisome residues of anything, the data and tools to do so are within reach. This is why we emphasize the need for Congress to modernize key provisions in the OFPA applicable to prohibited substances and risk mitigation, so that a greater share of certifier activities will focus on where the real risks are.