EPA human health risk assessment of pesticides used in organic products:

a different approach with the same goal

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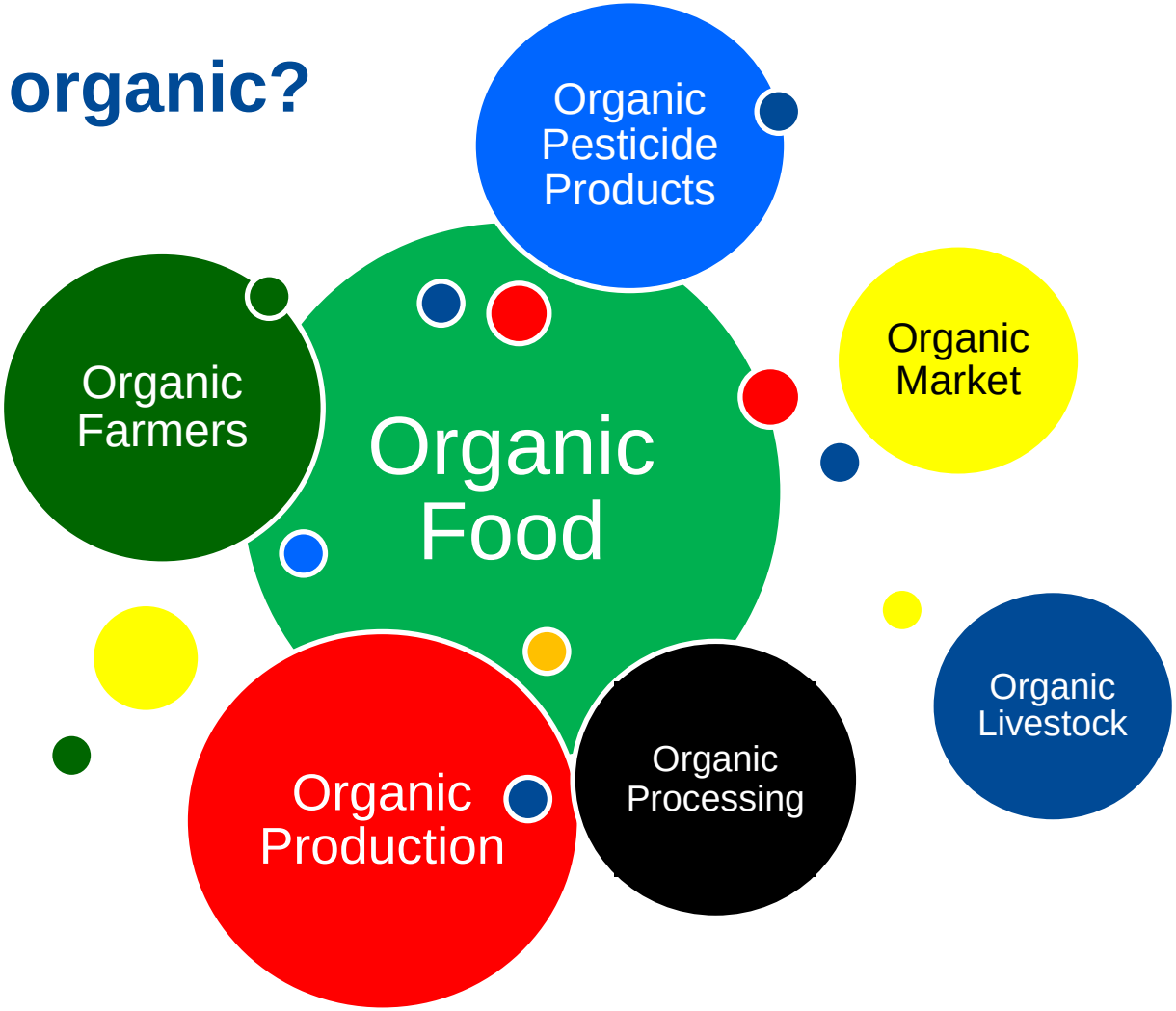
At the end of this presentation you will...

- Be able to identify the three types of pesticides that could be included in organic pesticide products.

- Understand the different regulatory approaches for toxicology and residue requirements for the different pesticide types.

- Appreciate the philosophical difference between human safety testing for synthetic pesticides and non-synthetic pesticides.

What is organic?



The National Organic Program Rule

7 CFR Part 205 – also known as the Organic Foods Production Act

The *National List of Allowed Synthetic and Prohibited Nonsynthetic substances*

Man-made

Synthetic substances allowed for use

Nonsynthetic substances prohibited for use

Natural source

Electronic Code of Federal Regulations

e-CFR data is current as of July 15, 2021

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Title 7: Agriculture
PART 205—NATIONAL ORGANIC PROGRAM

Subpart G—Administrative

Contents

THE NATIONAL LIST OF ALLOWED AND PROHIBITED SUBSTANCES

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.
§205.601 Synthetic substances allowed for use in organic crop production.
§205.602 Nonsynthetic substances prohibited for use in organic crop production.
§205.603 Synthetic substances allowed for use in organic livestock production.
§205.604 Nonsynthetic substances prohibited for use in organic livestock production.
§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
§205.607 Amending the National List.
§§205.608-205.619 [Reserved]

The National Organic Program Rule Philosophy

Number of synthetic substances permitted on the National List

In general, synthetic substances are prohibited for crop and livestock production unless specifically allowed.

The National Organic Program Rule Philosophy

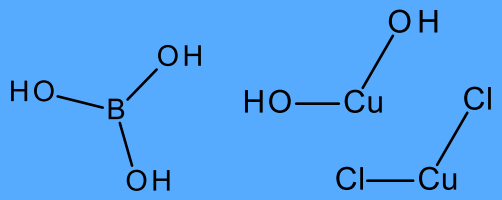
Number of nonsynthetic substances prohibited on the National List

In general, nonsynthetic substances are allowed for crop and livestock production unless specifically prohibited.

Pesticides used in organic production can be divided into 3 categories:

Nonsynthetic Substances

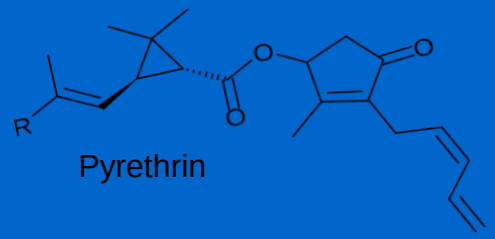
Synthetic Substances



Synthetic substances are man-made. They are not produced from a natural source.

Synthetic substances and their breakdown products must have no adverse effect on human health and must not contribute to contamination of crops, soil, or water.

Biochemicals

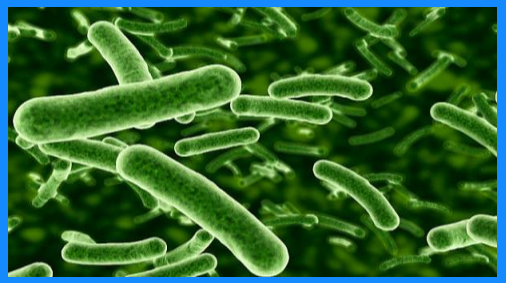


Pyrethrin

Biochemicals are naturally occuring or structurally similar to naturally occuring substances.

Biochemicals must have non-toxic mode of action and a demonstrated history of exposure to humans and the environment with minimal toxcity.

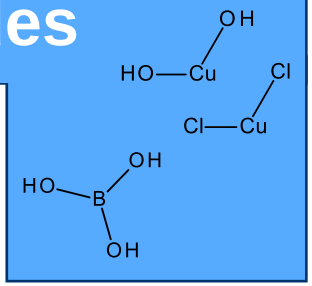
Microbials



Microbials are microorganisms such as bacteria, fungus, algae, virus or protozoan.

Microbials are intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant.

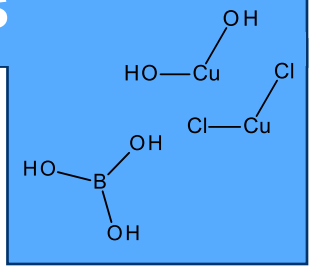
Toxicity testing required for Synthetic Pesticides



§158.500 Toxicology Requirements

1. Pharmacokinetics (absorption, distribution, metabolism and excretion)
2. Acute Toxicity
3. Genotoxicity (effect on genes or chromosomes)
4. Subchronic (short-intermediate term) Toxicity
5. Chronic (lifetime) Toxicity
6. Cancer Potential
7. Developmental Effects
8. Reproductive Effects
9. Neurotoxicity, Immunotoxicity

Residue data required for Synthetic Pesticides



§158.1410 Residue Requirements

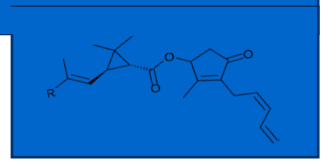
Crop Metabolism – including rotational crops	Required
Livestock Metabolism	Conditionally Required
Analytical Methods – including multiresidue methods	Required
Storage Stability	Required
Livestock Feeding (residues in meat, milk, poultry, eggs)	Conditionally Required
Crop Field Trials (residues in plant commodities)	Required
Processing (residues in processed food)	Conditionally Required
Residues in Rotational Crops	Conditionally Required
Residues in Potable Water, Fish and Irrigated Crops	Required for aquatic use
MRLs and risk assessment (unless tolerance exempt)	Required

Conditionally Required

Residue chemistry studies on livestock, processed foods and rotated crops are required if uses could lead to residues in these commodities.

Toxicology tiers required for Biochemical Pesticides

§158.2050 Toxicology Requirements



Tier I

- Acute Toxicity Studies
  - Oral, Inhalation, Dermal Toxicity
  - Dermal and Eye Irritation
  - Skin Sensitization
- Subchronic
  - 90-d oral, dermal, and/or inhalation
- Developmental
  - Prenatal, rat
- Mutagenicity
  - Bacterial Reverse mutation
  - *In vitro* mammalian cell assay

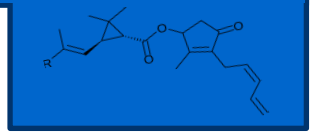
Tier II

- *In vivo* mammalian cytogenetics
- Prenatal, rabbit
- Imunotoxicity
- Applicator/User Exposure
  - Dermal outdoor
  - Dermal indoor
  - Inhalation outdoor
  - Inhalation indoor
  - Biological monitoring

Tier III

- Reproductive Toxicity
- Chronic/Carcinogenicity
  - Rat and mouse
- Immunotoxicity
- Mammalian spermatogenial chromosome aberration
- *Companion Animal safety*

Residue data required for Biochemical Pesticides



§158.2040 Residue Requirements

Crop Metabolism – including rotational crops	Conditionally Required
Livestock Metabolism	Conditionally Required
Analytical Methods – including multiresidue methods	Conditionally Required
Storage Stability	Not Required
Livestock Feeding (residues in meat, milk, poultry, eggs)	Conditionally Required
Crop Field Trials (residues in plant commodities)	Conditionally Required
Processing (residues in processed food)	Conditionally Required
Residues in Rotational Crops	Not Required
Residues in Potable Water, Fish and Irrigated Crops	Conditionally Required
MRLs and risk assessment (unless tolerance exempt)	Conditionally Required

Required for GH use

Conditionally Required

Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical agents in the biochemical human health assessment data requirements, §158.2050.

Toxicological tiers required for Microbial Pesticides

§158.2140 Toxicology Requirements

Tier I

- Acute Oral toxicity / pathogenicty
- Acute pulmonary toxicity / pathogenicity
- Acute injection toxicity/ pathogenicity/(intravenous)
- Acute injection toxicity/ pathogenicity/ (intraperitoneal)
- Cell culture

- *Acute Oral, Inhalation, Dermal Toxicity*
- *Dermal and Eye Irritation*

Tier II

- Acute Toxicity
- Subchronic toxicity / pathogenicity

Tier III

- Reproductive Toxicity
- Carcinogenicity
- Immunotoxicity
- Infectivity / pathogenicity analysis

Residue data required for Microbial Pesticides

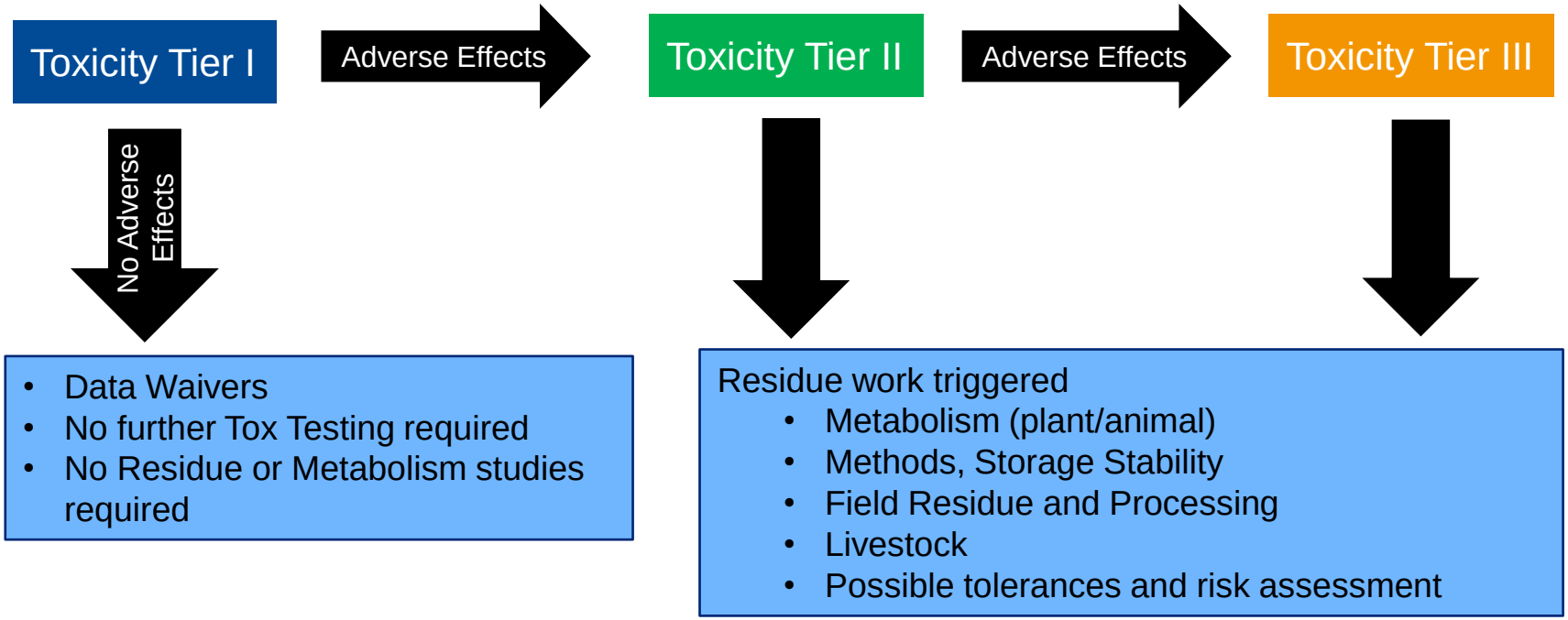
§158.2130 Residue Requirements

Crop Metabolism – including rotational crops	Conditionally Required
Livestock Metabolism	Conditionally Required
Analytical Methods – including multiresidue methods	Conditionally Required
Storage Stability	Conditionally Required
Livestock Feeding (residues in meat, milk, poultry, eggs)	Conditionally Required
Crop Field Trials (residues in plant commodities)	Conditionally Required
Processing (residues in processed food)	Not Required
Residues in Rotational Crops	Not Required
Residues in Potable Water, Fish and Irrigated Crops	Conditionally Required
MRLs and risk assessment (unless tolerance exempt)	Conditionally Required

Conditionally Required

Residue chemistry data requirements apply to microbial pesticide products when results of testing indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and the use pattern is such that residues may be present in or on food or feed crops.

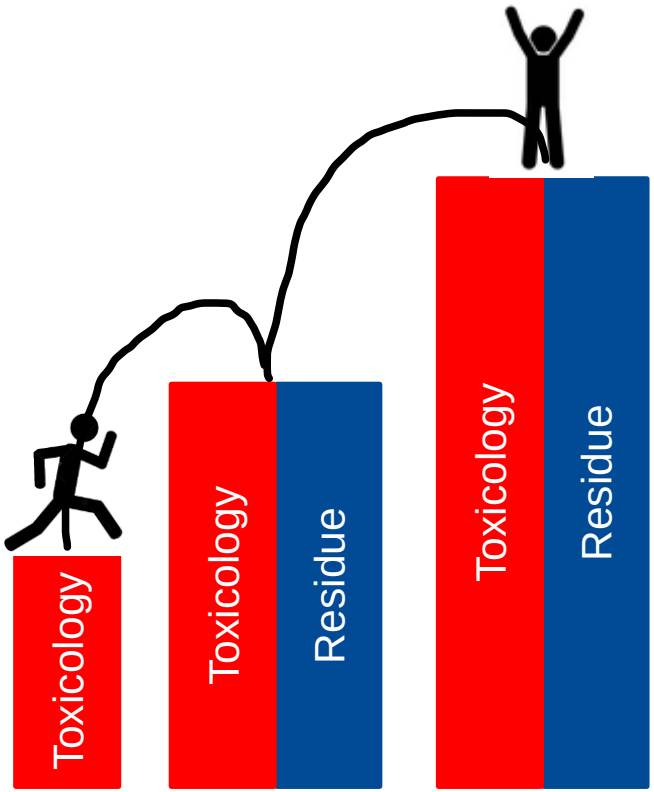
Nonsynthetic Pesticide: Product Testing Pathway



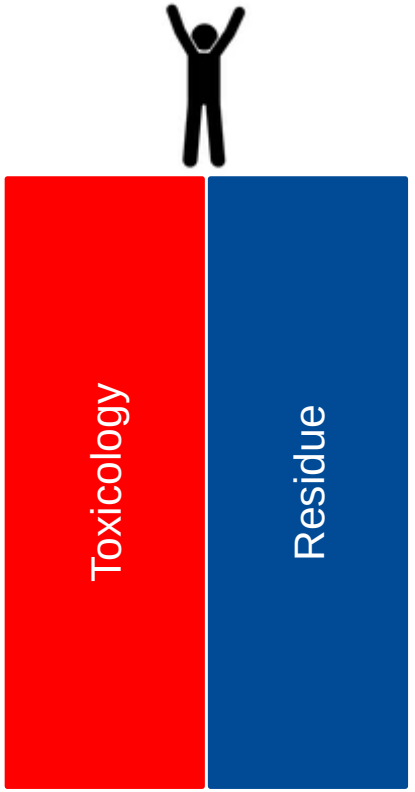
Applicants should consider the unique characteristics of their pesticide when addressing specific data requirements and protocols, and are encouraged to consult with the agencies before testing begins. Waivers for certain data requirements will be considered when accompanied by a sound scientific rationale.

Nonsynthetic *vs.* Synthetic Pesticide Human Safety Testing

Tiered approach *vs.* upfront approach



Nonsynthetic Pesticides
Biiochemicals - Microbials



Synthetic Pesticides

Thank You!

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