Brian Baker
Belcairn Concerns LLC
PO Box 12256
Eugene, OR 97440

Charles Benbrook
Benbrook Consulting Services and
ORG-Tracker
10526 SE Vashon Vista Drive
Port Orchard, WA 98367

Thank you for the opportunity to comment to the National Organic Standards Board. These written comments address questions raised in two documents on the April 2024 NOSB agenda: Residue Testing for a Global Supply Chain (February 6, 2024) and Inert Ingredients in Organic Pesticide Products (February 13, 2024). In addition, we look forward to offering oral comments during the NOSB in-person and preparatory meetings.

These comments are submitted by Brian Baker and Chuck Benbrook on behalf of a team working to develop a new system designed to compile and analysis pesticide residue data in organic and conventionally grown foods and crops. The system is called ORG-Tracker, which Chuck Benbrook will further explain and answer questions about at the in-person meeting in Milwaukee. Please consider our previous written and oral comments on these subjects.

We are co-authors of several peer-reviewed journal articles that compare pesticide use and relative pesticide dietary risks in organic and non-organic food (Baker et al., 2002; Benbrook, 2011; Benbrook et al., 2021; Benbrook & Baker, 2014). Other papers address issues and challenges in pesticide risk assessment and regulation that are at the heart of challenges confronting the NOSB, the NOP, state organic programs, certifiers, farmers, the food industry, and consumers.

Our research provides powerful evidence that certified organic food consistently and significantly reduces dietary risks from exposure to pesticides. Consumers often cite lower pesticides as a primary, or the primary reason for purchasing organic food (Eyinade et al., 2021; Hughner et al., 2007; Yiridoe et al., 2005). Much of the work over our long careers has been devoted to helping the organic community deliver on the promise to consumers embedded in the USDA organic seal. These comments build on that past work and are offered in the hope of assisting the NOSB and the organic community achieve continuous improvement in food safety and pest management system innovation.

Residue Testing

Organic agriculture is a process-based standard. Absence of residues of prohibited pesticides is not proof of organic status. While the presence of prohibited pesticides is evidence of possible fraud or negligence, that evidence needs to be corroborated by further investigation to rule out Unavoidable Residual Environmental Contamination (UREC) beyond the operator's control. Our published articles show that organic food is less likely to be contaminated by pesticides, less likely to be contaminated by multiple residues, and when contaminated, the levels are significantly lower than those found in the same foods grown on conventionally managed farms.

However, our results also show that organic food is not always pesticide residue free. A zero-tolerance policy for all crops, all foods, and all non-food matrices is not practical. While organic

producers and handlers do an excellent job to assure food safety, we believe they are willing and able to do better. Improved sampling and testing procedures, more timely and transparent reporting of results, better investigation of contamination incidents, and more rigorous analysis of the results can all lead to continuous improvement in organic. Doing so will protect organic integrity and maintain consumer confidence in the organic label.

The NOSB asks the following questions. Below are our responses.

NOP 2610: Instruction Sampling Procedures for Residue Testing

1. *Does this document instruction provide adequate information for certifiers and inspectors to collect samples in the field?*

   No. While we understand that most of the focus is on pesticide residues in food samples, we believe that a more pro-active and preventive approach requires that samples of matrices other than foods be sampled and analyzed for prohibited substances if residue testing is to be an effective deterrent to fraud and if dietary risks in organic food are to be reduced. Not all prohibited pesticides used on an organic field, or drifting onto it, will contain residues in the harvested crop. While the instruction recognizes that soil, water, waste, seeds, or plant tissue may be sampled, the rationale and risk factors for sampling these non-crop matrices should be explained more clearly.

   Seed treatments with prohibited fungicides, pre-plant fumigants, many insecticides and fungicides not applied to the edible portion of the crop, and most herbicides will rarely be detected by sampling and testing a food or feed product as consumed. To detect residues of such applications, soil must be tested, or foliage collected relatively early in the crop's developmental cycle. Prohibited pesticides applied during the dormant season in perennial fruit systems will rarely be detectable in the fruit. Sampling the bark of fruit trees is more likely to result in the detection of the deliberate, fraudulent dormant-season use of a prohibited pesticide.

   We look forward to opportunities to work with certifiers and inspectors to develop improved sampling procedures capable of detecting a more diverse cross-section of prohibited pesticide use on organic farms and ranches.

   The scope of this key NOP guidance document should also include the sampling of inputs stored on-farm and farm equipment. Materials Review Organizations, such as the Organic Materials Review Institute, sample fertilizers, compost, pesticides, and other inputs for the presence of prohibited substances. Certifiers can also sample fertilizers, pesticides, and other inputs as evidence that they have been adulterated with prohibited substances. One potential source of contamination is the use of the same pesticide application equipment for both allowed and prohibited pesticides. If the equipment is not properly cleaned between uses, detectable levels of prohibited pesticides can be applied to organic land and crops. Such activities may not necessarily be fraudulent, but such negligence is avoidable and can still be considered a non-compliance, or an inadequacy in an Organic System Plan under the requirements of 7 CFR 205.201(a)(5).

2. *Are there areas pertaining to sample collection (sample size, when to collect samples, sample selection, etc.) that need to be developed or improved? Please provide suggestions*.

   Yes, more detailed instructions will be needed for the samples to be valid as evidence of fraud or negligence, and for a certifier to be able to withstand an appeal based on inappropriate or unreliable sample collection and handling. We suggest more detailed instructions that will help inspectors gather corroborating evidence at the time of sampling and to support any follow-up investigation that are a consequence of positive results. Such details could be solicited during a public comment period and would help the NOP identify areas in need of more specificity or clarification.

   In terms of instructions for sample documentation in 4.4 of NOP 2610, certifiers are called upon to record the variety of a crop, as well as the brand name. However, circumstances will arise in which this information is not available or apparent to the individual collecting the sample. Accordingly, we suggest this provision call for the collection of such information "when available."

3. *How can additional instruction or guidance on sample collection support the veracity of testing results so that adverse actions are more defendable?*

   We suggest that such instructions be prepared as best practices by consensus of certifiers and the inspectors qualified to collect samples, rather than issued as formal guidance. Once such best practices are commonly accepted by the organic community, they will be widely implemented by the organic community. If non-compliance emerges as an issue, appropriate steps can be taken via the accreditation process or in future revisions of guidance documents.

NOP 2611: Instruction Laboratory Selection Criteria for Pesticide Residue Testing

1. *Section 4.1 describes one type of residue screen that can be used for testing. What additional tests should be included in this section (e.g., heavy metals, synthetic solvents, fumigants, herbicides, etc.)? What should be the threshold for validating additional testing methodologies in this section to ensure results are actionable?*

   While the QuEChERS method and variations on it has several advantages in conjunction with multi-residue analytical methods, it is not necessarily the best approach in every case nor the sole approach that should be utilized.

   In particular, the guidance does not address pro-active and preventive practices that operators can do to avoid known sources of environmental contamination. Examples include maintaining adequate buffers to avoid drift, informing neighbors of those buffers and asking for their cooperation to spray less heavily in proximity to the boundary between

the organic and conventional field, soil testing for legacy pesticides such as DDT, and cleaning pesticide application equipment used for both organic and conventional production.

The thresholds for validated methods and acceptable laboratories should be spelled out as clearly as possible and include:

- Publication in an appropriate peer-reviewed journal,
- Verification and acceptance by government entities conducting similar testing, and
- Routine participation in a recognized analytical methods verification and QA/QC program that includes periodic participation in round-robin efforts to calibrate methods (e.g. the quality control schemes managed by the Centre de toxicologie du Québec (CTQ) in Canada (CTQ, 2024).

2. *Sections 4.2 and 4.3 describe laboratory selection criteria and suggested laboratory practices. Do either of these sections need to be updated to align with current best practices?*

   The sections provide minimum standards. Ideally, the USDA / AMS laboratories that conduct PDP testing can be involved in NOSB/NOP discussions of quality control and verification of procedures. As noted earlier, laboratories should also consent to ring-test shared samples and share samples and data in cases where results are challenged on appeal.

   We also encourage organic certifiers to work with labs to get bulk pricing or volume discounts. However, such discounts must not compromise the quality of results. We also think that rapid turnaround is vital to fulfilling the OFPA's mandate. Labs need to return results in a timely manner to prevent products that do not comply with organic standards from reaching the market.

   These data quality, cost, and timeliness issues are among those that the ORG-Tracker project will work on and support organic community-wide efforts to make residue testing more accurate, less expensive, and more useful.

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

   As addressed earlier, such additional instruction should be voluntary and handled by best practices issued by certifiers. The ORG-Tracker team is prepared to provide technical assistance to cooperating certifiers.

NOP 2611-1: Prohibited Pesticides for NOP Residue Testing

1. *Does this list of prohibited substances provide value to certifiers in evaluating organic compliance?*

   We believe that the list of prohibited substances provided is incomplete and including it as guidance could lead to the mistaken impression that it is comprehensive. Analyses should be based on what are the most likely pesticides to be found on the crop in question in the region where it is grown, and especially those that pose the highest dietary risks. Such an approach will sometimes require additional analysis.

   We recommend using pesticide use data to develop a list of prohibited substances that are the most likely to be used for a specific crop in a production region. Data from the USDA / AMS Pesticide Data Program (PDP) and the Dietary Risk Index (DRI) system can be used to determine which crop-pesticide data pairs (CPDPs) pose the greatest dietary risk to the most vulnerable population, including infants, children, and pregnant women.

2. *How can this document be improved?*

   The list is inadequate and outdated. The most glaring omission is that glyphosate is not included on the list. Glyphosate is by far the most widely used pesticide worldwide and is prohibited in organic production. It is often the last pesticide that farmers will apply prior to starting transition. The metabolites aminomethylphosphonic acid (AMPA) and glyphosine should also be included on the list. These degradants are more likely to persist in the soil and would be strong evidence that glyphosate had been applied in the recent past on a given field. But like OC residues, the soil half-life for glyphosate and AMPA are variable across soil physical and chemical properties, farming systems, and climatic conditions. Extremely low levels are now routinely detected in almost all corners of the environment (air, soil, water, plant biomass, and in mammals). Presence of glyphosate and/or AMPA is unlikely to be drift or unavoidable contamination. Also omitted are the herbicides 2,4-D and dicamba. With the advent of glyphosate-resistant weeds, the use of these herbicides has increased dramatically in recent years. They are already ubiquitous environmental contaminants that have toxic metabolites and degradants with highly variable soil half-lives.

   Another category that appears to be missing from Guidance 2611-1 are the antibiotics, specifically streptomycin and oxytetracycline. While these were once on the National List, they were removed and are now prohibited for organic production. They were never permitted for use on fruit to be sold to the European Union. Another antibiotic in use is natamycin.

   In 4.1, a discussion appears of current analytical methods. The NOP appears to call for policies and procedures "to ensure that false positives and false negatives are not reported." While a goal to work toward, there are no 100% effective policies or procedures that can be adopted – and affordable – in the context of a pesticide testing program. We

suggest revising this to state something like "…ensure that false positives and negatives rarely occur…" Imposing such an aggressive requirement on testing labs would raise costs and trigger unjustified anxiety.

The last sentence in 4.1 states that certifiers "should initiate sampling/testing and investigation" when they "suspect" a prohibited substance was used that is not detectable via the analytical methods used by the lab they send their samples to. We urge the NOSB/NOP to reconsider this requirement because it could effectively impose a mandate on certifiers to hire an analytical lab to develop a novel method. If certifiers and the labs with which they contract are required to develop the capacity to use a specialized method designed to detect a single compound, that could potentially impose unbearable costs on certifiers, and unfair costs on organic consumers.

Instead, we would urge future guidance to emphasis additional effort to build on and confirm the information leading a certifier to "suspect" that a prohibited substance has been utilized.

If categories of prohibited substances warrant screening and analysis—such as certain synthetic nanoparticles or genetic material from excluded methods—the NOP should work with other parts of AMS to seek assistance in the development of practical and affordable testing methods.

In section 4.3, of NOP 2611, suggested sample preparation steps are described. The second paragraph begins with: "Samples should not normally be washed or peeled (e.g. bananas, oranges)…" This guidance conflicts with the PDP sample preparation protocol, which calls for food to be tested as close to "as eaten" as possible. Oranges and bananas would be peeled. Husk on sweet corn or field corn would be removed. Sample preparation is an example of the tradeoffs between important program goals. Testing for pesticide residues on the banana peel would be more likely to find prohibited pesticides that were deliberately applied in a high-volume imported crop with a history of fraud. Similarly, preparing the whole ear of corn, including the husk, is more likely to detect of residues of prohibited pesticides that were f any are present, For the data to be comparable to the PDP and useful in human health risk assessments, it is more reliable to just quantify residues in banana flesh or corn kernels.

This also highlights a challenge for the ORG-Tracker team. We need to track the food forms tested, the tissues tested, and how samples were prepared to avoid introducing bias into estimates of dietary exposure levels and risks.

3. *Would certifiers find value in developing a decision tree to determine which tests should be conducted depending on the commodity, geographical location, and position within the supply chain? Please describe how a decision tree could assist certifiers with testing and compliance verification*.

We expect that a variety of methods are used across certifiers to select which foods to test each year and when a detected residue warrants further investigation, and possibly enforcement actions. A major goal of ORG-Tracker is to compile residue data and translate it into quantitative measures of dietary risk that can be compared to residues and risk levels in conventionally grown food, as well as policy-driven thresholds, such as "inadvertent residues" (a residue at or below 1/10th of the mean of the positives in conventionally managed fields).

NOP 2613: Instruction Responding to Results from Pesticide Residue Testing

We find the instruction to be reasonably comprehensive and consistent with the intent of the regulations, but still think additional clarification and instruction is needed.

We ask that the NOSB recommend revisions to the Guidance to instruct laboratories to report results to all interested parties simultaneously in real time, rather than only to the certifiers on a schedule that can undermine the effectiveness of follow-up investigations. These should include the owner of the matrix sampled—in most cases the operator—as well as the USDA, FDA, state agencies responsible for enforcement of food safety regulations, and any private entities that identify themselves and register with the USDA to receive such data. Any positive result above the established UREC limit should be treated as possible evidence of fraud and needs to be investigated as such.

We acknowledge that anonymity of the source of the sample needs to be respected at the time of submission to the laboratory. While the results can be made public once the analysis is complete, anonymity is needed at the time of submission to prevent tampering with evidence and biasing the analysis.

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

   First, tolerances apply to the presence of pesticide residues on or in the harvested part of a crop when it moves off the farm and into the human food or animal-product supply chains for both conventional and organic farms. Organic certifiers are obligated to share data on residues in food products that are over tolerance, or present in the absence of a tolerance or a tolerance exemption, when the food is shipped off the farm.

   However, a lab report to a certifier documenting presence of a pesticide on a leaf of a tomato plant does not constitute a tolerance violation, even if there is no tolerance allowing residues of the pesticide in harvested tomatoes. If the certifier receives a lab report documenting a residue of a pesticide with no tomato tolerance on a tomato ready for harvest, or already harvested, that is a reportable tolerance violation.

   Follow-up investigations of *all* positive samples for prohibited substances need to be prioritized and carried out promptly. We believe that the labs should provide the results instantly and

simultaneously to certifiers, the NOP, FDA, and—when appropriate, the pesticide control officials of the state or country of origin and the state organic program.

We hope that Org Tracker will also routinely receive residue results in a format that can be uploaded into the system smoothly so that we can assist the certifiers with follow-up investigations and analyses to validate and improve their risk models and judgements regarding testing and investigatory priorities. The simultaneous broadcast reporting of all results—both negative and positive—will facilitate that.

2. *Are additional sections within this instruction needing updating or improvement? Please provide suggestions*.

We call upon the NOSB, the NOP, and certifiers to establish a platform and analytical capability that provides easy public access to the data in real time, as well as analytical results useful in placing into perspective the findings for several audiences interested in such results for different reasons.

Such a system will advance knowledge and science and deter fraud, bolster consumer confidence, and make organic food even safer than it already is. We also ask that the NOSB recommend ways to seek compensation for producers who are damaged by pesticide residues caused by circumstances beyond their control—particularly drift or deliberate sabotage by a neighbor or a disgruntled contractor/employee—but also by legacy persistent pesticides.

The Guidance document should explain how certifiers, inspectors, operators, and other interested parties are supposed to address residue results obtained from other sources. Most importantly, it is not clear how results from FDA's Pesticide Residue Monitoring Program interfaces with the NOP. According to a chemist at the FDA's Center for Food Safety and Applied Nutrition (CFSAN) laboratory, the FDA does not specifically notify the USDA NOP or the accredited certifying agent identified on the label if pesticides are found in foods labeled as organic. The FDA does not enforce the USDA NOP regulation and acts only if the results contamination levels exceed the EPA tolerances—even for organic foods.

We urge the NOSB to recommend stronger inter-agency cooperation, including an agreement with FDA 1) to identify all samples of foods products labeled as organic; 2) share *all* positive pesticide residue results with both the USDA NOP and the certifiers in an expedient way, 3) assist with the investigation of the source of contamination; and 4) consider food labeled as organic and have prohibited pesticides that were deliberately applied to be adulterated under the Food, Drug, and Cosmetic Act.

The Guidance should also contain instructions for how to deal with laboratory results from state programs such as the California Department of Pesticide Regulations, private testing programs, and even results submitted anonymously, by the operator's customers, or by competitors with the operator in question. These are all real-world scenarios that certifiers have faced. Certifiers need guidance about how to respond to analytical results of pesticide residue testing across a diversity of sources. It is reasonable to have different procedures

depending on the circumstances, but we believe all results deserve at least some follow-up action by the certifiers.

Post-harvest handling amplifies risks in many ways, particularly for handling facilities that receive, re-pack, or consolidate organic and non-organic foods. It is our experience and observation that commingling and cross-contamination in such facilities is a common source of pesticide contamination of organic food that is not the fault of the producers.

Co-formulants (Inert Ingredients)

We are pleased to see that the NOSB has made progress on co-formulants— also called "inert ingredients"—in pesticide products. We offer the NOSB our considerable experience and expertise on the review and evaluation of pesticides used in organic production.

The NOSB asks the following questions regarding inerts. Below are our responses.

1. *Please provide feedback on the format and analysis of Appendix A. The Board will use this to comprehend the practical impact the various options will have on the number of substances that would need to be added to the National List based on the corresponding option (e.g. if all inerts are listed individually or that would be allowed under various subsets of EPA regulations depending on the option)?*

   The format is difficult to navigate. The list contains many non-synthetic substances that do not need to be on the National List. As such, it appears that the NOSB is asking whether any non-synthetic substances that appear in Appendix A should be prohibited by being added to 205.602. That is a separate consideration. We recommend removing those substances that have commercially available non-synthetic sources.

   We are among many who explained in comments to the proposed rule why the research community, farmers, farmworkers, occupational health specialists, and the public need to have easy access to information on the coformulants in end-use pesticide products that are allowed for use on any farm or ranch, and certainty also organic farms/ranches. The disclosure of information on the purpose served by the addition of a given coformulant is essential because such information can be highly relevant in assessing how the presence of a single or mix of coformulants in a formulated pesticide might impact environmental fate, exposure levels and pathways, and risk outcomes.

   The litigation on glyphosate-based herbicides and non-Hodgkin lymphoma, chlorpyrifos and developmental neurotoxicity, and paraquat and Parkinson's disease has uncovered previously unknown information about the profound impacts of coformulants and formulation chemistry on pesticide product environmental fate, ADME (Absorption, Distribution, Metabolism, Excretion), and risk outcomes.

   Without full and accurate information on both the identify and concentrations of coformulants in end-use products, it is also more difficult to evaluate whether there are

non-synthetic substitutes or alternative practices to attain the same or comparable pest management goal.

2. *What areas of expertise should the [Materials Subcommittee] consider when inviting speakers to subcommittee meetings in order to obtain the fullest and most accurate understanding of this topic?*

   Invited experts should know how formulations are currently evaluated for compliance with the organic standards. They should understand the legal, scientific, and socio-economic basis for the current NOP policy. The people who developed the current regulation have important institutional memory that needs to be preserved to minimize disruption and build broad acceptance of forthcoming recommendations.

   The NOSB is required by OFPA to work with EPA on this subject, so expertise from that agency is essential to move forward. Experts need to be familiar with a wide range of pesticide formulations used in organic production—allowed synthetics such as copper and sulfur products, as well as biopesticides and botanicals. Formulators and registrants need to be willing and able to publicly disclose to the NOSB what specific ingredients are needed in the respective pesticide formulations and why they are necessary. Experts need to understand the historical context responsible for the current standards and policies governing the lack of disclosure of inert ingredients, and information needed to meet OFPA criteria and requirements.

3. *Please provide feedback on whether the list of inert ingredients currently in use (see Appendix A), is accurate*.

   Because pesticide formulations are confidential, it is not possible to publicly comment on whether the list is accurate. Almost certainly, it is not.

   Answering the question will require full public disclosure from pesticide registrants for pesticides seeking to be on the national list. In the public comments submitted to the USDA as part of the inerts Advanced Notice of Proposed Rulemaking in 2022, the Heartland Health Research Alliance made the case for full disclosure as a cost of gaining access to the organic market.

   We also remind the NOSB of our public comments in the October 2023 meeting. Appendix A also does not necessarily include co-formulants in pesticide products that are made and used entirely outside the US. Full disclosure of all ingredients identified by internationally recognized codes such as CAS numbers resolves the question of whether pesticides used by organic farmers in third countries comply with the standard, overcoming differences in regulatory regimes and language.

4. *Does the potential reduction in the number of substances the Board must review outweigh the inflexibility associated with the option to develop a single, external list of allowed inert ingredients?*

   The "single, external list of allowed inert ingredients" under consideration is not identified in the discussion document. We ask the NOSB to specify the list to which they are referring before we offer any further comment in response to this question. Without that public disclosure, the question poses a false dichotomy predicated on a hypothetical situation that may or may not happen.

   We respectfully ask the NOSB to reframe the question in a way that 1) specifies the entity responsible for creating and maintaining the list, and the decision-criteria to be adhered to; 2) the procedure by which that organization evaluates and maintains the list of inert ingredients in a way consistent with the letter and spirit of the OFPA; and 3) how that entity is held accountable to the NOP and organic community.

5. *Would designation of a specific entity responsible for maintaining the single external list of allowed inert ingredients change stakeholder's opinions of this option?*

   That would depend on which organization maintained the external list, how that organization was governed and held accountable for its decisions, and whether the decisions made are transparent and consistent with the requirements of OFPA and the principles of organic agriculture.

   It is our opinion that such an entity would need to operate with complete transparency about what ingredients are used as co-formulants, the criteria by which they determine why the ingredients are necessary, how they are evaluated to meet the OFPA criteria, and the specific applications or functionality for which they are used.

   As the discussion document notes, the NOSB is ambiguous in identifying what it means. We ask the NOSB to consider our previous comments on this subject. Full disclosure of all ingredients used in pesticide formulations allowed for organic production is a core and fundamental need to resolve this long-standing issue. Full stop. Without full disclosure it is impossible for the NOSB and the public to appraise the suitability of any end-use product in the context of pest management on organic farms.

   Pesticide registrants and the vendors of their co-formulants need to cooperate and participate with the NOSB, the USDA, and the EPA to resolve these complicated issues. As noted in our previous comments, granting the EPA such authority may require a statutory change to the OFPA, federal pesticide regulations, or both.

   It is worth noting, as well, that efforts are underway worldwide to change the long-standing policy that has allowed pesticide manufacturers to keep scientists, farmers, the food industry, and the public in the dark for decades. The significant degree to which

coformulants can alter pesticide environmental fate, ADME, and toxicity is the pesticide industry's most consequential, dark, and hidden secret.

To give an example, chlorpyrifos has been one of the most heavily researched and debated pesticides on account of strong evidence of adverse neurodevelopmental impacts in children. However, it was only recently learned through litigation, discovery, and expert witness work that coformulants in chlorpyrifos-based insecticides significantly contribute to the health risks of chlorpyrifos products—in some cases more than the active ingredient.

It is virtually certain that since passage of OFPA, the coformulants in some of the pesticides on the national list have posed greater risks than the active ingredients in the products. There is only one way to address lingering concerns about whether and how coformulants placing organic farmers, applicators, farm workers, and consumers at risk – full disclosure of coformulants, and credible, independent testing of formulated products, not just active ingredients.

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