Draft Guidance
Responding to Results from Pesticide Residue Testing

1. Purpose

This document provides guidance for certifying agents who conduct pesticide residue testing about how to interpret and respond to test results.

2. Scope

This guidance applies to certifying agents who review pesticide residue test results from organically produced agricultural products.

3. Policy

7 CFR 205.670 of the NOP regulations specifies the conditions under which responsible parties should conduct testing of agricultural products that will be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." To meet this requirement, these parties are responsible for the analysis of samples from organic agricultural products to detect the presence of residues in violation of the NOP regulations as specified under § 205.105 or other applicable laws as provided for at § 205.670(e). The NOP is issuing the following guidance to ensure consistency in the response by certifying agents to any residue detections per § 205.670 and in the provision exclusion from organic sale at § 205.671 of the NOP regulation.

3.1 No Detected Residues

- The product may be sold as organic.
- The certifying agent will notify the operator and the NOP (or State Organic Program (SOP) if applicable) of test results.
- The certifying agent will maintain records of the analysis and provide results to the public upon request.

3.2 Responding to Detected Residues

When a certifying agent receives a report from the laboratory indicating a detection of one or more pesticide residues, they must determine if the residue has a current U.S. Environmental Protection Agency (EPA) tolerance or Food and Drug Administration (FDA) Action Level (AL) established *for the tested sample*. Details concerning the determination of tolerances are given in Section 4.0. Once the certifying agent has identified whether a tolerance is established for a given residue, they should use the decision points described below in 3.2.1 through 3.2.4 to determine what reporting and adverse actions are appropriate.

3.2.1 If U.S. EPA tolerance levels are established for pesticides that are registered for use on the agricultural product and residues are:

A. Detected above tolerance, then:

- The certifying agent will *immediately* notify the NOP, FDA, state food safety programs or foreign health agency (if outside of the U.S.).
- The product may not be sold as organic.
- The certifying agent will issue notice of noncompliance.
- The certifying agent will investigate why residues are present; if intentional or direct application of prohibited substances is found, it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.

B. Detected between 5% of tolerance and the tolerance level, then;

- The certifying agent will *immediately* notify the operator and the NOP (or State Organic Program (SOP) if applicable) of test results.
- The product may not be sold as organic.
- The certifying agent will issue a notice of noncompliance.
- The certifying agent will investigate why residues are present; if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.

C. Detected below 5% of U.S. EPA tolerance level but above: trace level, below quantifiable limits (BQL), or limit of detection (LOD), then:

- The certifying agent will notify the operator and the NOP (or State Organic Program (SOP) if applicable) of test results.
- The product may be sold as organic unless residues are due to intentional or direct application of prohibited pesticides.
- The certifying agent will investigate why residues are present, if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.
- If residue presence is determined to be due to inadequate buffer zones or inadequate management practices to prevent commingling or contact with prohibited substances, then a notice of noncompliance should be issued by the certifying agent to implement corrective actions to remove contaminant source.

If there is not an EPA tolerance established, then certifying agents should check for an FDA action level. The FDA action levels are established for persistent pesticides such as chlorinated hydrocarbons that are no longer registered by EPA for use in crop or animal production, but continue to be detected in crops due to the persistent nature of these chemicals in the environment.

3.2.2 If FDA action levels are established for persistent pesticides and residues are:

A. Detected above the action level, then;

- The certifying agent will *immediately* notify the NOP, FDA, state food safety programs, foreign health agency (if outside of U.S.).
- The product may not be sold as organic.
- The certifying agent will issue notice of noncompliance.
- The certifying agent will investigate why residues are present; if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.
- If residue presence is determined to be due to inadequate management practices to prevent commingling or contact with prohibited substances, then a notice of noncompliance should be issued to implement corrective actions to remove contaminant source.

B. Detected below action level but above 0.01 ppm (0.01 mg/kg), then;

- The product may be sold as organic.
- The certifying agent will investigate why residues are present; if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.
- If residue presence is determined to be due to inadequate management practices to prevent commingling or contact with prohibited substances, then a notice of noncompliance should be issued to implement corrective actions to remove contaminant source.

C. Detected below action level and at or below 0.01 ppm (0.01 mg/kg), then:

- The product may be sold as organic.
- The certifying agent will investigate why residues are present; if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.
- If residue presence is determined to be due to inadequate management practices to prevent commingling or contact with prohibited substances, then a notice of noncompliance should be issued to implement corrective actions to remove contaminant source.

3.2.3 If no EPA tolerance level or FDA action level is established and residues are:

A. Detected above 0.01 ppm, then:

- The certifying agent will immediately notify the NOP, FDA, state food safety programs, foreign health agency (if outside of U.S.).

- The certifying agent will issue notice of noncompliance.
- The certifying agent will investigate why residues are present, if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.
- If residue presence is determined to be due to inadequate buffer zones or inadequate management practices to prevent commingling or contact with prohibited substances, then a notice of noncompliance should be issued to implement corrective actions to remove contaminant source.

3.2.4 If multiple residues are detected:

A. Detection of multiple residues at any level (which would be evidence of conventionally produced product) then:
   - The certifying agent will immediately notify the NOP, FDA, state food safety programs, foreign health agency (if outside of U.S.).
   - The certifying agent will issue notice of noncompliance.
   - The certifying agent will investigate why residues are present, if intentional or direct application of prohibited substances is found it may lead to suspension or revocation of certification. The certifying agent will coordinate adverse actions with the NOP.
   - If residue presence is determined to be due to inadequate buffer zones or inadequate management practices to prevent commingling or contact with prohibited substances, then a notice of noncompliance should be issued to implement corrective actions to remove contaminant source.

4.0 Additional Information on U.S. EPA Tolerances:

A. How Tolerances are Established

The U.S. EPA establishes pesticide tolerances based on field studies performed on raw agricultural and processed commodities and feedstuffs derived from crops and certain products derived from livestock (U.S. EPA Residue Chemistry Test Guidelines). This EPA guidance defines the form of raw agricultural commodity (RAC) (e.g., carrot root), or processed product (e.g., raisins) to be used for testing purposes. To determine a tolerance for sweet corn, for example, residue data would be developed from sweet corn samples with kernels and cob with the husk removed. As another example, establishing almond tolerances would require data on nutmeats and hulls whereas tolerances on other nuts require data on the nutmeat only. These values are published in the Code of Federal Regulations (40 CFR part 180) and an electronic version (eCFR) can be accessed from the Government Printing Office (GPO) website listed in the references section of this document.

B. How Certifying Agents Should Use Tolerance Values

Tolerances are established with the expectation that a sample submitted for analysis for enforcement of the U.S. EPA tolerances would consist of the RAC, specific processed product, or animal tissue or animal product. It is important to distinguish between the forms of the RAC and note that a sample of sweet corn analyzed with the husk should not be compared to an established U.S. EPA tolerance for sweet corn to make a determination of an U.S. EPA tolerance violation since the sweet corn tolerance level was established from a sample with the husk removed. In determining whether a product is above or below 5% of the U.S. EPA tolerance, certifying agents must use the results of testing from the RAC as specified in U.S. EPA guidance, an appropriate processed product, animal tissue or animal product for which a tolerance is established.

Tolerances are not specifically established for processed products (i.e. raisins, tomato paste) unless the residue is determined to concentrate in the final product. In cases of processed products, certifying agents should use the tolerance for the RAC for the processed product.

Often the U.S. EPA establishes tolerances for a pesticide and any significant metabolites such that the tolerance is a sum of the "parent" compound and the metabolites. For the majority of pesticides, the metabolites included in these tolerances will not be analyzed by laboratories and their amounts will remain unknown. However, if the metabolites are analyzed, then the amount of the parent compound should be added to the amount of the metabolite(s) to determine the total residue amount. If the metabolite is not detected, certifying agents should add the limit of quantitation (LOQ) to the parent to determine the total residue. In rare cases, metabolites will be detected, but the parent pesticide will not. In this case, certifying agents should add the value of the LOQ of the parent compound (if known) to the metabolite amount to determine total residue level.

For example, aldicarb tolerances are determined as the sum of 3 compounds commonly named aldicarb, aldicarb sulfoxide and aldicarb sulfone. The current eCFR citation is:

§ 180.269 Aldicarb; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the insecticide and nematocide aldicarb (2-methyl-2-(methylthio)propionaldehyde *O* -(methylcarbamoyl) oxime and its cholinesterase-inhibiting metabolites 2-methyl 2-(methylsulfinyl) propionaldehyde *O* -(methylcarbamoyl) oxime and 2-methyl-2-(methylsulfonyl) propionaldehyde *O* -(methylcarbamoyl) oxime.

If an analytical report is received that shows detection of metabolites, the total residue should be determined by adding the value of the detection for the parent and the metabolite(s). If one or more of the compounds are not detected the value of the LOQ (usually 0.01 ppm) would be used in this calculation of the total residues rather than "zero."

5.0 References

5.1 NOP Regulations

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

§ 205.671 Exclusion from organic sale.

5.2 Environmental Protection Agency References

Environmental Protection Agency. OCSPP Harmonized Test Guidelines Series 860 - Residue Chemistry Test Guidelines. United States Environmental Protection Agency, Aug. 1996. Web. 21 Dec. 2010. http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series860.htm

U.S. EPA tolerances: CFR Title 40: Protection of Environment Part 180. www.gpoaccess.gov/ecfr/

5.3 Food and Drug Administration References

"Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed." U.S. Food and Drug Administration Home Page. 22 Dec. 2010. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm