

June 28, 2011

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National Organic Program, USDA–AMS–NOP
Room 2646–So., Ag Stop 0268
1400 Independence Ave., SW.
Washington, DC 20250–0268

Docket: AMS-NOP-10-0102; NOP-10-10

RE: National Organic Program, Proposed Rule for Periodic Residue Testing

Dear Dr. Brines:

OTA is pleased to submit comments on the National Organic Program (NOP) proposed rule for periodic residue testing that clarifies the residue testing provision of the Organic Foods Production Act of 1990 (OFPA), and related regulations that require such testing to be conducted by NOP accredited certification agencies.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members, and its mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy (<http://www.ota.com/>).

OTA strongly supports the requirement for periodic residue testing, as set forth in OFPA. However, we do see several areas in the Proposed Rule and related documents that should be clarified in order to enhance the quality and utility of the residue testing program.

In Summary:

- OTA supports the minimum periodic testing of 5% of certified operations.
- The purpose of NOP's periodic residue testing program is compliance and enforcement. In order to add meaning to the testing program and maximize its effectiveness, required residue testing should utilize a system that selects certified entities by taking into consideration the type and risk of an operation rather than by using a purely random selection process. Certifiers should be provided with guidance that explains the general process that should be used when selecting operations while still allowing them the flexibility to conduct appropriate sampling and tests on the most appropriate or relevant crops and fields.
- The rule should clearly communicate that required testing may be conducted *pre-harvest or post-harvest* and include all applicable testing targets of an organic system such as plant tissue, soil, inputs and water.

- NOP must assure that adequate sampling of imported organic products be included by both domestic and foreign accredited certification agencies (ACAs).
- Positive test results should be reported immediately, whereas negative test results should be reported quarterly. A reporting template, preferably electronic, should be provided to certifiers so that data are submitted to NOP in a uniform manner.
- In addition to pesticide residues, testing for residues of other prohibited materials and excluded methods such heavy metals, synthetic nitrogen, antibiotics and genetically modified organisms should be encouraged and included in the five percent minimum. OTA requests that NOP make this clear to ACAs.

Number of Samples: OTA supports the minimum periodic testing of 5% of certified operations. We support residue testing as a tool to monitor compliance and support testing programs in general under NOP as a means of enforcement¹. Required residue testing conducted according to § 205.670(c) will be used to monitor the presence of prohibited residue or contaminants such as pesticides, herbicides, antibiotics, nitrates, sulfites, and genetically modified organisms, and accordingly will result in appropriate corrective actions to prevent further occurrence.

In the course of discussions with OTA members regarding the proposed rule, some members voiced concern that the proposed rule may inadvertently reduce or limit the amount of investigative testing conducted by certifiers due to budget constraints and their ability to continue investigative tests in addition to meeting the required 5% periodic testing level. In general, trade members strongly support required periodic testing *in addition* to investigative testing. However, the possibility that certifiers would shy away from or have less incentive to perform investigative testing is of great concern.

For example, glyphosate testing is a good example of a highly specific and relatively expensive investigative test that is usually performed in response to a complaint. Glyphosate is a main herbicide of choice for GMO crops, and it's widely used for weed control. However, glyphosate is not on the NOP Target Pesticide List and therefore may not be included in a periodic testing program. OTA supports a rule that will encourage investigative testing and continued surveillance for the fraudulent use of glyphosate. Thus, we bring this concern to the attention of NOP and request that the situation be carefully monitored and addressed as needed.

Operator Selection: In several places, the supplementary information in the proposed rule refers to testing being conducted on a “regular and random” basis whereas the actual proposed regulatory language refers to “periodic testing” conducted on an “annual basis.” A random selection process would result in inconsistent testing programs among certifiers and ultimately result in a costly requirement that would not be meaningful. Random is generally defined as “having no specific pattern, purpose, or objective,”² whereas the purpose of testing under NOP is to assist in enforcement of the regulations. The organic sector has an opportunity to carry out required residue testing in such a way that will help assure the organic integrity of the organic label and discourage fraudulent activity. However, this will only happen if testing is conducted with purpose (i.e., risk-based) and consistently among all certifiers according to selection process guidelines that are established by NOP.

¹ OFPA SEC. 2112 [7 U.S.C. 6511] (a) – The Secretary, the applicable governing State official, and the certifying agent shall utilize a system of residue testing to test products sold or labeled as organically produced under this title to assist in the enforcement of this title.

² The American Heritage Dictionary of the English Language, Fourth Edition, © 2000

In order to support the development of a required and focused testing program that would be used for compliance and enforcement purposes, the term “random” should be removed from the supplementary information section to be consistent with the actual language included in the proposed rule. **See Appendix 1 for suggested revisions.**

Certifiers should be given guidance regarding the general process that should be used when selecting operations. The guidance should be published as the 5th instruction document³ related to residue testing as part of the NOP Program Handbook. It’s important that the guidance provide general guidelines that will ensure a consistent selection process among certifiers while still allowing them the flexibility to conduct appropriate sampling and tests on the most appropriate or relevant crops and fields. The process must assure that the same entities are not selected every year and that, over time, most entities are tested. The likelihood of finding a positive residue must be used to determine which crops and which fields to sample on a given certified entity. Additionally, NOP must assure that adequate sampling of imported organic products be conducted by both domestic and foreign ACAs.

OTA suggests that the data collected for the AMS Pesticide Data Program (PDP) be utilized by NOP to help identify the organic crops most likely to have positive detections, and that this information be used to inform guidance on the selection of crops to be tested so that certifiers can target these risks when determining sampling methodology for each entity that will be subjected to pesticide residue testing.

Sample Selection: OTA is concerned that the proposed regulation may be read as a requirement to test finished product only. Unlike § 205.670(b)⁴ that refers to “*preharvest* or post harvest testing of any agricultural input used or agricultural product sold as...”, § 205.670(c) states that “certifiers must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” While we believe that testing of “agricultural products” labeled as “organic,” for example, would allow for the testing of any and all aspects related to the production and handling of that organic product within the organic system, we have heard concerns otherwise from our members.

To be clear, we request NOP to clarify that required testing may be conducted pre-harvest or post-harvest, and may include all applicable testing targets of an organic system such as plant tissue, soil, leaf and petiole, water and production inputs. OTA suggests that the language in § 205.670(c) be revised so that the scope of the testing subject is consistent with § 205.670(b). We suggest the following revision:

A certifying agent must conduct periodic **pre-harvest or post-harvest** residue testing of **any agricultural input used or** agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

³ Reference to a 5th Instruction Document acknowledges the 4th and recent NOP Draft Guidance (NOP 5028) “Responding to Results from Pesticide Residue Testing”.

⁴ § 205.670 Inspection and testing of agricultural products to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

The NOP instruction document on Sampling Procedures for Residue Testing (NOP 2610) should also be revised to clearly accommodate pre- and post-harvest sampling and include risk-assessment criteria (the likelihood of finding a positive residue) that can be used to determine which crops and which fields to sample on a given certified entity. It would also be very helpful if the document were expanded to include procedures and sample amounts that should be used for sampling other types of prohibited residues such as genetically modified organisms, nitrogen isotopes, and antibiotics.

To read OTA's additional comments on NOP Instruction for Sampling Procedures for Residue Testing (NOP2610), see Appendix 1 (also submitted separately to the NOP Standards Division as per instructions under "Related Documents," Pg. 23916 of the *Federal Register*, Vol. 76, April 29, 2011).

Testing Methodology & Analytes for Pesticide Residue Testing: The proposed rule requires that residue testing must be performed in an accredited laboratory and describes allowed chemical analysis methodology for determining the presence of contaminants in agricultural products. Specific instructions on laboratory selection criteria for pesticide residue testing and a published list of suggested target pesticides that certifying agents should test for are published as part of the NOP Handbook.

While OTA recognizes that specific testing procedures are not included in proposed rule, we would like to take this opportunity and encourage NOP to explore the practicality and cost of having the NOP pesticide residue-testing program adhere to the established Pesticide Data Program (PDP)-required laboratory testing protocols. This would require certifiers to use the same labs and the same testing protocols used by the PDP. If practical, this would greatly enhance the collective database allowing for easier comparison of results from PDP testing and NOP testing. We also encourage NOP to negotiate master contracts with laboratories to reduce the testing costs for certifiers by way of volume discount. If possible, working with AMS to include the NOP residue-testing program in the master contracts with laboratories used by the PDP would be ideal.

For additional OTA comments on NOP Instruction on Laboratory Selection Criteria for Pesticide Residue Testing (NOP 2611) and the NOP Target Pesticide List (NOP 2611-1), see Appendix 2 (also submitted separately to the NOP Standards Division as per instructions under "Related Documents," Pg. 23916 of the *Federal Register*, Vol. 76, April 29, 2011).

Reporting Requirements: The proposed regulation requires that the results of all analyses and tests performed according to the proposed requirements be "**promptly**" provided to the Administrator. OTA suggests that this requirement be stated more explicitly and distinguish between positive test results and negative test results. Positive test results should be reported immediately in the course of adverse action. Negative results should be reported on a quarterly basis in order to assist in a consistent and orderly submission and data compiling system.

In order to better analyze and utilize the test results, a standard reporting template should be created by NOP and used by certifiers in order to uniformly submit test results to NOP or State Organic Program (SOP). This would preferably be an electronic template or reporting system. The standard reporting template should provide a place for certifiers to include a description of the material tested (finished product intended for sale, plant tissue, soil, water, etc.) and whether the test performed was for investigation, complaint-based, monitoring, or as required under § 205.670(c).

Finally, OTA would like to reiterate the purpose of the testing with respect to reporting and analyzing the results. The purpose of testing under NOP is to ensure that certified operators are in compliance with the regulations. The purpose is not to survey pesticide use in organic. Provided that tests will be conducted on crops or fields that are inherently at higher risk, OTA is sensitive to the ultimate use of the data reported because it will largely represent higher-risk operations rather than a random sampling overview or general level of occurrence as reported by the AMS Pesticide Data Program. OTA requests that the utility of the information collected be kept within the context of the NOP testing program, and its compliance and enforcement purpose clearly stated.

Conclusion

OTA applauds the issuance of the proposed rule and believes the implementation of required residue testing will strengthen the organic standards and boost consumer confidence. We strongly believe that non-random, risk-based targeting of sampling sites during pre- or post-harvest will bolster the organic sector's ability to prevent contaminated products from entering the marketplace, deter the use of or contact with prohibited substances, and maximize the cost-effectiveness of a residue testing program.

Consistent with OFPA, we are pleased to see the proposed rule require “**residue testing**” under § 205.670 “Inspection and testing of agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” In addition to ensuring that certified production and handling operations are in compliance with the requirements set forth in the regulations, required testing of *any type of prohibited residue* will add to the certifiers’ means for monitoring drift and unavoidable residue contamination of certified products. This comes at a critical time for the organic sector because of the proliferation of genetically modified (GM) organisms in the environment due to unrestricted deregulation of genetically modified crops such as Round-up Ready Alfalfa.

The continued health and growth of the organic industry require that our supply chain not be compromised. Contamination by GM crops threatens the organic sector's ability to meet consumer demand. Therefore, we encourage NOP to explore the explicit incorporation of required periodic residue testing for GM contamination into the NOP residue testing program along with supporting guidance documents in order to monitor its presence, and ensure that certified operators are meeting the standards by adequately implementing contamination prevention measures. OTA welcomes this conversation, and we provide our support.

Provided that specific contaminants or residues are not called out in the proposed rule, it's our understanding that the required 5% minimum for periodic residue testing includes the testing of *any prohibited material* collected from a certified operation. In other words, testing for antibiotics in milk, sulfites in certified wine (total concentrations over 100 ppm), genetically modified organisms in organic corn, and nitrogen isotopes in fertilizer will all count towards the required five percent minimum of testing. OTA respectfully asks NOP to clarify this point in the preamble to the final rule.

Again, on behalf of our members across the supply chain and the country, OTA thanks NOP for the opportunity to comment and for carefully considering our comments.

Respectfully submitted,



Gwendolyn Wyard
Associate Director of Organic Standards and Industry Outreach
Organic Trade Association

cc: Laura Batcha
Executive Vice President
Organic Trade Association

Appendix 1 – Suggested Revisions to the “Supplemental Information” to the Proposed Rule

Pg. 23915, 1st column, 3rd paragraph

In response, the AMS conducted a legal review of the issue. The AMS has concluded that under 7 U.S.C. 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular ~~and random~~ basis, as well as when there is reason to believe contamination has occurred.

Pg. 23915, 1st column, last paragraph

This action will clarify the amount and frequency of testing and will ensure consistency across all certifying agents in their inspection and testing of agricultural products certified to the NOP regulations. The proposed rule specifies that certifying agents would be required, on an annual basis, to ~~randomly~~-sample and test agricultural products from a minimum of five percent of the operations they certify.

Pg. 23915, 2nd column, 2nd paragraph

While the proposed action would expand the amount of testing of organically produced agricultural products to include a ~~requirement~~ **required testing conducted on an annual basis** ~~that is regular and random in scope~~, certifying agents are already required.....

Pg. 23915, 3rd column, 1st paragraph

Testing of products when there is reason to believe a violation has occurred, e.g., complaint-driven testing, would not be considered to be ~~random~~, **regular or** periodic testing, and must continue to be conducted in addition to the proposed five percent requirement for periodic residue testing

Appendix 2 - Sampling Procedures for Residue Testing (NOP 2610)

OTA reached out to membership and requested feedback on the NOP Instructions for Sampling Procedures for Residue Testing. We have compiled suggestions that should be useful and considered when the instructions are revised:

- Risk-assessment (the likelihood of finding a positive residue) must be used to determine which crops and which fields to sample on a given certified entity. Prioritizing crops with a history of residues is a good common sense approach.

- Instructions for risk-based sample collection could be incorporated into the sampling procedures (indicate zones, scenarios, commodities, etc.) that represent greater risk.
- Sampling should not be specific to the harvested fruit or vegetable as indicated in the instructions because many crops are washed and therefore testing will not accurately represent the use or occurrence of prohibited materials. The instructions should apply to residue testing conducted during pre-harvest as well as post-harvest, and include examples for plant tissue, soil, leaf and petiole, and water.
- The sampling density for the crops selected by the certifier for testing by a given entity must reflect the scale, crop diversity, and geographic diversity (multiple farm locations) of the entity's operations.
- Field sampling pattern is important and should not be limited to leaves or fruits from one area in the field. "V" shaped sampling patterns have been shown to be as effective as "S" or "Z" (www.cdpr.ca.gov/docs/whs/memo/hsm01002.pdf).
- The instructions lack a section on the "Sample Information Worksheet" for the sampler to identify the test and processing time that need to be run for the samples (eg., NOP Target Pesticide List, FDA PAM vol 1, USDA PDP residue test, etc.).
- Instructions need to address sampling of multi-ingredient products.
- A unified data form to be used by all entities could be used that feeds into a master data base NOP can use to monitor the following: 1) certified entities being tested; and 2) the ACA or SOP conducting the testing and the geographical conditions. This will enhance NOP's ability to determine at risk conditions that will help further develop who should be tested according to a risk-based system.
- Under Section 4.2 on Page 2 of 6: *Sample collectors should collect a sample of a given organic agricultural product, selected from a single location in a field, bin, or pallet. We are concerned that this may not be appropriate for general monitoring. It makes sense if there is high risk or if contamination is suspected at that single location. But if one is performing general monitoring, in order to obtain a representative sample, a common protocol is to collect multiple samples from around the field (or from multiple bins or pallets in a given lot) and combine them into a single sample (composite). If a target analyte is detected in the composite sample, then one can collect additional samples to be analyzed individually to determine the extent of the contamination.*

Appendix 3 - Testing Methodology & Analytes for Pesticide Residue Testing

OTA reached out to membership and requested feedback on the NOP Instructions for Laboratory Selection Criteria for Pesticide Residue Testing (NOP 2611) and the NOP Target Pesticide List (NOP 2611-1). We have compiled suggestions that should be useful:

- **Testing Methodology - NOP Instructions for Laboratory Selection Criteria for Pesticide Residue Testing (NOP 2611)**

- OTA encourages NOP to explore the practicality/cost of having the NOP pesticide residue-testing program adhere to the established PDP-required laboratory testing protocols. This would require certifiers to use the same labs and the same testing protocols used by the PDP. If practical, this would greatly enhance the collective database allowing for easier comparison of results from PDP testing and NOP testing.
 - The NOP should negotiate master contracts with laboratories to reduce the testing costs for certifiers (volume discount). If possible, working with AMS to include the NOP residue-testing program in the master contracts with laboratories used by the PDP would be ideal.
- **Analytes for Pesticide Residue Testing - NOP Target Pesticide List (NOP 2611-1)**
 - OTA requests clarification: Would a lab be required to test for the complete target list, or could the lab test for select ones? The answer would address some of the concerns about lab cost. For example, as reported by the ACAs, one laboratory indicated that it was developing a profile to test the complete range of the NOP Targeted List, but the cost would likely be \$1,000.
 - It will be difficult to find labs that can analyze all 188 compounds on this list. There is currently no one test method that can accommodate all of these analytes as varying instruments will have different matrix effects, making results for certain analytes more reliable on one instrument than on another. Furthermore, many labs will not analyze for some of these analytes because it will not be economical for them to maintain standard solutions and instrument calibrations for those analytes if they are not receiving sufficient volume of samples.
 - The instructions to use an ISO 17025 accredited laboratory is problematic in that there are very few laboratories that have this accreditation, and fewer still that have a testing profile in place to address the NOP Target Pesticide List. According to ACAs, five laboratories have been identified that either are ISO 17025 accredited for chemical analysis or are in the process of obtaining ISO 17025 accreditation. Only one of these laboratories is able to test for the complete range of pesticides on the NOP Target List.
 - OTA notes that the Target Analyte List (NOP 2611-1) was created by examination of **all** pesticides/metabolites/environmental contaminants that have been detected in samples analyzed for the USDA Pesticide Data Program. OTA suggests that the list at least indicate which ones are the most commonly detected analytes.

