Understanding the EPA Product Registration Review Process

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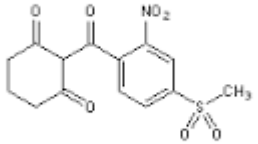
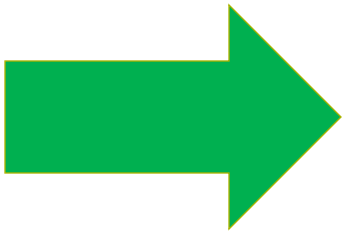
September 13, 2016

New Product to Growers





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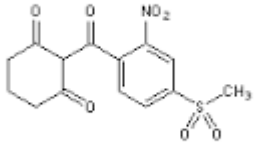


Federal Regulations

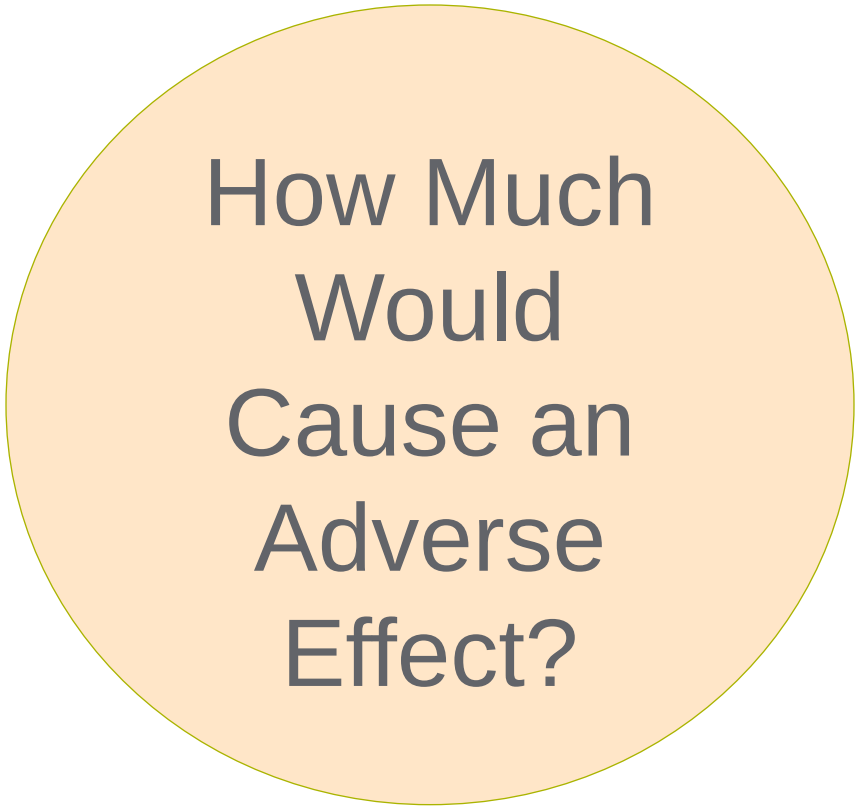
Objectives of the Regulatory Process

The product will perform its intended function without unreasonable adverse effects on the environment

Reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue

Evaluating Pesticide Risk

Risk = Hazard X Exposure



Toxic vs Non-toxic

How can a pesticide be used to benefit agriculture

without unreasonable effects on the environment

with reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue?

Evaluating Pesticide Risk

Hazard

- Toxicity to humans
- Toxicity to wildlife
- Toxicity to plants
- Surface water / ground water

Exposure

- Food
- Drinking water
- Residential use
- Handling/Applying
- Spray Drift
- Runoff

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This amount resulted in no observable adverse effect

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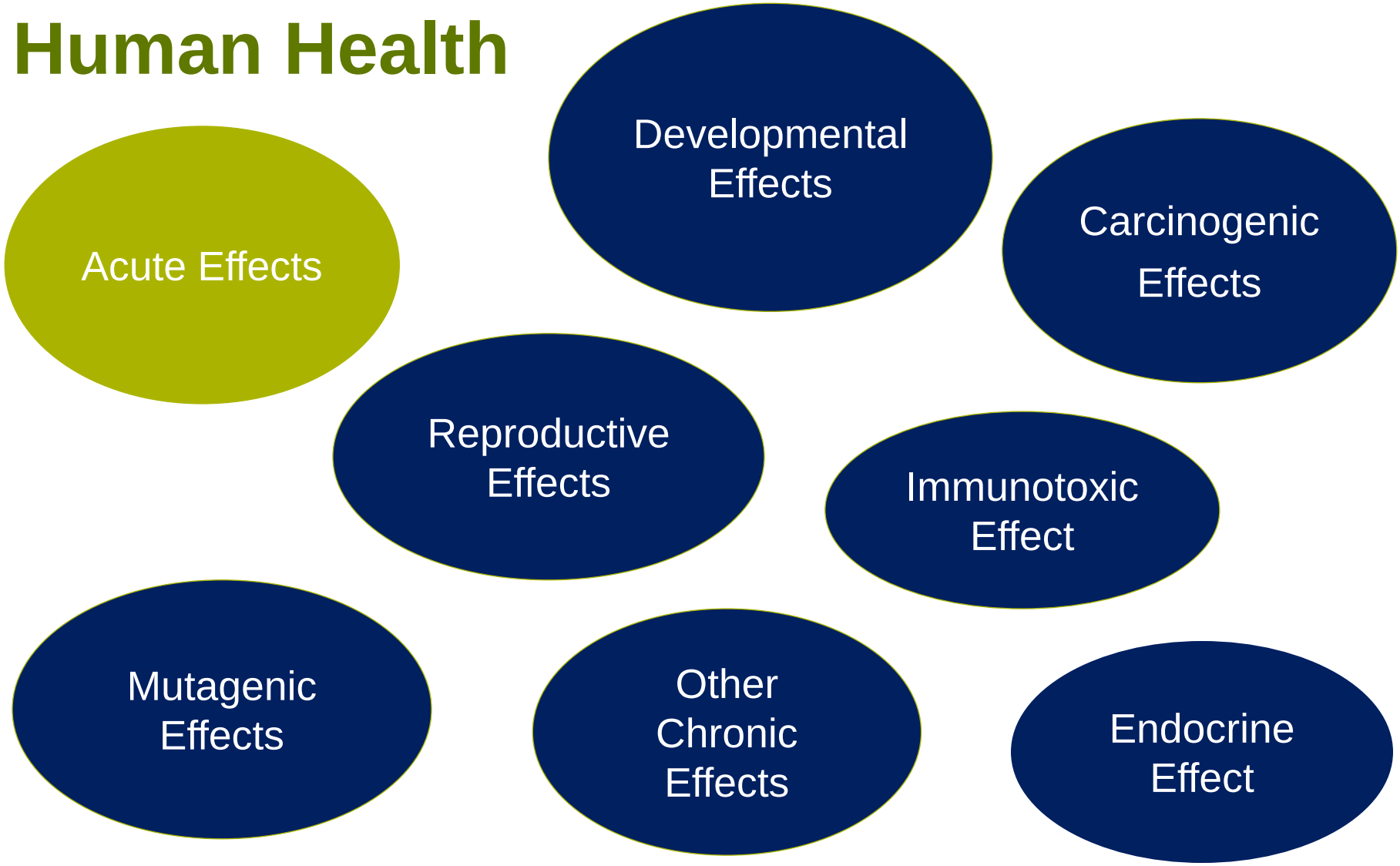
Expected exposure

Human Health



Chronic Toxicity Testing

0 mg/kg bw/d | 10 mg/kg bw/d | 50 mg/kg bw/d | 200 mg/kg bw/d

Chronic Toxicity Testing

0 mg/kg bw/d	10 mg/kg bw/d	50 mg/kg bw/d	200 mg/kg bw/d
No Effect	No Effect	An Effect	Increasing Effect

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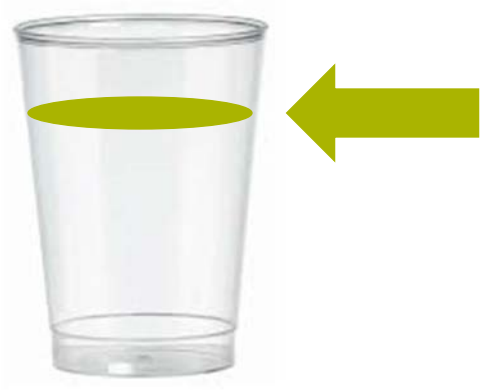
0 mg/kg bw/d	10 mg/kg bw/d	50 mg/kg bw/d	200 mg/kg bw/d
No Effect	No Effect	An Effect	Increasing Effect
	No Effect Level	Lowest Effect Level	

Hazard

No Effects at 10 mg/kg bw/day



Hazard

Safety Factors

No Effects at 10 mg/kg bw/day

10X 

10X 

10X 

Safety Factors

No Effects at 1~~0~~ mg/kg bw/day

10X 

10X 

10X 

0.01

~~10~~

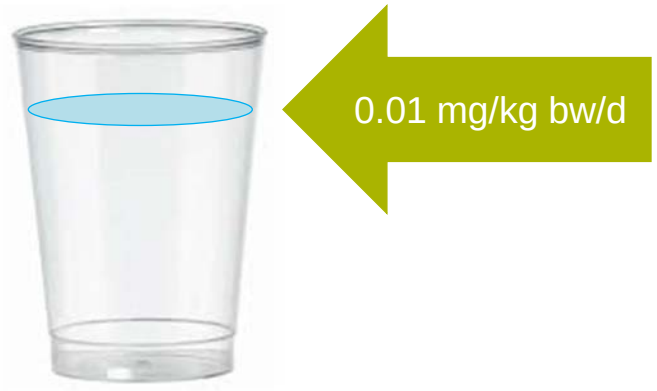
~~1.0~~

~~0.1~~

0.01

Hazard

0.01 mg/kg bw/day (Reference Dose
or Point of Departure)



Hazard

Exposure

Exposure

Exposure - Food

Wheat

- grain
- bran
- flour
- shorts

Grapes

- fruit
- juice
- raisin

Exposure - Food

USDA

FDA
U.S Food and Drug Administration

Diets (25 sub populations)

- Age
- Gender
- Region
- Ethnicity
- Seasonal

Exposure - Food

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Wheat

- grain
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- flour
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Grapes

- fruit
- juice
- raisin

Most sensitive population – 0.000843 mg/kg/day

Duration

Availability

Frequency

Dissipation

Risk

0.01 mg/kg bw/day (Reference Dose
or Point of Departure)

0.0001 mg/kg bw/day (Aggregate Exposure)

Hazard

Exposure

Acute Toxicity

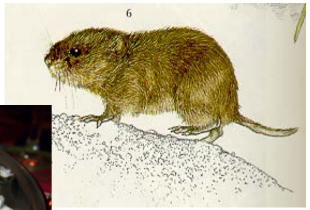
Single Exposure

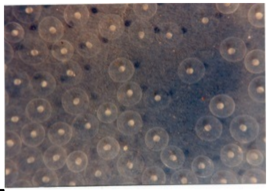
Risk to Wildlife & Environment

- Birds and Mammals
- Aquatic Organisms
- Non-Target Plants
- Non-Target Insects

Hazard vs.

Exposure

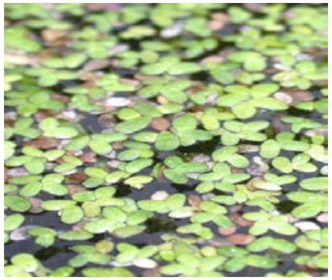


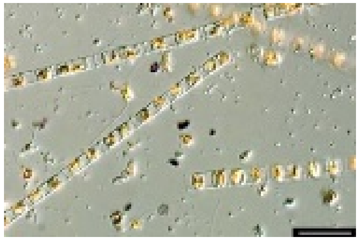


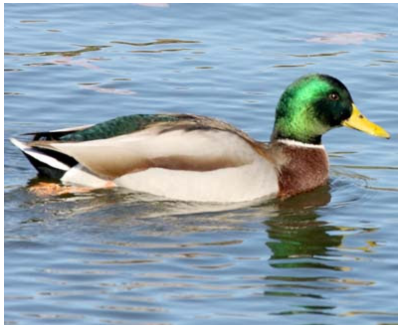


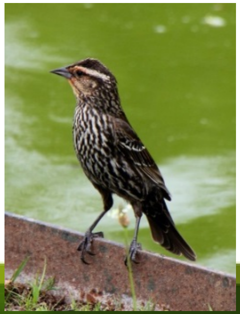


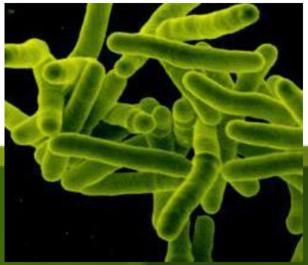
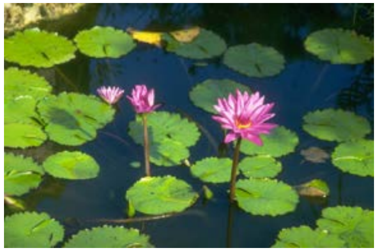






Pesticide registrations are re-reviewed every 15 years

On average: 11 years and nearly $300 million to develop a single active ingredient

Greater than 250 scientific studies required for EPA’s evaluation

Two year review time required

syngenta