Certified Agent Training
Topic: Periodic Residue Testing

January 15, 2013
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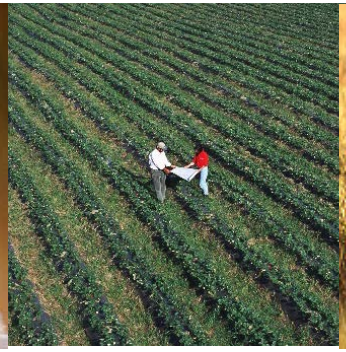
USDA Agricultural Marketing Service
National Organic Program




Today's Learning Objective:

Learn what to do if your tests show residues of a prohibited substance(s)

Final Rule for Periodic Residue Testing

Beginning January 1, 2013:

- Certifying agents must test products from at least 5 percent of the operations they certify each year.
- Program will help certifying agents identify and take enforcement action against farms and businesses using prohibited substances or methods, such as:
  - Prohibited pesticides
  - Antibiotics
  - Synthetic hormones
  - Genetic engineering

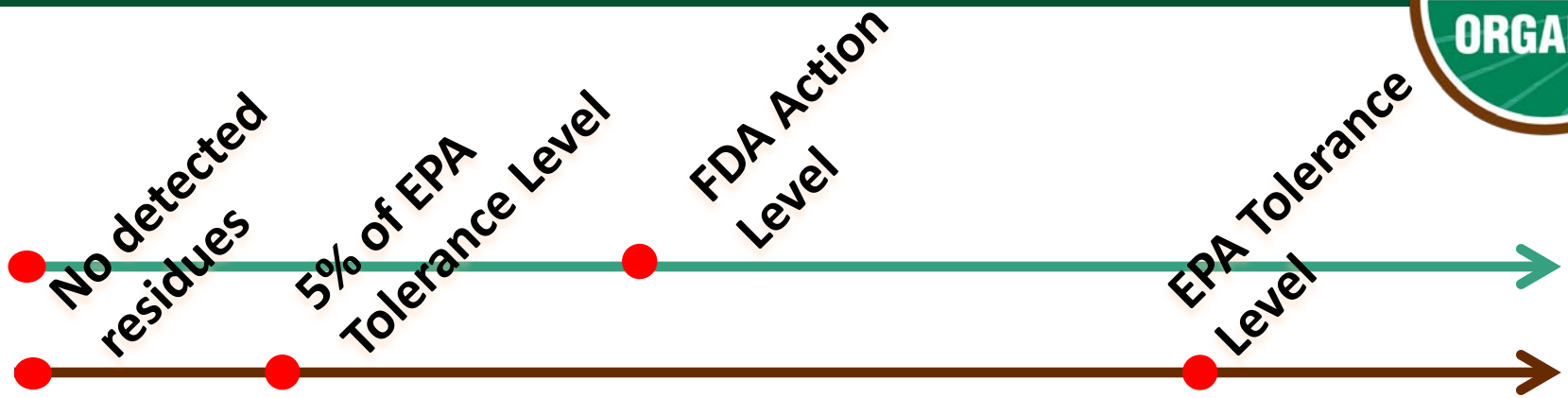
Detected Pesticide Residues on final product

Three possible references if residues are detected:

Pesticide Residue	• U.S. Environmental Protection Agency (EPA) Tolerance Level established for the tested sample
Pesticide Residue	• Food and Drug Administration (FDA) Action Level (AL) established for the tested sample
Pesticide Residue	• No tolerance or action level

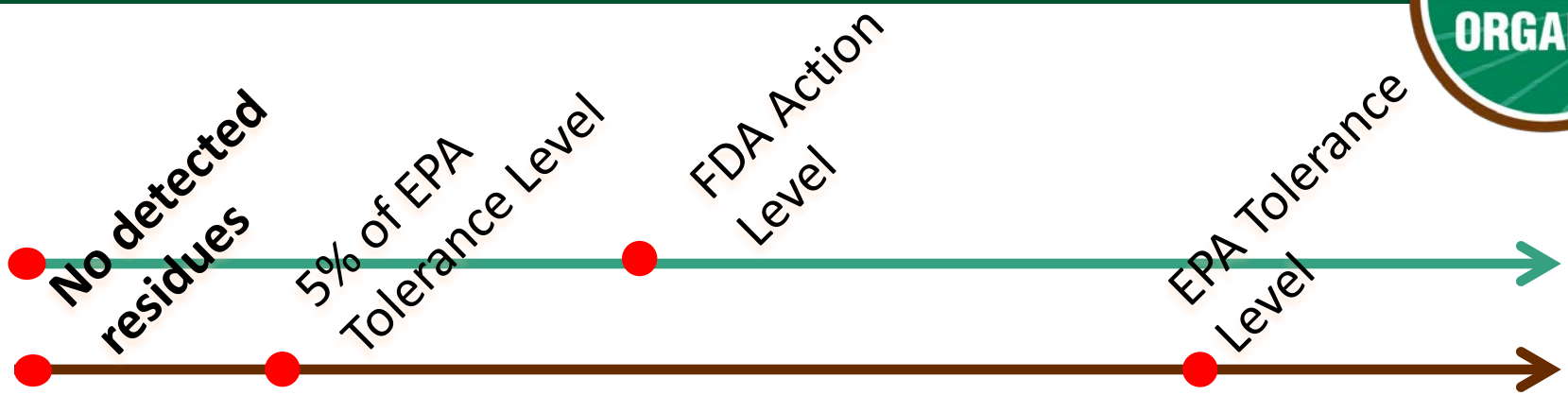
NOTE: Action levels only exist for edible crops and products. Other sample sources, such as soil or leaves, do not have established tolerance or action levels at this time.

Action levels and tolerance levels



- **EPA** establishes tolerance levels for registered pesticides allowed to be applied on specific crops
- **EPA** tolerances are applicable to specific crops; if there is no registered use for the crop, then the EPA sets no tolerance for the pesticide on that crop
- **FDA** sets action levels for older pesticides that are no longer EPA registered but are still persistent in environment

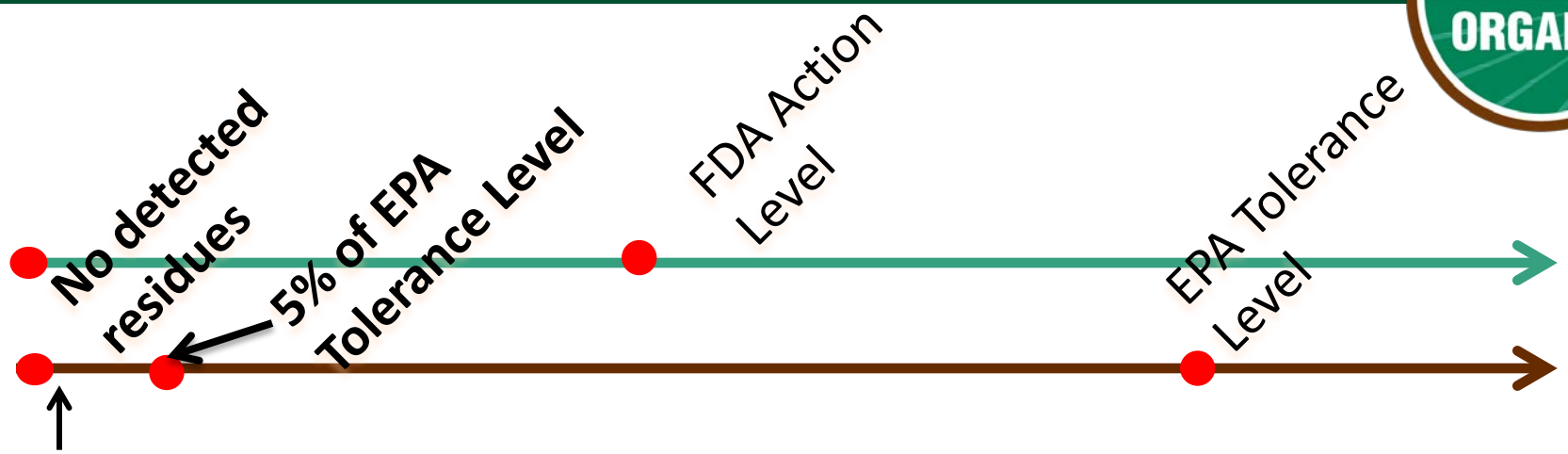
1. No Residue Detected



No residues detected:

- The product may be sold as organic.
- The certifying agent will notify operator of test results.
- The certifying agent will maintain records of analysis and provide results to the public upon request.

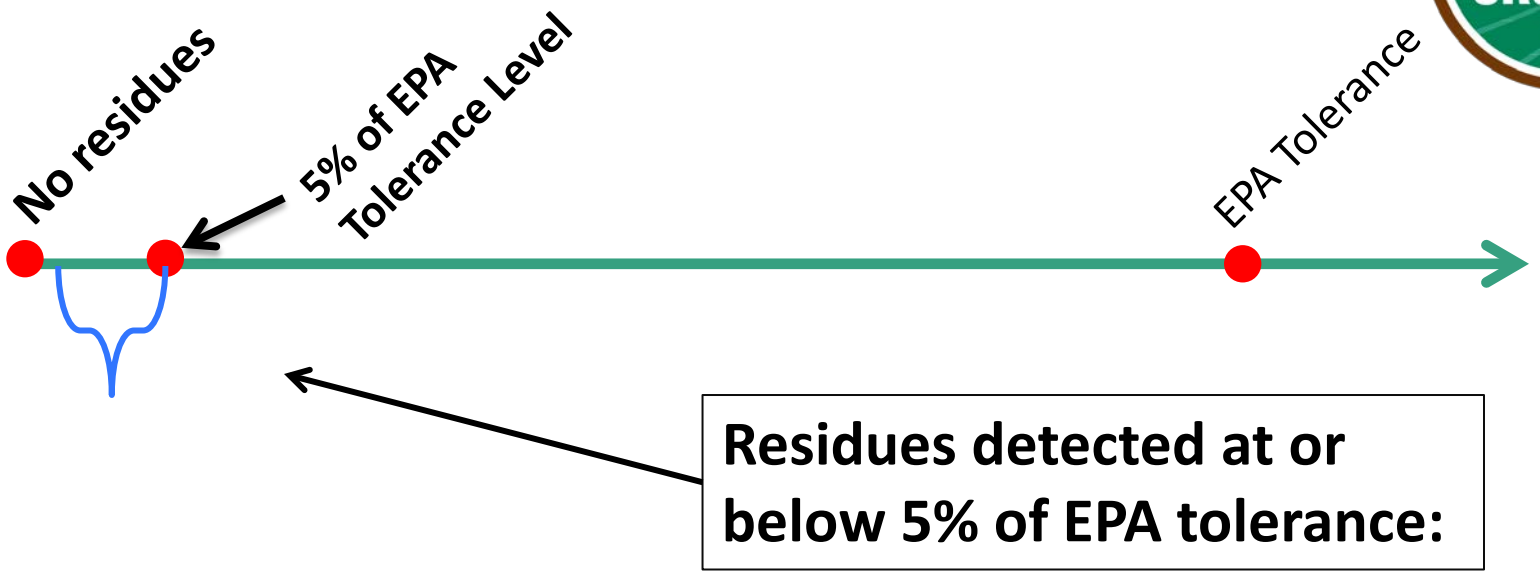
2. Residues at or less than 0.01 ppm (trace)



Residues detected at or less than 0.01 ppm (10 ppb)
BQL – Below Quantifiable Levels or LOD – Limit of Detection

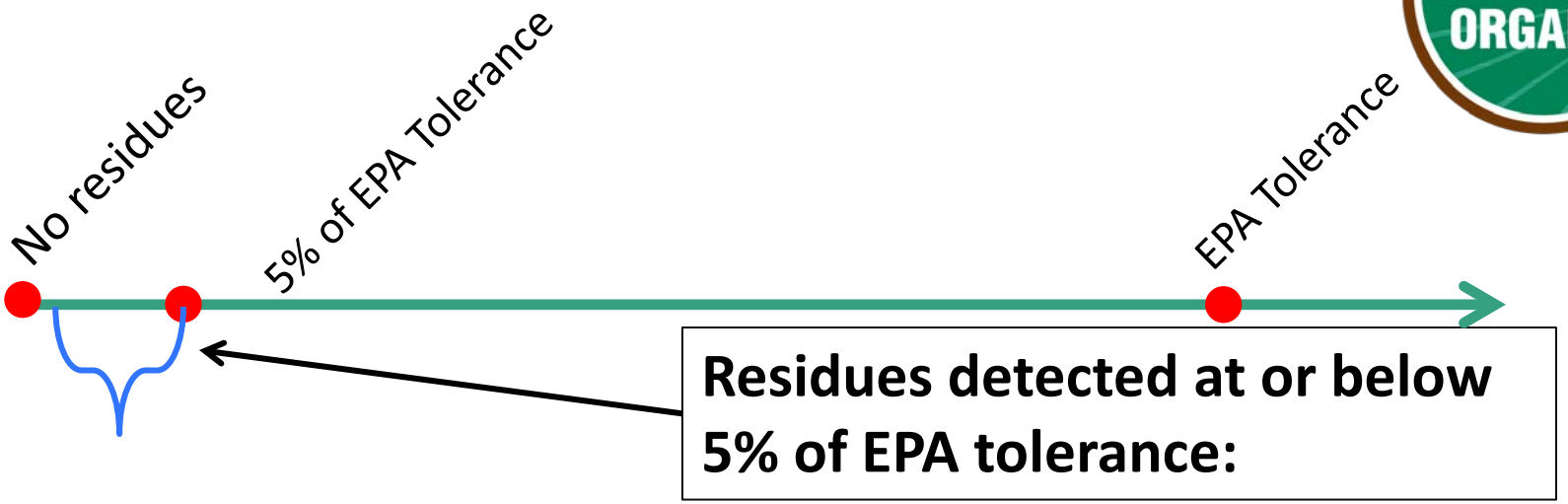
- The product may be sold as organic.
- The certifying agent will notify operator of test results
- Assess why the residue is present and follow up with operation as appropriate.
- Maintain records of analysis and provide results to the public upon request.

3. Residue samples detected at or below 5% of EPA tolerance



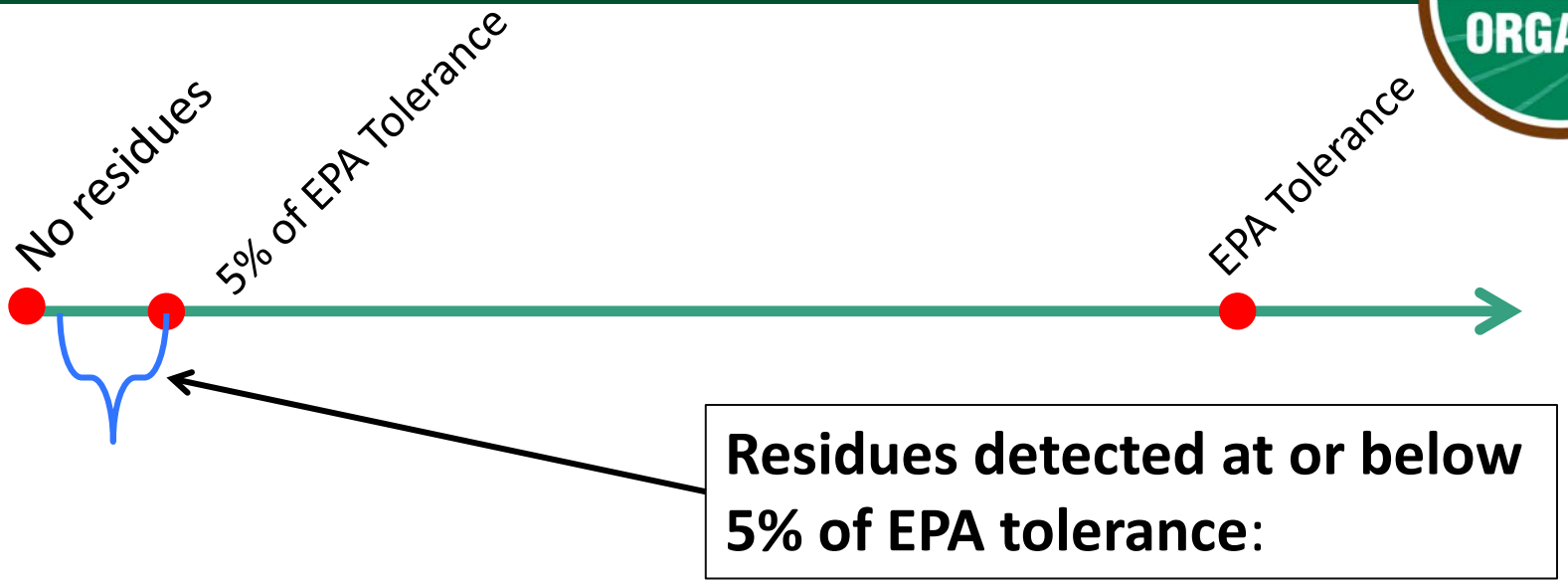
- The certifying agent will notify the operator of test results.
- The product may be sold as organic if residues are not a result of application of prohibited pesticides or commingling.

3. Residue samples detected at or below 5% of EPA tolerance continued



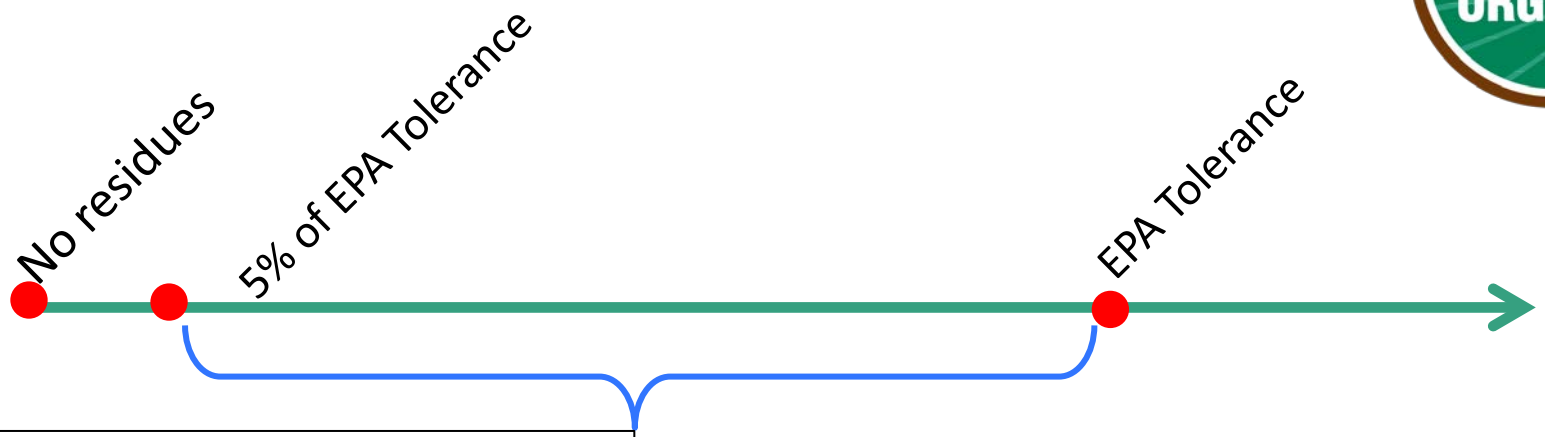
- The certifying agent will investigate why residues are present
- If residue presence is determined to be due to inadequate buffer zones or inadequate management practices to prevent commingling or contact with prohibited substances, issue an Notice of Noncompliance and require corrective actions to prevent future contamination.

3. Residue samples detected at or below 5% of EPA tolerance continued



- If **evidence of intentional** application of prohibited substances is found, the certifying agent should propose suspension or revocation of certification.
- The certifying agent may coordinate adverse actions with the NOP.

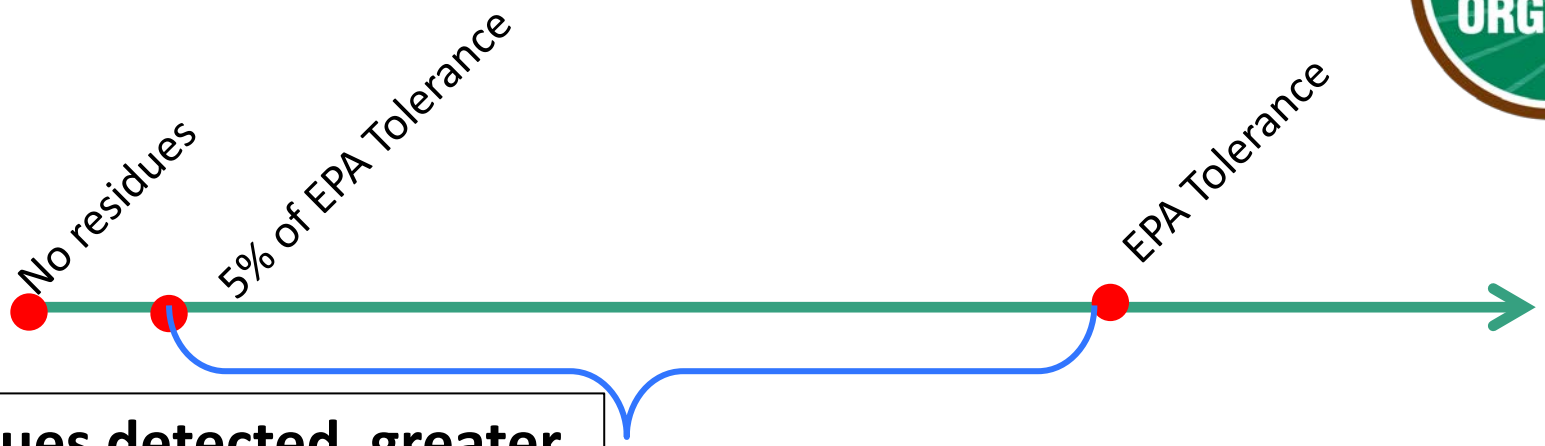
4. Residue samples detected greater than 5% of EPA tolerance, but not above the EPA tolerance level.



Residues detected greater than 5% of EPA tolerance, but not above the EPA tolerance level:

- The certifying agent will **immediately** notify the NOP or State Organic Program, if applicable, of test results.
- The product **may not** be sold as organic.

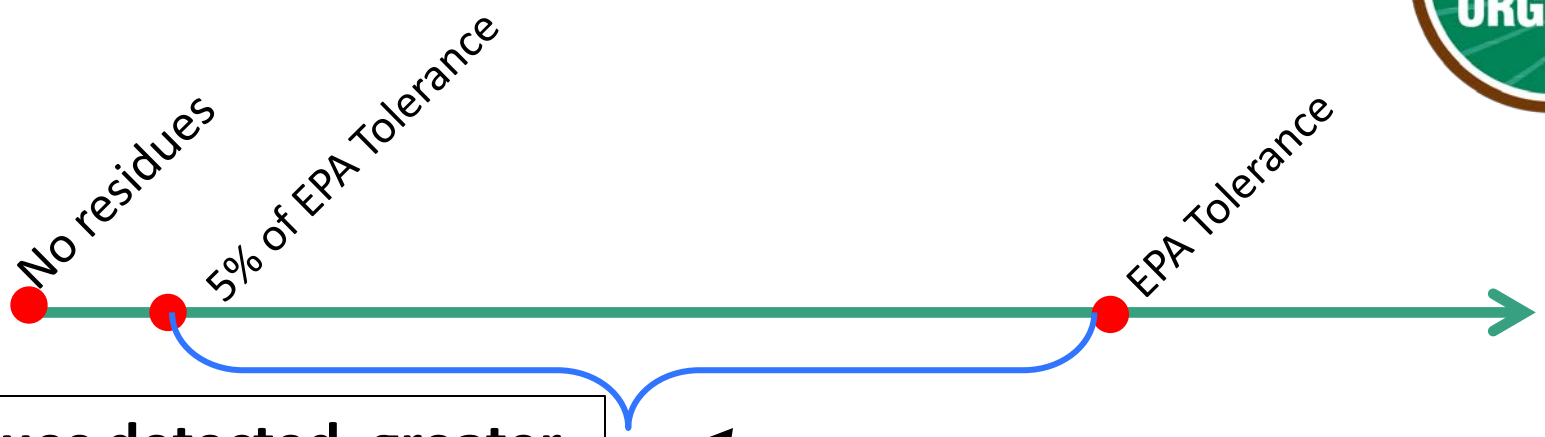
4. Residue samples detected greater than 5% of EPA tolerance, but not above the EPA tolerance level



Residues detected greater than 5% of EPA tolerance, but not above the EPA tolerance level:

- Investigate why residues are present
- Issue a Notice of Noncompliance for violation of having prohibited substances at levels greater than 5 percent of the EPA tolerance level.

4. Residue samples detected greater than 5% of EPA tolerance, but not above the EPA tolerance level



Residues detected greater than 5% of EPA tolerance, but not above the EPA tolerance level:

- If application of prohibited substances is found, the certifying agent should propose suspension or revocation of certification.
- The certifying agent **should** coordinate adverse actions with the NOP.

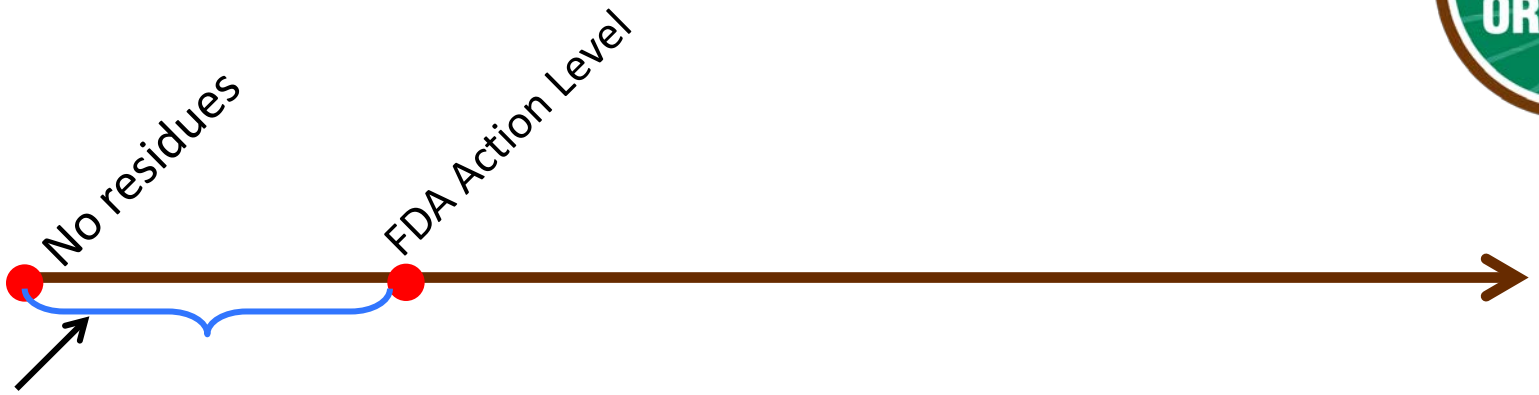
5. Residue samples detected above EPA tolerance level.

- ***Immediately*** notify the NOP, EPA, state food safety programs or foreign health agency (if outside the U.S.)
- The product **may not** be sold as organic.
- Investigate why residues are present and issue a Notice of Noncompliance for violation of having prohibited substances at levels greater than the EPA tolerance level.

5. Residue detected above EPA tolerance level continued

- The certifying agent will follow adverse action procedures.
- The certifying agent **should** coordinate adverse actions with the NOP.
- NOP may pursue civil penalties.

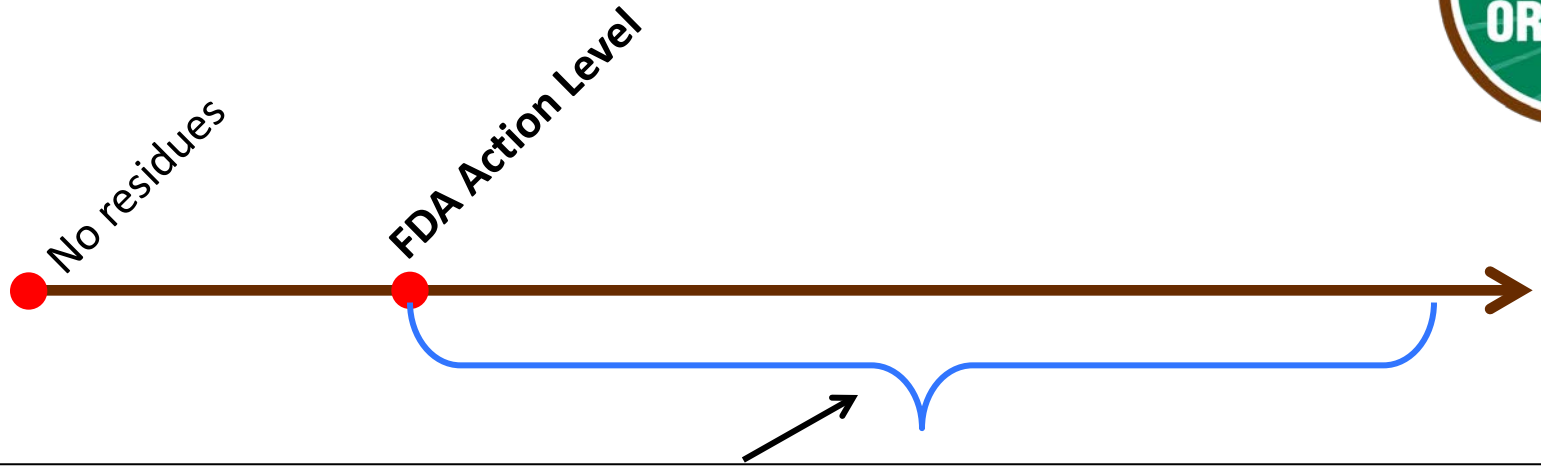
6. Residue detected below FDA Action Level



When there is no EPA tolerance level established for the tested residue sample, but the residue is below the FDA Action Level:

- The certifying agent will notify the operator of test results.
- The certifying agent will investigate why residues are present to determine if residues are a result of application of prohibited pesticide or were due to unavoidable residual environmental contamination.
- The product may be sold as organic if residues are not a result of the application of prohibited pesticides, commingling or contamination during handling.

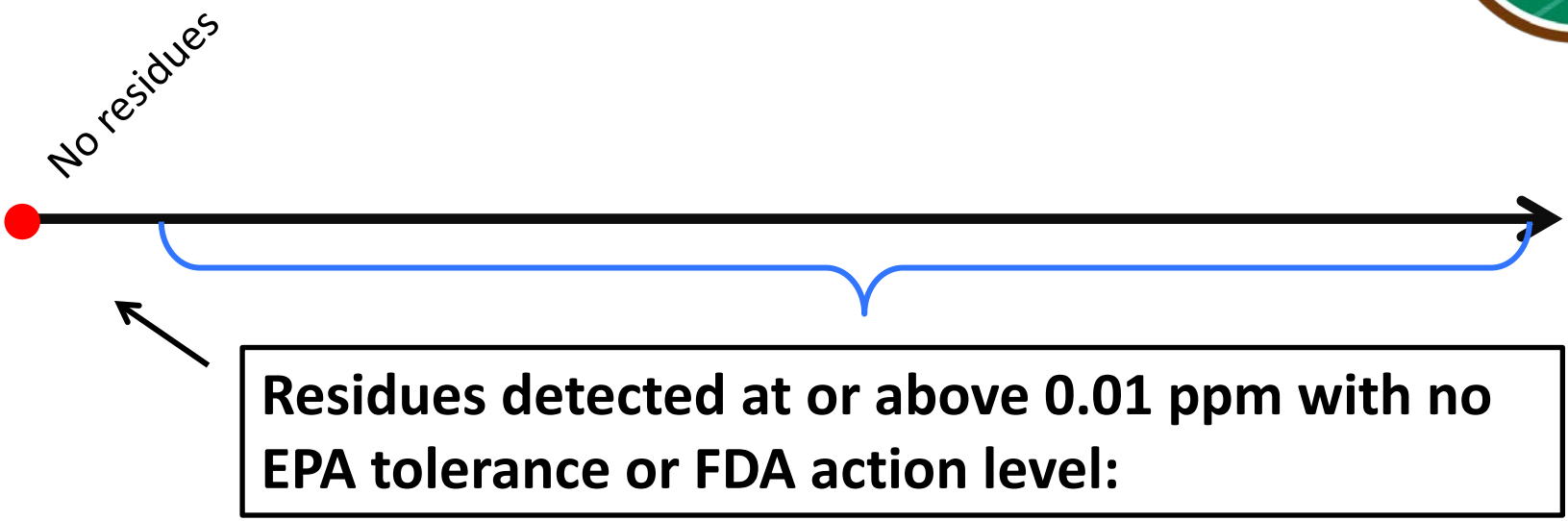
7. Residue detected at or above the FDA Action Level



When residues are detected at or above the FDA Action Level:

- ***Immediately*** notify the NOP, FDA, state food safety programs, and/or foreign health agency (if outside of U.S.).
- Investigate why residues are present.
- Product may not be sold as organic.
- Work with NOP to identify violations and take enforcement action.

8. Residue detected with no EPA tolerance or FDA Action level



- The certifying agent will immediately notify the NOP, FDA, state food safety programs, and/or foreign health agency (if outside of U.S.).
- Product may not be sold as organic.
- Investigate why residues are present and issue a Notice of Noncompliance for possible violations, if applicable.

Resources

U.S. EPA Pesticide Tolerances

- http://www.epa.gov/pesticides/regulating/tolerances.htm

European Organic Certifiers Council task force residues – Guidance document for the certification decision making process

- http://www.eocc.nu/home/pdf/survey_guidelines/AS_EOCC_Pesticide_Guidelines_version_Sept2012.pdf

EOCC task force residues

- Risk based approach and sampling
- Effective sampling determined by three parameters
  - At the right place
  - The right product
  - At the right time
- Guidance on distinguishing use from contamination or commingling

Resources

- **US EPA Index to Pesticide Chemical Names**, Part 180 Tolerance Information

  http://www.epa.gov/opp00001/regulating/tolerances-commodity.pdf

- FDA Guidance for Industry: Action Levels for Poisonous or Deleterious Substance in Human Food and Animal Feed

  http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm

Examples

- **0.05 ppm chlordane on winter squash**
  - No EPA tolerance level
  - FDA Action Level = 0.1 ppm
  - Investigate and take appropriate action
  - If chlordane was not applied, the product may be sold as organic
- **0.2 ppm DDE on tomatoes**
  - No EPA tolerance level
  - FDA Action level = 0.05 ppm
  - Product cannot be sold as organic
  - Notify FDA and NOP, coordinate investigation

Examples

- **0.2 ppm Metalachlor on buckwheat**
  - EPA tolerance – 0.1 ppm
  - Exceeds EPA tolerance
  - May not be sold as organic
  - Notify EPA if field sample, FDA if non-field sample
  - Notify NOP, investigate and take appropriate action
- **1 ppm Chlorpropham on potatoes**
  - EPA tolerance = 30 ppm
  - Less than 5% EPA tolerance level
  - Investigation indicates operation knowingly used CIPC (chlorpropham) for sprout inhibition
  - Appropriate adverse action – combined NONC/NOPR

Sampling results: actions

For all sample results:

- Notify applicant or certified operation of test results.
- Maintain records of analysis and provide results to the public upon request.
- Maintain sample collection information and sample results for review during NOP accreditation audits.
- When residues are found, investigate why residues are present and take enforcement action as appropriate.

Reporting test results to authorities

In the U.S., report test results that indicate violations of EPA and FDA regulations as follows:

- Notify the EPA if the violation of the EPA regulation can be traced back to a prohibited application of a pesticide in a field in the U.S.
  - A prohibited application occurred if a pesticide was applied but was not permitted to be applied to a particular crop (i.e. there is no EPA tolerance) or a pesticide was applied at levels that were too high for a particular crop (i.e. above the tolerance).
- Submit notice of such EPA violations to **www.epa.gov/tips/**.

Reporting test results to authorities

- Notify the FDA of violations of the EPA tolerance levels or FDA action levels when :
  - The product that was tested is in the stream of commerce, and
  - The location and time of violation that may have occurred in a field cannot be determined.
  - Report notice of such violations to the FDA district office where the violation was discovered.
  - To find Information on district offices, go to: www.fda.gov/food/foodsafety/foodsafetyprograms/rfr/default.htm

Responding to detected residues other than pesticide residues

Antibiotics, hormones, medications, GMOs

Investigate to determine source of residues and take appropriate adverse action.

- Use of prohibited substance or method:
  - Knowingly, willful, reason to know = Proposed Revocation
  - Inadvertent, Error = Proposed Suspension
- Inadequate measures to prevent contamination or commingling:
  - Notice of Noncompliance: require corrective actions to mitigate future contamination.

Responding to detected sample residues other than pesticide residues

Example: GMO residues

- The NOP regulations prohibit the use of genetically modified organisms, prohibit commingling or contamination during processing and handling, and require preventative practices to avoid contact with genetically modified organisms (GMOs).
- Organic agricultural products should have minimal, if any, GMO presence.
- However, no tolerance level has been established for the presence of GMO material.

GMO residues, continued

- If investigation determines that the residue levels indicate use of excluded methods, then take adverse actions to suspend or revoke certification.
- If investigation determines that the residue levels are due to inadequate measures to avoid contact with excluded methods from adjoining land use or commingling, then issue NONC. Corrective actions must include measures to mitigate contamination.

Final Rule for Periodic Residue Testing

Review:

Test Results-
Provide copy to operator and make available to public

Investigate positive results to determine source

Take appropriate action: adverse actions and notification of authorities