Organic vs. Conventional Pesticides – what are they and how they impact human health and the environment

Michigan Occupational and Environmental Medicine Association (MOEMA) Annual Scientific Meeting (ASM)

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October 10, 2020

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Outline

- What are organic and conventional pesticides and how they are regulated
- Organic industry facts
- Data requirements and how safety assessment is conducted
  - Hazard vs. risk
  - Human health safety assessment
  - Ecological safety assessment
- Case studies

What are organic and conventional pesticides and how they are regulated

Pesticides are essential for farming and food production

Organic Pesticides

- Pesticides permitted in certified organic production are certain pesticides that have been approved for use in organic agriculture according to the U.S. Department of Agriculture (USDA).
  - USDA National List: National Organic Program (NOP) is responsible to list which substances should be allowed and prohibited for organic production.

  The national list of allowed and prohibited substances: Part 205-national organic program

- Regulated by US Department of Agriculture (USDA) and US Environmental Protection Agency (USEPA)
  - All pesticides are reviewed and registered by the EPA prior to sales and distribution in the United States. In addition to the federal process, each state government has its own review process for new pesticide products. A product approved by the EPA must also be registered in the state.

Biopesticides

- Biopesticides are certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. For example, canola oil and baking soda have pesticidal applications and are considered biopesticides. Biopesticides fall into three major classifications: Biochemical, Microbial, and Plant-Incorporated Protectants (PIPs).

https://www.epa.gov/pesticide-registration/biopesticide-registration#what

  - There are some biopesticides that are NOT approved for organic production. Such as salts of phosphorous acid and all genetically-engineered PIPs
  - Some fungicides approved for use in organic production systems are not biopesticides, including mineral oils, copper, and sulfur.

Conventional Pesticides

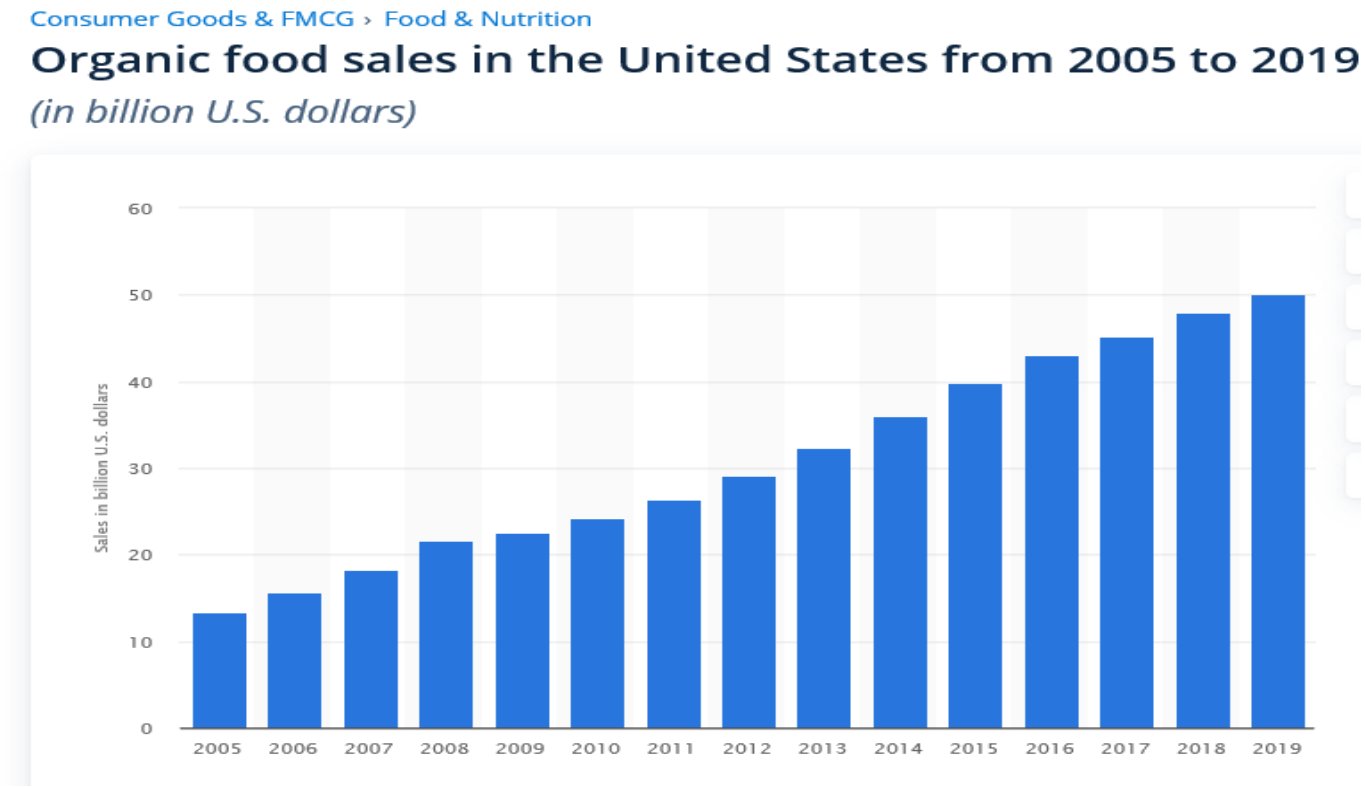
- Definition: are all active ingredients other than biological pesticides and antimicrobial pesticides. Conventional active ingredients are generally produced synthetically. (They can also be produced from microbials.)

- Regulation: USEPA

https://www.epa.gov/pesticide-registration/conventional-pesticide-registration

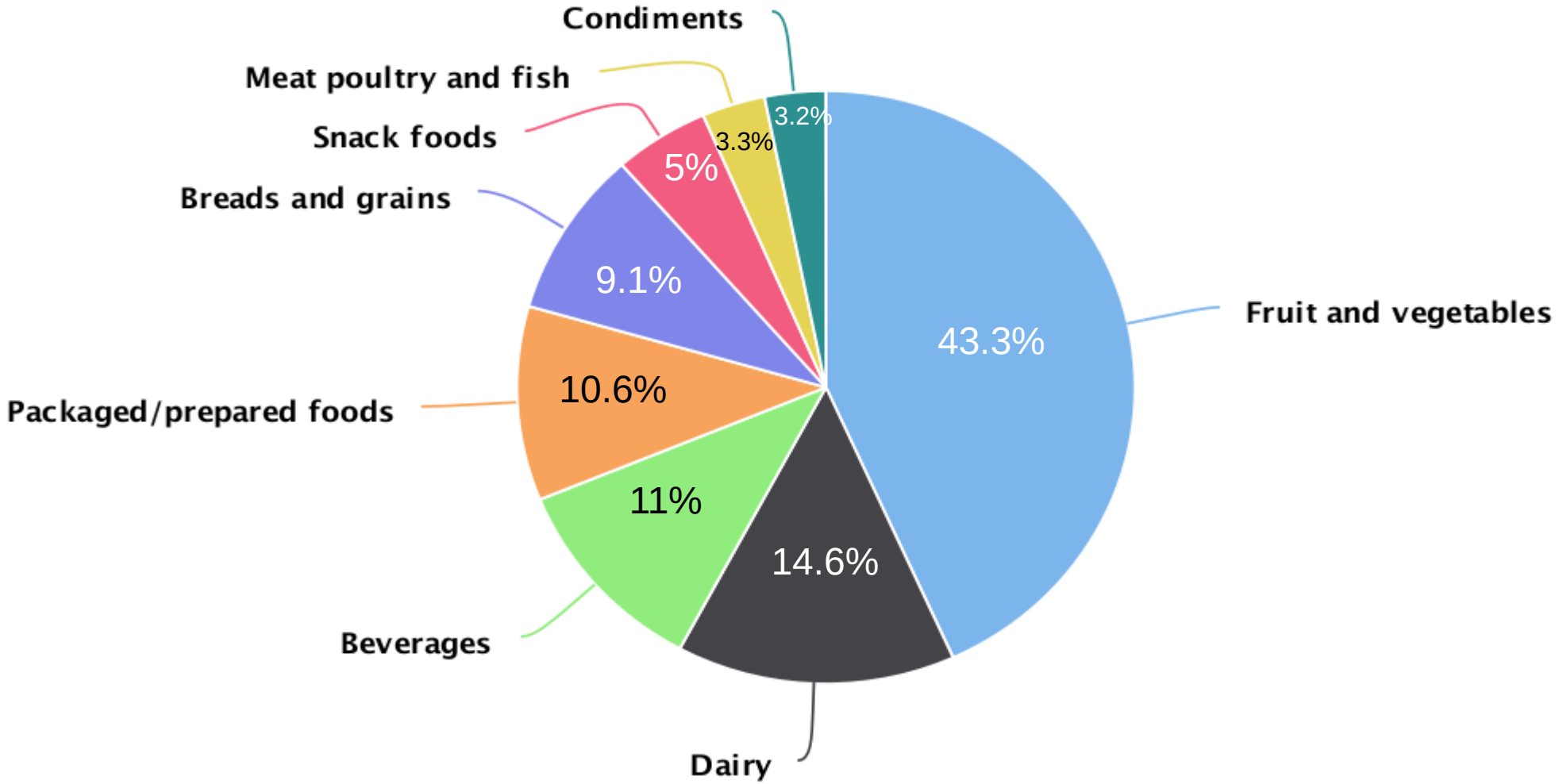
Organic Industry Facts

Organic Food Industry



https://www.statista.com/statistics/196952/organic-food-sales-in-the-us-since-2000/

Organic Food Market in 2014



http://www.city-data.com/blog/4717-natural-food-market-united-states/

Organic Seal

USDA certified organic foods are grown and processed according to federal guidelines addressing such as soil quality, animal raising practices, pest and weed control and use of additives.

- Products containing only organically produced ingredients may use seal and be labeled “100% organic”
- Products that contain at least 70% organic ingredients can be labeled “made with organic ingredients” but cannot use USDA seal.

Why Consumers Choose Organic Foods?

- Perceived health and nutrition benefits
  - **Avoid pesticides**
  - **Health and nutrition**
  - **Natural/organic pesticides: no toxicity**
  - **Synthetic/conventional pesticides: very toxic (misconception)**
  - Avoid genetically modified foods (misconception)

Pesticide Residues in Organic Fruits and Vegetables

U.S. Department of Agriculture's Pesticide Data Program (PDP)

1994-1999: 23% of 127 samples have detectable residues

California Department of Pesticide Regulation (CDPR)

1989 to 1998: 6.5% samples have detectable residues

Consumers Union study

1998: 27% detection rate

Belgium study

1995-2001: 12% detection rate

Baker et al., 2002. "Pesticide residues in conventional, integrated pest management (IPM)-grown and organic foods: insights from three US data sets". Food Additives & Contaminants
Pussemier et al., 2004. " Chemical safety of conventionally and organically produced foodstuffs: a tentative comparison under Belgian conditions" Food Control

- **Pesticide residue in organic products is not zero.**

Are Organic Foods More Nutritious?

- Data Sources
  - Medline (Jan 1996-May 2011)
  - EMBASE, CAB Direct, Agricola, TOXNET, Cochrane Library (Jan 1996-May 2009)
- Studies: 223 met inclusion criteria
- Conclusion: lacks strong evidence that organic foods are significantly more nutritious than conventional foods

Smith-Spangler et al., 2012. Are organic foods safer or healthier than conventional alternatives? A systematic review. Annals of Internal Medicine

Data Requirements and How Safety Assessment is Conducted

Development of Pesticides

- **Research intensive**:

  It takes 11 years to research, develop, and register a new crop protection product

- **Tightly regulated**:
  - A product undergoes > 100 rigorous studies to support the health, safety, and environmental assessments required for registrations

  - From a mammalian toxicology perspective, pesticides have the most comprehensive data requirements of any chemical sector, including pharmaceuticals

Global Regulatory Environment

CORTEVA™ agriscience

Paracelsus (1493-1541)

“All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy."

Hazard: potential to cause harm (determined in toxicity studies)

Risk: likelihood of harm occurring

Hazard ≠ Risk

Risk = f(Exposure, Hazard)

Protect the Environments where our products are released and Humans who consume treated commodities or can be subjected to exposures

Risk Assessment

Human Health Assessment

- Operator
- Re-entry
- Bystander
- Residential
- Dietary

Ecological Assessment

- Aquatic ecosystems
- Terrestrial ecosystems

Human Health Safety Assessment

- **Hazard Characterization**
  - Covering different durations: acute, short-term, and long-term studies
  - Covering life-stages: developmental and reproductive
  - Covering health concerned endpoints: systemic toxicity, genotoxicity, immunotoxicity, neurotoxicity, carcinogenicity, endocrine disruption, developmental and reproductive toxicity
- **Dose-Response Analysis**
- **Exposure Assessment**
  - Dietary exposure: acute and/or chronic exposure durations
  - Non-dietary exposure: operator, bystander, resident
  - Exposure related with Cancer risk: chronic exposure duration
- **Risk Characterization**
  - Acceptable/unacceptable risk

Key Definitions

- Endpoints: The adverse effect upon which the risk assessment is based
- Lowest Observed Adverse Effect Level (LOAEL): Lowest dose from a study at which adverse effects are observed
- No observed Adverse Effect Level (NOAEL): The dose at which no adverse effects are observed
- Point of Departure (PoD): The dose level used to quantify risk (generic)

Types of Studies for Hazard Characterization

Acute Exposure Toxicity	Short to intermedium Exposure Toxicity	Long-term Exposure and Sensitive Life Stages	Genotoxicity and other Special studies
Acute oral toxicity – Rat	90-day Feeding – Rodent	Chronic feeding – Rodent	Bacterial reverse mutation assay
Acute dermal toxicity – Rat	90-day Feeding – Non-rodent	Carcinogenicity – Rat and Mouse	In vitro mammalian cell mutation assay
Acute inhalation toxicity – Rat	21-day Dermal	Developmental Toxicity – Rat & Rabbit	In vivo cytogenetics
Primary eye irritation – Rabbit	90-day Dermal	Reproduction – 2 generation	Other mutagenicity studies
Primary dermal irritation – Rabbit	90-day Inhalation – Rat		Delayed neurotoxicity (acute) - Hen
Dermal sensitization – Mouse			90-day Neurotoxicity – Rat
Acute neurotoxicity – Rat			Developmental Neurotoxicity
			Delayed Neurotoxicity (subchronic) Hen

Key Toxicity Points of Departure Derivation

	Oral	Dermal	Inhalation
Acute	√		
Short-term (up to 1 month)	√	√	√
Intermediate-term (up to 6 months)	√	√	√
Chronic (> 6 months)	√		
Cancer (> 6 months)	√		

Exposure Assessment

Dietary Exposure

Dietary exposure= consumption x residue

- USDA's What We Eat In America (WWEIA): national representative food consumption survey
- US EPA's Food Commodity Intake Database: Recipe database that links WWEIA foods to residue data
- Residue Data: from residue trials

Residential Exposure: SOPs for Residential Exposure Assessment

- Handler exposure (dermal and inhalation routes)
- Post-application exposure (dermal, inhalation; oral for children only)

Occupational Exposure

- Occupational Handler Exposure= Application rate X Area treated x Unit Exposure
- Occupational Post-application Exposure= DFR or TTR X Transfer coefficient X Exposure time

Dislodgeable Foliar Residue (DFR) or Turf Transferable Residue (TTR): residue on foliage that can transfer to a worker's skin

Risk Characterization

- **Dietary Risks: % acute and chronic reference doses**
  - Reference dose= Point of Departure (NOAEL)/Uncertainty factor
  - Risk= dietary exposure/reference dose
  - When risk is < 100%, safe use/acceptable risk is established

- **Occupational/Residential Risks: Margin of Exposure (MoE)**
  - MoE= Point of Departure/exposure
  - When MoE is greater than targeted MoE (uncertainty factor), safe use/acceptable risk is established

- **Cancer Risks:**
  - Risk= Cancer slope factor x exposure
  - Typically, an acceptable risk is lower than 1 person /million population

Human Health Data Requirements for Organic Pesticides

- Biochemical pesticides: similar to conventional pesticides with reduced and tiered testing requirements
  - acute toxicity, a battery of genotoxicity, 90-d oral, dermal, and inhalation, immunotoxicity and developmental studies
- Microbial pesticides: based on pathogenicity and infectivity hazard endpoint in addition to tiered toxicity testing

https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-885-microbial-pesticide-test-guidelines

Leahy et al., 2014. Biopesticide oversight and registration at the US Environmental Protection Agency. American Chemical Society Symposium Series

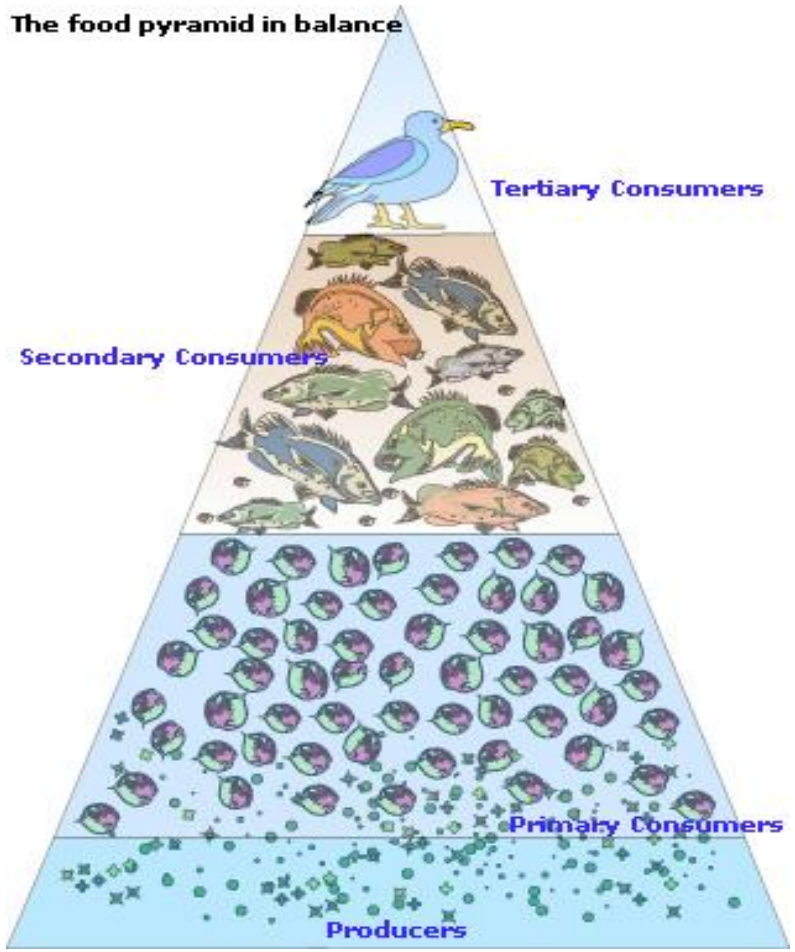
Ecological Safety Assessment

- Objective: To evaluate the impacts of pesticides on non-target organisms
- Safety assessment to aquatic and terrestrial wildlife and plants
- Testing principles are that for the initial hazard characterization, laboratory tests using representative species
- Duration of tests
  - Acute: generally 96 hours or less; measure lethal effect (LD50 or LC50 or EC50)
  - Chronic: longer-term (at least 10% of species normal life-span); measure growth and reproduction (NOAEL/NOAEC, LOAEL/LOAEC)

Main Study Areas for Hazard Characterization

- Birds
- Terrestrial vertebrates other than birds (utilize data from mammalian tox)
- Aquatic organisms
  - Fish
  - Invertebrates
  - Algae
  - Aquatic plants
- Pollinators (mainly bees)
- Non-target plants

Aquatic testing: Food Chain Guides Species Selection



Secondary consumers (Fish)

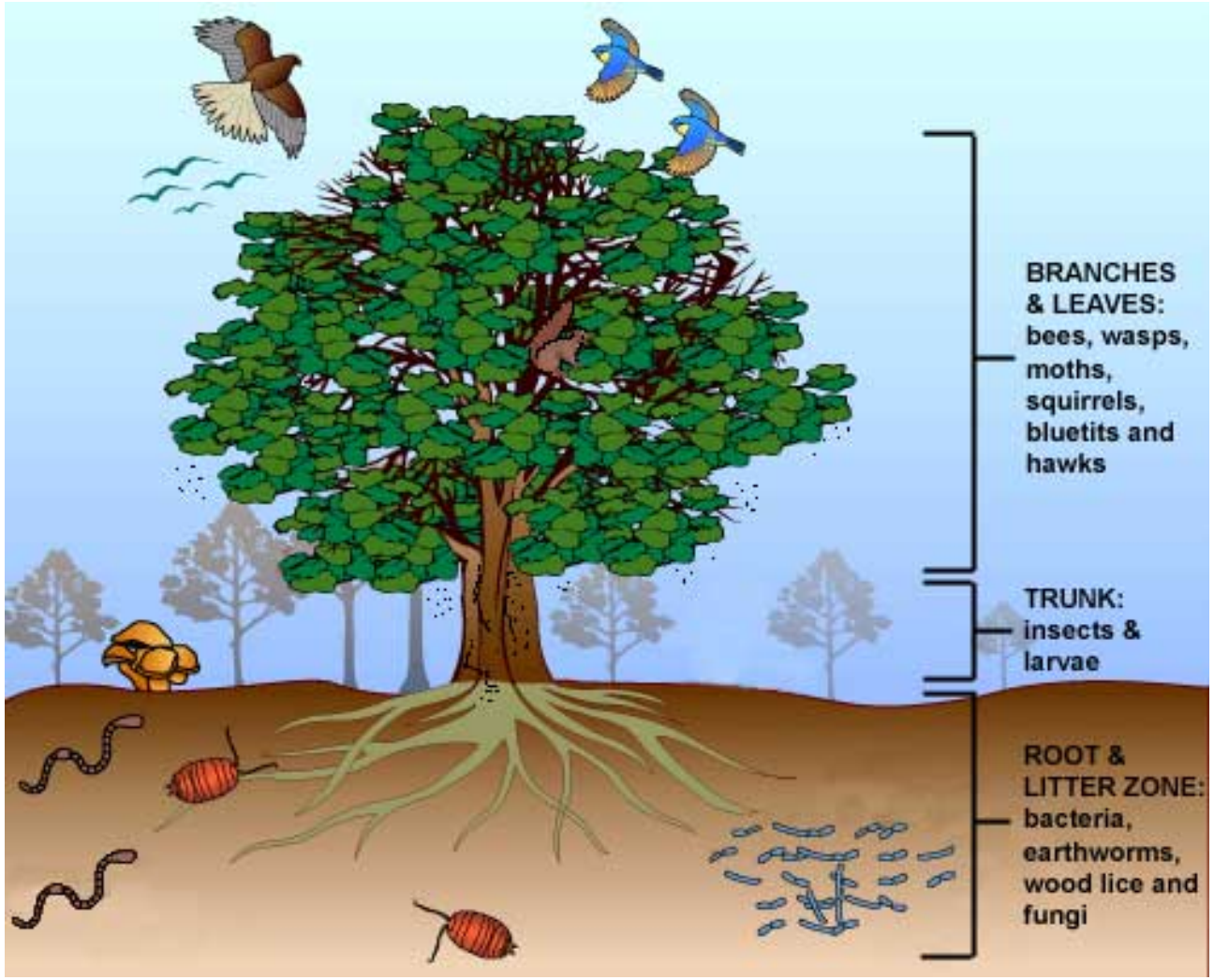
↑

Primary consumers (*Daphnia*)

↑

Primary producers (Algae)

A Terrestrial Ecosystem



Vertebrates
birds and mammals

herbivores
insectivores
predatory

Invertebrates
arthropods
worms

Plants
close to crops

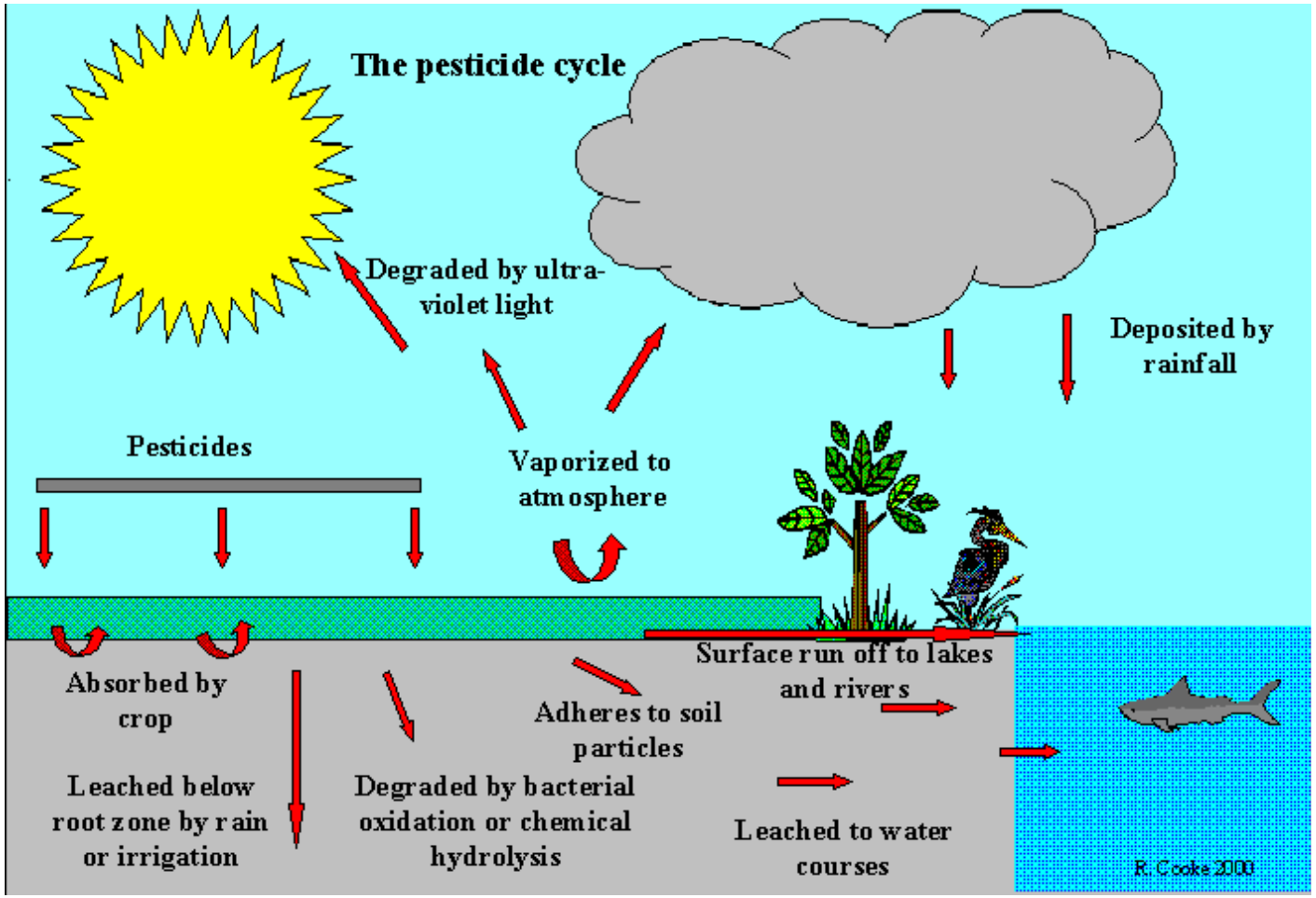
Microflora
Bacteria, fungi, protozoans

Tiered Testing and Risk Assessment Approach

- Tier 1= Laboratory
  - Standardized protocols with representative species
- Tier 2= Extended laboratory, Semi-field
  - Some realism introduced, e.g., relevant environmental conditions/exposure
  - Often single species, but mixed age/sex population, recovery, but limited immigration
  - Focused on risk refinement
- Tier 3= Field
  - Relevant environmental conditions
  - Multi-species “natural” communities
  - Risk refinement and/or quantification

Exposure Assessment

- Driving factors
  - Application pattern (rate, method and timing)
  - Environmental conditions (weather, soil)
  - Pesticide properties (physical-chemical and environmental fate)
- Exposure assessment
  - Modeling
  - Monitoring



Exposure Models

- Terrestrial birds and mammals
- Terrestrial and wetland plants
- Bees
- Fish, aquatic-phase amphibians, aquatic invertebrates, aquatic plants
- Spray drift

https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Risk Characterization

- Risk Quotients= Exposure/Toxicity
- Risk quotients compared to levels of concerns to determine if there is potential risk,
- When risk quotients are below levels of concerns, acceptable risk is established

http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical

http://www.epa.gov/risk/guidelines-ecological-risk-assessment

Non-Target Organism Data Requirements for Organic Pesticides

- Biopesticides: follow the same tiered approach as conventional pesticides, but rarely are biochemical pesticides subjected to testing above Tier I.
- Microbials: follow the tiered approach

Leahy et al., 2014. Biopesticide oversight and registration at the US Environmental Protection Agency. American Chemical Society Symposium Series

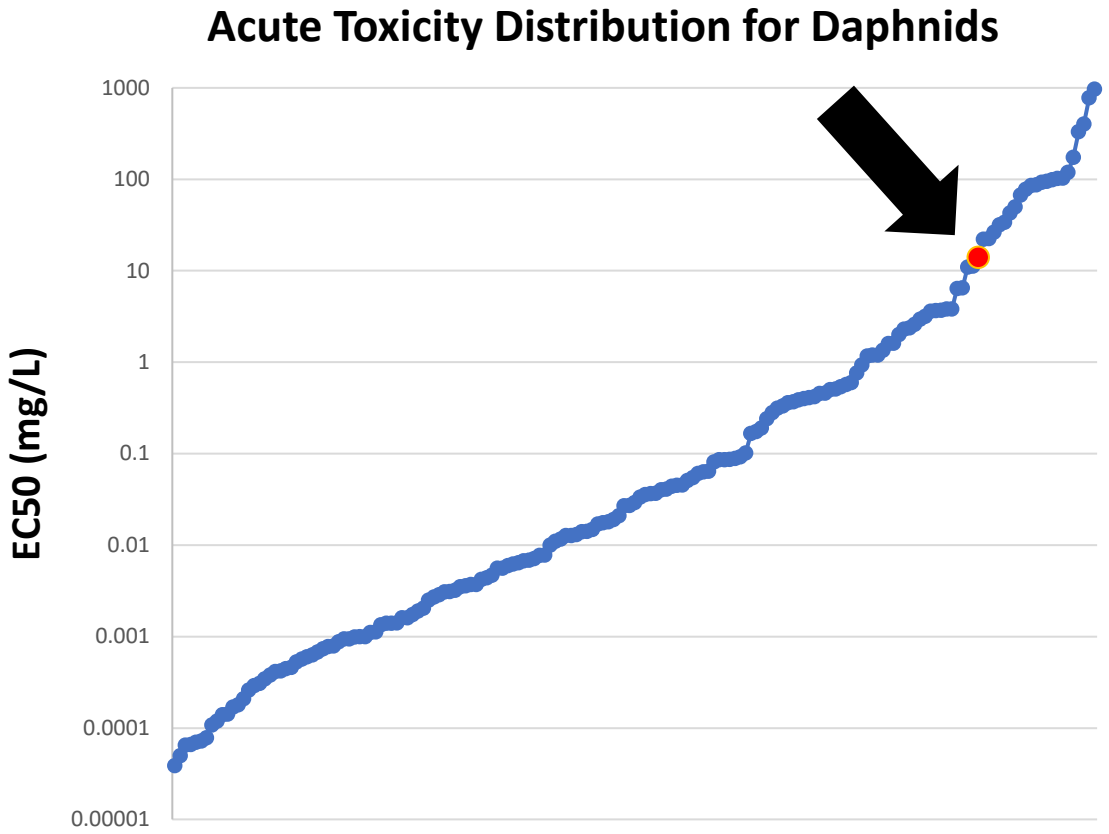
Case Studies

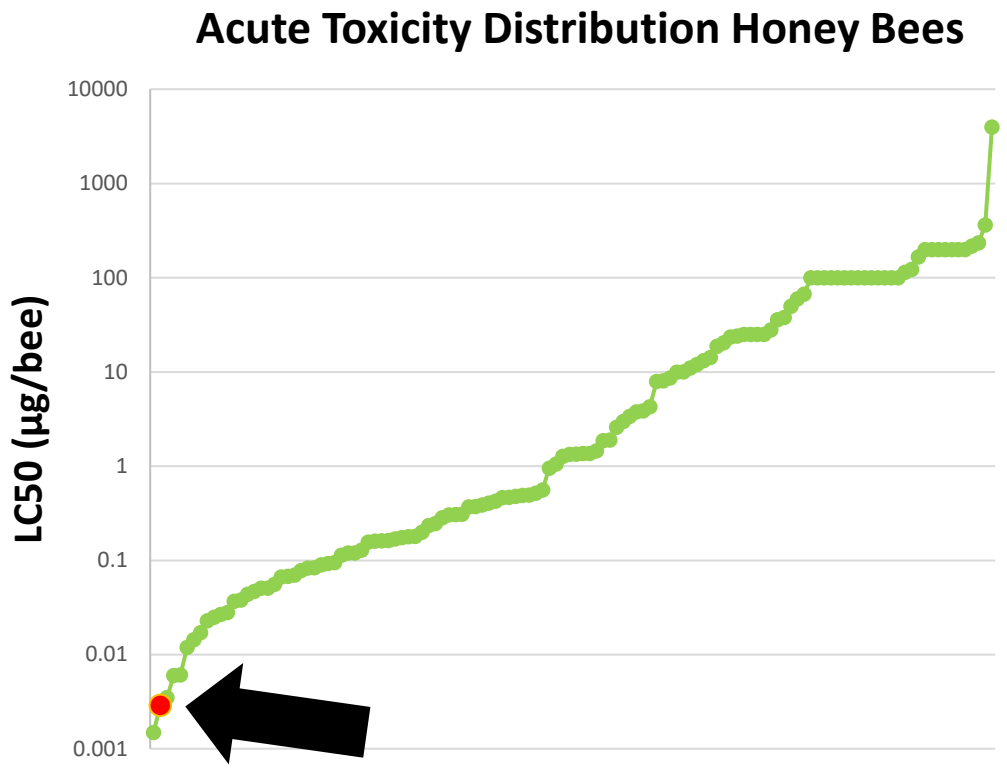
Case Study I: organic insecticide A vs. conventional insecticide B: Human Health Assessment

	A (organic)	B (conventional)
Reference dose (from Hazard characterization)	0.02 mg/kg bw/day	0.06 mg/kg bw/day
Dietary exposure (from Dietary exposure assessment)	0.0078 mg/kg bw/day	0.005 mg/kg bw/day
Chronic dietary risk assessment	39%	8.3%
Acceptable Risk?	Yes	Yes

- **Organic is not necessarily less toxic from human health toxicity endpoint perspective**
- **Both A and B have acceptable risk for human health**

Case Study II: Organic Insecticide C Selected Ecological Toxicity Endpoint to Compare with Overall Insecticide Database (~175 insecticides)





- Organic is not necessarily less toxic to ecological species
- C has acceptable ecological risk assessment according to US EPA methods

Summary

- Pesticides are essential to pest control and feeding the world
- Organic pesticides are primarily regulated by USDA and USEPA vs. conventional pesticides are regulated by US EPA
- Extensive toxicity studies and well understood exposure data are required to ensure product safety
- Hazard is NOT equal to risk
- Use of conventional and organic pesticides achieve acceptable risk when applied following label instruction

Acknowledgements

Corteva Agriscience

- Dr. Vincent Cramer
- Dr. Sean Gehen
- Dr. Mingming Ma
- Dr. John Marton
- Dr. Claire Terry

Juberg Toxicology Consulting LLC

- Dr. Daland Juberg

Bayer U.S.- Crop Science

- Dr. Jay Petrick