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Comments to the NOSB on the Risk-Based Certification Discussion Document Under Consideration During the October 2024 Meeting in Portland, Oregon

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Executive Summary

We support the National Organic Standards Board's (NOSB's) work on risk-based oversight. The approach offers an opportunity to improve the cost-effectiveness of organic certification systems, while enhancing overall beneficial contributions to the organic community. Toward this end, we ask the USDA to adopt a broader and more nuanced view of "risks" arising from and impacting organic farming and food systems.

"Risk" has different, context-dependent meanings. In this discussion document, "risk" is faced by certifiers in the event of failure to detect serious non-compliance or fraud, and can lead to loss of reputation, and at worse, loss of accreditation. But to many organic stakeholders and most consumers, "risk" refers to the probability of adverse health outcomes from dietary or worker exposures to pesticides, or other prohibited or toxic substances, as well as adverse environmental, soil health, and biodiversity impacts. Limiting risk-based oversight of organic operations by focusing just on the risk of missing or failing to mitigate fraud or non-compliance will likely prove counterproductive and will not effectively address some of the greatest risks to organic integrity.

Our main takeaway points are:

- Risk oversight needs to protect organic integrity in a more comprehensive way that goes beyond ensuring compliance with certification standards.
- Health risks should be prioritized over other risks from non-compliance.
- Risk reduction requires resources and systematic action from inside and outside of the organic community to cost-effectively address risks imposed on the organic sector that have little or nothing to do with fraud or negligence by certified entities.
- The definition and policies related to Unavoidable Residual Environmental Contamination (UREC) need to be revisited by the NOSB, the National Organic Program (NOP), and likely as well, the U.S. Congress.
- Action and no action thresholds based on UREC and current, hazard-specific chronic References Doses are necessary for organic certification to reduce health risks and protect organic integrity, while sparing producers, handlers, and certifiers the burden of investigating and addressing all instances of low-risk exposure.

We conclude that amendments to the OFPA in the forthcoming farm bill are needed to retain, and better yet, build consumer confidence in the organic label. Modernizing the OFPA is essential to enhance the economic vitality of organic producers, handlers, and support industries. Another critical goal in amending OFPA is creating pro-growth economic fundamentals across the sector in order to attract badly needed capital to build new and better organic infrastructure (handling, processing, packing, storage, and transportation/distribution).

Changes are badly needed in certain outdated provisions in OFPA that have allowed a series of divisive controversies to fester (e.g. inerts, hydroponics). Other changes are needed to enable the organic community, certifiers, and the NOSB/NOP to address new and emerging challenges that were not on the radar screen when the OFPA went through the legislative process in 1988-1990.

Updates and upgrades in certifier responsibilities, coupled with new tools to more quickly detect non-compliance and fraud, and deal more decisively with those responsible, will set the stage for continuous progress in expanding the health benefits stemming from organic food and farming. Such benefits are already substantial and supported by the USDA's own data and research, yet remain conspicuously absent in public statements by the USDA and its senior officials.

Support for Risk-Based Certification and Oversight

We appreciate the NOSB's request for public input on the critical issues involving risk-based certification and oversight. These comments are submitted on behalf of the ORG-Tracker team which we lead, and the Heartland Health Research Alliance (HHRA). ORG-Tracker is a project of HHRA.

The most important question we see in implementing risk-based certification is how "risks" are defined, identified, and addressed in this document. The term is not used in a way that is commonly understood by most consumers who buy organic food. This has implications that we believe organic certifiers should consider as they strive to use their limited resources more effectively to protect organic integrity and build consumer confidence in the organic label.

The August 9, 2024, discussion document relies heavily on the Accredited Certifiers Association's (ACA) Best Practices and the Organic Integrity Learning Center's (OILC) NOP-230 rubric for understanding risks to organic integrity. The OILC defines "risk" as "[a]n effect of uncertainty on an organization's objectives."

In this discussion document, the term "risk" refers to the probability that a certifier will fall short of attaining organizational objectives, and at worse, become subject to sanction by the NOP, or even loss of accreditation. Hence, the focus is the risk that a certifier will not detect instances of fraud and/or non-compliance with NOP rules and requirements. From this intended meaning of the term risk, it follows that the concept of "organic integrity" is based on the ability of certifiers to detect and deter fraud and deal with non-compliances.

The document's use and meaning of the terms "risk" and "organic integrity" makes clear that certifiers are to prioritize their activities, inspections, residue testing programs, and enforcement activities to detect and deter fraud and non-compliances that can erode consumer confidence in organic integrity.

We understand and support these goals and their key role in shaping the NOP rule and the day-to-day activities of certifiers. The current focus on fraud and non-compliance in the context of organic integrity is appropriate in this risk-based certification discussion document, the ACA "best practice" documents, and the OILC's Risk-Based Oversight course. However, ***confusion persists in and outside the organic community about whether and how human health and environmental risks are factored into the enforcement of the OFPA and the NOP rule, as well as in the routine activities of certifiers.***

Risk Oversight Needs to Protect Organic Integrity

We ask the NOSB to clarify whether and how the activities of certifiers should also be guided by the expected impact in avoiding or mitigating risks to human health and the environment, and especially those adverse impacts stemming from instances of fraud, negligence, or other non-compliant actions by certified entities.

We understand that organic is a process-based standard. However, our research and other empirical evidence shows that the organic production process results in predictable outcomes specifically related to pesticide dietary risks and ecological hazards. Ongoing organic community and SOE initiatives must deter fraud and mitigate non-compliant activities. But in our opinion, it is equally important for organic farmers to steadily drive down food safety and environmental risks to, or as close to zero as possible. We believe the certification process can more effectively guide the organic community in attaining this goal. Our comments suggest ways to move forward toward this welcomed outcome.

For most consumers, the true value of the voluminous, detailed NOP rule, and all the effort invested in organic farming system plans and annual inspections, is reducing risks to people and the environment. Continuous improvement in driving down recognized risks, and avoiding new ones, almost certainly matters more to consumers than how many instances of fraud or non-compliance are detected and mitigated, and how quickly.

Hence, we urge the NOSB to see risk in a broader context that looks at the foundational purposes of organic farming and food systems, beyond paperwork and process compliance. In our opinion, health-related human, environmental, soil, and farm animal risks should be managed in the context of the organic principles of health, ecology, care, and fairness. While certifiers bear key, specific oversight responsibilities, promoting public and environmental health by reducing or avoiding risky practices and prohibited inputs is the responsibility of everyone that works along organic food chains, from farmers and ranchers to handlers and retailers, all the way from field to fork.

Avoiding dietary risks stemming from pesticide residues in food and beverages is often top-of-mind when consumers first seek out organic food. Ending or markedly reducing the negative impacts of farming and ranching on above- and below-ground biodiversity and ecosystem health and resiliency are also core objectives that attract consumers to purchase organic food and support organic farmers and ranchers. As a result, growers, certifiers, the NOP, and businesses along organic supply chains need to remain focused on delivering on the key promises embedded in the USDA organic seal.

Toward this end, we suggest that the NOSB include in its recommendations to the NOP, and broader organic food and farming communities, that the terminology used in discussions of risk-based certification be clarified in two important ways.

First, we suggest that the word "risk" needs to be put in context when it is used. When the focus is deterring fraud and addressing instances of non-compliance, the term "risk" should always be paired with the intended outcome through use of phrases like "risk of detecting and mitigating fraud and non-compliance", or simply "risk of fraud" or "risk of non-compliance".

Second, when the word "risk" is intended to refer to the human health, soil health, or environmental impacts of farming systems and input use decisions, the term risk should be coupled with a short phrase describing the nature of risk being discussed or of concern.

These simple steps would unambiguously distinguish between compliance-related risks and the risks to human health and environmental quality. Reducing compliance-related risks can be expected to reduce health and environmental risks, but not eliminate them. Compliance-related risk is a function of the policies, rules, and expectations that OFPA, the NOP, and the broader community have chosen to accept and adhere to in the interests of organic integrity. However, risks to human health and the environment risks related to organic production and handling are diverse and often are not under the control of organic farmers, nor certifiers and those working along organic supply chains. Policies are also needed to protect organic producers and handlers from the health and environmental risks caused by conventional production. It is unfair to impose the entire burden of living on a polluted planet on the organic community.

But clearly, some risky practices and uses of prohibited substances on organic farms are willful and these are surely the appropriate focus of certifier efforts to detect and deter fraud, negligence, and instances of non-compliance. Certifiers must find ways to deal with the complex challenges inherent in differentiating instances of willful non-compliance from circumstances whereby an organic farmer, or her or his harvest, is found to be contaminated with a prohibited substance that somehow came onto the farm from nearby conventional operations or other sources by drift or runoff.

We also urge the NOSB, NOP, and organic community to recognize and reflect on another key point. Consumers will continue to seek out organic food, and support organic farmers, to the extent they believe and expect organic farming is delivering positive human health,

environmental, and social justice outcomes. In forming their impressions of whether certified organic food is delivering these widely embraced benefits, consumer do not differentiate between practices, input uses, or residues detected that fall under the compliance-related purview of certifiers, versus some other category. This realization supports the need for a broadening of the operational goals of certifiers, the NOP, and the organic community to just make food and farming safer and more aligned with promotion of health in all its dizzyingly complex venues and dimensions.

In short, organic integrity rises and falls with the degree to which organic farming and food chains are demonstrably pro-health.

Prioritize Health Risks

Certifiers need to decide how to prioritize allocation of staff time to achieve both compliance goals and reduce risks to people and the environment. We recommend that the NOSB and NOP provide certifiers greater clarity on how, in making decisions about priorities, they can also assure that they continuously improve on the outcomes that matter the most to consumers: promoting human and the environmental health.

If the NOSB and/or NOP believes this is not possible under current law and regulations, an opportunity will arise as the next farm bill is crafted to clarify the meaning of the term "risk" within OFPA. The farm bill could also direct the USDA to guide and empower certifiers to prioritize their efforts to detect and deter fraud and deal with non-compliances, ***while also steadily driving down human and environmental health risks from wherever they arise along organic supply chains.***

Because reduced health risks from exposure to pesticides is a major factor cited by consumers for purchasing organic food, our comments focus on pest management and pesticide-related aspects of the OFPA, the NOP rule, and the certification process. We believe that compliance-risk-based oversight to minimize fraud is and will continue to reduce the adverse human health and environmental impacts of pesticide use. There is also abundant scientific literature reporting that reduced pesticide use on organic farms delivers benefits for farm workers and nearby neighbors, and promotes above- and below-ground biodiversity.

Risks from other kinds of fraud and negligence are important and should not be ignored, but we believe that pesticide risk reduction should be a clear priority. We also are certain that efforts beyond identifying and deterring fraud and non-compliance will accelerate progress in reducing the presence of high-risk residues in organic food regardless of how they found their way onto an organic farm or into organic food supply chains.

Risk Reduction Requires Resources Beyond the Organic Community

This risk-based certification document begins by discussing the need for guidance and resources to support certifier efforts in promoting organic integrity via detection of fraud and instances of

non-compliance. The document provides solid criteria to help certifiers evaluate the likely frequency of instances of fraud and non-compliance.

Certifiers and certified operations are encouraged to be proactive. However, with pesticide use fraud and pest management system non-compliance, certifiers, certified operations, pesticide manufacturers, materials review organizations, pest control advisors, and pest control operators need better guidance and technical support to delineate conscious fraud or clear non-compliance from a situation caused by:

- Drift, runoff, and volatilization of chemical inputs.
- Contaminated soil, irrigation water, or post-harvest wash water.
- Residues in pesticide application equipment that is not properly cleaned between uses.
- Pesticide residues in a food processing plant or retail operation carried over from handling both organic and conventional produce.
- Unknowing use of contaminated and/or fraudulent production inputs that are labeled and marketed as approved for use on organic farms/ranches.

In passing OFPA, Congress mandated the NOSB and NOP to address Unavoidable Residual Environmental Contaminants (UREC) to provide the NOP and organic farmers a way to deal with persistent organochlorine (OC) insecticides in soil and food chains, among other persistent and ubiquitous pollutants. Organic food could be sold as organic with UREC residues up to 5% of EPA-set tolerances, although certifiers were required to track down the source of the residues at or below 5% of tolerances to rule out fraud or non-compliance.

OC residues continue to show up in organic crops, despite being banned some 40 to 50 years ago. Transgenic gene flow from GMO crops classified as plant pesticides by EPA continues to contaminate seed-breeding lines. Pollen from GMO crops can move onto almost any organic farm producing corn, soybeans, cotton, alfalfa, and sugarbeets. Low levels of adventitious presence of genetically altered DNA in certain crops, conventional or organic, is now unavoidable nearly worldwide.

The purity and safety of both conventionally grown and organic food is threatened by a long list of chemicals, such as heavy metals and PFAS being found in organic crop fields as a legacy government-sponsored spread of sewage sludge. The nature of such persistent prohibited substances will evolve over time and respects no boundaries.

Buffers and other measures to prevent such pollution can be expensive and unfairly burdensome to organic farmers by imposing the cost of mitigation on them rather than the polluters and those that produced the pollutants.

The question that certifiers, producers, handlers, and others in the organic supply chain face is, what risks of contamination are avoidable, which ones are not worth the effort to mitigate, and which are simply unavoidable?

Dealing with UREC in the context of organic certification is an enormous and costly challenge. If organic farmers and ranchers were to address the long and growing list of contemporary toxic chemical- and genetic-technology-driven challenges via additional testing and certification requirements, ***the added costs incurred will undermine efforts to expand the supply of organic food while keeping premiums within reach of the average consumer***.

This is especially true when new costs and obligations are imposed on organic farmers and food chains, but not conventional growers and supply chains. This obviously places organic farmers and food companies are a competitive disadvantage. SOE was needed to address rampant fraud, but an unintended consequence has been to increase the cost and burden of compliance for honest producers and handlers.

In our comments at the Spring, 2024 NOSB meeting in Milwaukee, we addressed several examples of added costs compared to conventional growers arising from the NOP's pesticide-residue testing rule. One way to begin to reduce upward pressure on the price of organic food is for the Congress, NOSB, and NOP to specify toxicity- and human-health risk-based criteria that should govern the response by certifiers when a residue of ***any*** pesticide, including prohibited substances and permitted, OMRI-listed biopesticides, is found on a sample of organic food, on foliage growing on an organic farm, or in the soil on an organic farm.

UREC Needs to be Revisited

We have argued previously, and reiterate in these comments, the need to revisit and modify the definition of UREC, as well as what should happen when such a contaminant is detected, including adventitious presence in organic crops of transgenes from GMO crops.

Fortunately, there is widespread concurrence in the organic community that current law and regulations are not working cost-effectively. No wonder given that the core prohibited substance provisions in OFPA were crafted in the late 1980s and have not been updated to address the unique scope of contemporary farming and food safety risks and challenges (e.g. climate change, gene flow, residues in food, and pathogens with pandemic potential). Some of the shortcomings in OFPA can be addressed effectively in technical amendments in the new farm bill, or via other legislative or administrative processes.

In 1990, defining UREC residues as up to 5% of applicable EPA tolerances or FDA action levels was a way forward. But EPA-set tolerances are not consistently health-based. When passed, there was a widely accepted assumption that a residue at or below 5% of EPA tolerances or action levels would pose little or no risk. This was not true then and is not now. Moreover, embedded in this policy construct is the assumption that a residue present in an organic food sample at a level above 5% of an EPA tolerance is possibly risky. This is also not even remotely true.

Basing UREC levels of pesticides on some fraction of EPA-set tolerances and action levels is no longer defensible. Instead, UREC levels should be set based on thresholds set in relation to

chronic Reference Doses (cRfDs). EPA sets chronic Reference Dose (cRfD) based on the No Observed Adverse Effect Level (NOAEL) when known, coupled with uncertainty factors, or the Lowest Observed Adverse Effect Level (LOAEL) in the absence of a NOAEL, with additional safety factors.

Such an approach will ensure the best available science is the basis of certifier and NOP actions and inaction. It will also ensure that ***UREC levels are aligned with risk assessment methods and thresholds applicable to the same or similar chemicals when they are regulated because of presence in air, water, the workplace, or waste dumps***.

Furthermore, 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 below some defined low-risk threshold based on the chemical's cRfD and is also regarded as an "inadvertent" UREC-like residue.

Such "inadvertent residues" would be ones that almost certainly are not present in a sample of organic food as a result of a conscious and fraudulently application of the detected pesticide in the hope of managing some target pest. Setting the unavoidable 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 fraud or negligence.

Any residue at or above the 25th percentile level of residues in conventional crops is plausibly a result of a direct application, and unlikely 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 or sabotage.

In the USDA's Pesticide Data Program and other datasets related to pesticides in foods, we have seen organic samples that are contaminated with multiple residues. While each of these residues may be below 5% of EPA tolerance, the cumulative adverse health effects may and sometimes do pose a greater risk. Synergistic effects sometimes occur. We also believe that multiple residues above inadvertent residue levels 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 the neighbor.

Weeds are perennially identified by organic farmers as one of their biggest production challenges. Weed control drives the risk of fraudulent applications of prohibited herbicides. Dealing with fraudulent or otherwise non-compliant herbicide use is a more vexing problem that requires a different approach to address both compliance risk and health risks. Because herbicide residues in food at harvest are rarely detectable in raw agricultural commodities, certifiers sometimes sample and test soil or foliage of a growing crop or weeds when they suspect such fraud based on complaints or inspector observations. Because the sample is not of the edible harvested crop, a different approach will be needed to set UREC levels. A default "no

action" level is needed in determining if a fraud investigation is warranted and is discussed in more detail below.

What happens when a certifier detects a pesticide on the foliage of an organic crop or a harvested commodity for which EPA has not established a tolerance or exempted it from the requirement for a tolerance? Such cases are usually from unavoidable events beyond a farmer's control but may also be the result of pesticide applications that are not just fraudulent, but also illegal under FIFRA. They may also come from negligent post-harvest handling and the handler or retail level, contaminated application equipment, or fraudulent production inputs.

Action Thresholds are Needed

The distribution of residue levels in conventional crops can also be drawn upon by the NOP and certifiers in setting residue thresholds for prioritizing sample selection, use in fraud investigations, tracking the impact of organic farming, and other purposes. A residue at the 40th percentile of the distribution of residues in conventional crops is likely associated with a willful application of a pesticide, and hence fraud or negligence when in an organic sample.

While we are confident that a residue present at or below 1/10th the mean of positive samples likely fits the definition of UREC, it is harder to make such judgements between 1/10th 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.

But we also believe that additional efforts to track down the sources of the residue are warranted only if the risk level associated with such a residue exceeds the applicable "minimal-risk warranting no further action" threshold. Such thresholds can be established based on a serving of food delivering no more than some small percent of the exposure level EPA regards as "safe" (e.g. 1% of EPA's "level of concern" exposure). Minimal risk chemical thresholds in water, air, and workplace are set in basically the same way, and for basically the same reason.

There are vast differences between chemical levels and associated risks in all corners of the environment, as well as in food and water. It is not practical to avoid all of it, and it is both logical and beneficial to identify and mitigate the greatest sources of risky chemical exposures, especially those that can easily be avoided like toxic pesticides in food. We hope this simple reality will ultimately find its way into OFPA, NOP rules, and the day-to-day activities of certifiers, and the sooner the better.

The threshold allows certifiers to determine whether further investigation and possible adverse action is needed and what cases can be safely closed. Without an action threshold, certifiers will lack the resources to mitigate high risks. ***This is the practical reality the Congress, NOSB, and the NOP must embrace 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 suggestions:

1. The thresholds should be based on the best estimate of cRfDs and the hopefully "safe" levels of exposure based upon them. An exposure level deemed "safe" in drinking water, the workplace, and in the air should be accepted by the organic community as also valid for use in certification processes and compliance and enforcement actions, and in tracking the impact of organic farming.
2. The "minimal-risk warranting no further action" threshold for substances in a serving of a specific organic food could be initially set at 1% of the level deemed acceptable by EPA or other regulators. This would correspond to a DRI value of 0.01. Most residues found in organic food will fall below this threshold (see the table below).
3. The "risk mitigation action threshold" could be set at a level where the detected residue level in one serving of food corresponds to 50% or more of the level of risk 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 action thresholds and below the minimal risk level, coupled with the ability to periodically lower one or both risk thresholds given the success of efforts targeting high-risk residues.

The ORG-Tracker system that is currently under construction can easily generate the above thresholds for all foods and pesticides. All the data needed to do so is in the system. The table below provides an overview of the 1,496 residues detected in domestically grown and imported organic samples tested by the PDP from 2016-2022. This analysis utilizes cRfDs adjusted by Consumer Reports to reflect broader adherence to the added 10-X safety factor called for in the Food Quality Protection Act (FQPA) to more assuredly prevent harm to pregnant women, infants, and children. 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 0.1 and the majority fall in the minimal risk zone or category.

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 USDSA's Pesticide Data Program from 2016 through 2022. This sample of organic green beans from Mexico contained high and illegal levels of methamidophos and its breakdown product acephate. If that one fraudulent shipment and sample had been prevented from entering the organic food supply, pesticide dietary risks 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.

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%

Methamidophos, acephate, and other high-risk organophosphate insecticides had been detected by the PDP in imported organic green beans from Mexico in prior years. Hence, certifiers and those working along organic produce supply chains 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.

ORG-Tracker will also provide key information to certifiers and the NOP in delineating low-risk, UREC residues from possibly fraudulent and/or risky residues that 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, giving all certifiers a set of baseline levels to determine how common or unusual a given residue is.

In addition, residue levels can easily be translated into dietary risk levels in a single serving of food using EPA-set cRfDs/cPADs included in the Dietary Risk Index system. 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 UREC, and
- Has been detected for the first time in a crop-region, is rare, or is frequently found.

This is the sort of information certifiers will benefit from in prioritizing their follow-up actions when a residue is detected in an organic food or foliage 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 compared to conventional food, in U.S. grown organic versus imports, and by food and production region. Knowing where the real risks are will surely help certifiers target and mitigate them.

Questions to Stakeholders

1. How does your organization define risk?

We have emphasized throughout these comments that "risk" has different meanings depending on the context, and hence the term should be used in conjunction with other words that specify the context. The ORG-Tracker team is focused on risk in the context of the probability of adverse impacts on human health and the environment stemming from use of agricultural chemicals. HHRA as an organization is focused on the public health and environmental impacts of farming system choices, with current focus on human reproduction and children's health.

a. Would it be valuable for the definitions listed above (Risk-based oversight, Risk management, Risk, Vulnerability) to be included at §205.2 Terms Defined?

Yes. We believe a clearer definition is needed of what is meant by the word "risk" in the context of risk-based organic certification. As stated in the first part of these comments, we suggest that the word "risk" in the context of risk-based certification always be used as follows: "risk of fraud", "risk of non-compliance", or "risk of adverse action on certification", as opposed to risk of adverse human health or environmental outcomes. Such an operational definition of risk is useful and does not preclude talking about human health or environmental risks caused by fraud, negligence, and UREC.

b. Are there other definitions that would be beneficial to include at §205.2 Terms Defined besides those listed above? Is it important that all certifiers use the same risk criteria to evaluate certifier operations? Why or why not?

Yes and yes. We recommend defining and adopting the chronic Reference Dose (cRfD) of prohibited substances as the basis for setting health-risk thresholds, as well as tools to prioritize the selection of samples to test and the need for follow-up, compliance-focused actions when a

residue is detected. The EPA's definition of a cRfD is: "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments."

We also ask that Unavoidable Residual Environmental Contamination (UREC) be redefined as follows: "Background levels of ~~naturally occurring or synthetic chemicals~~ prohibited substances and excluded methods that are ~~present in the soil or present in organically produced agricultural products that are below established tolerances~~ not caused by actions taken by organic farmers and ranchers, and are hence typically beyond the control of certified organic operations."

2. What other resources (e.g. trainings, models, certifications/credentialing program) are currently available that would help an organization become more proficient at risk-based oversight and/or risk evaluation?

Yes. ORG-Tracker can be a resource to provide information helpful to certifiers and other actors in the supply chain as steps are taken to implement the NOP rule and reduce compliance and health risks posed by pesticides.

3. What are the unintended consequences that could arise from using a risk-based oversight approach?

Certifiers need decision-making tools, access to data, and models that will enable them to differentiate between detected residues worthy of follow-up action and those that pose little risk of fraud or negligence, and little risk of adverse impacts on human health and the environment. If a risk-based oversight approach does not establish clear levels and decision tools, the costs imposed on certifiers and the organic community in chasing down the source of every chemical and genetic contaminant that finds its way onto a sample of food from an organic farm will become untenable. In the absence of policy reforms, such increased oversight will undermine the economic viability of certified organic production in the U.S.

4. What other ways are there to reduce burdens on low-risk operations?

Data gathered and risk-models can identify low-risk operations. These are likely to be small operations that are entirely certified organic. Additional data analysis can be used to make certification more efficient and lower costs to all operators, particularly low-risk ones.

5. How can the community provide information to NOP and/or certifiers on acute risks?

ORG-Tracker will be able to provide data on the distribution and mean levels of specific pesticides found in various foods. Such data, and analysis of it, will help the NOP, certifiers, and

the organic community in determining both whether a residue is unusual and whether it poses a public health or environmental risk worthy of follow-up.

Conclusion

Many of today's challenges inherent in cost-effective risk-based certification were unimaginable in the late 1980s when the community debated the core provisions of OFPA and in 1990 when the Congress passed the OFPA. The compliance and health-oriented risks that impact organic farms and certified organic food have obviously changed. The USDA's Pesticide Data Program provides strong and mounting evidence that eating organic foods dramatically reduces dietary risks from exposure to pesticides. It is time for the USDA to recognize its own scientific evidence and acknowledge that organic agriculture benefits human health.

The technology to detect very low levels of possibly damaging pesticides, toxic pollutants, heavy metals and pathogens has advanced. Risk assessment science has sharpened the ability of investigators to distinguish worrisome risks from those that are minimal, or likely zero. Food supply chains and channels of trade have become more complex and layered in the U.S. and worldwide. The global economy that has emerged since OFPA includes trading partners that have less stringent pesticide laws and oversight of organic farmers than the U.S.

No wonder that the NOP, the organic community, and certifiers sometimes find the tools in the regulatory toolbox a poor match to the tasks at hand. The obvious solution to this problem is to revisit and modernize the OFPA. We conclude that the data and models developed since the passage of OFPA can be used to revise the pesticide-related provisions in OFPA and the NOP rule in ways that would benefit farmers and ranchers, certifiers and the NOP, and—ultimately—consumers.