



EPA: Research Needs and Considerations for Microbial Pest Control Agents and Plant-incorporated Protectants

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Pesticide Regulation under FIFRA

- **Federal Insecticide Fungicide and Rodenticide Act**
- **Licensing statute**
- **Intent-based statute**
- **Costs and Benefits considered**
- **Registration required for commercial sale, use & distribution**
- **Record keeping and maintenance**
- **Fee for service under the Pesticide Registration Improvement Act (PRIA)**
- **EPA does not deregulate pesticide products**



Regulatory Oversight by US EPA

The EPA Office of Pesticide Programs regulates the sale, distribution, and use of all pesticides in the U.S. in order to protect human health and the environment.

Including:

- Microbial Pest Control Agents**
- GE Plant-Incorporated protectants (PIPs)**



US EPA Regulation of GE Microorganisms

- **Microbial Pest Control Agents (MPCA)** – treated as pesticides
 - Regulated under FIFRA if intent is pesticidal
 - Risk assessment and registration process essentially the same as non-GE
 - Subject to Biotech Notification requirements 40 CFR 172.43
- **Intergeneric ‘New’ Microorganisms** - Bioremediation, biofuels, environmental biosensors, biofertilizers, closed system fermentation for the production of enzymes and specialty chemicals, and pesticidal intermediates
 - Regulated under the Toxic Substances Control Act (TSCA)
 - Regulated organisms are those with intergeneric rDNA (‘new’ chemicals)
 - http://www.epa.gov/biotech_rule/pubs/fs-001.htm



Genetically Engineered Microbial Pest Control Agents

- **Microorganism** – bacterium, fungus, alga, virus or protozoan 40 CFR 172.43
- **MPCA** – require a tolerance or exemption from a tolerance for application to food / feed crops unless experiments are considered as ‘crop destruct’ and will not enter food / feed supply
 - http://www.epa.gov/oppbppd1/biopesticides/reg_of_biotech/eparegofbiotech.htm
- **Biotechnology Notification** – intended for small scale field testing of genetically engineered microorganisms and those considered as exotic / non-indigenous in origin
- **Experimental Use Permit (EUP)** – typically required at 10 ac (4 ha) or greater land area, or 1 ac (0.4 ha) or greater for aquatic applications
 - Time limited; for gathering experimental data to support a registration action



What is a Plant-Incorporated Protectant (PIP)?

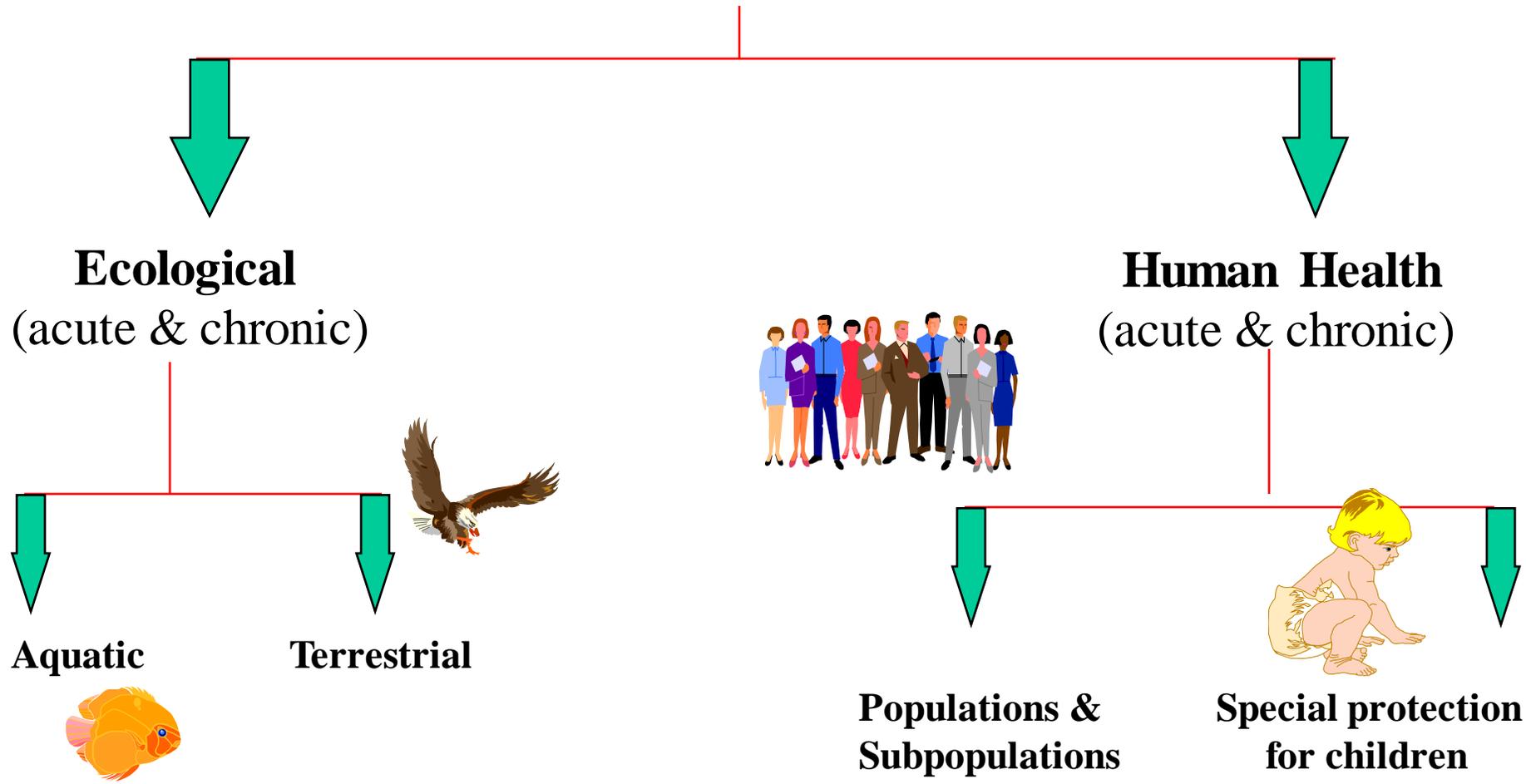
“ . . . a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. “

It also includes any inert ingredient contained in the plant, or produce thereof.” (40 CFR Sec. 174.3)

- e.g., antibiotic or herbicide tolerance marker used in the selection or development of a PIP product.



RISK





Food / Feed Tolerance

- **Federal Food Drug and Cosmetic Act**
 - Residue of pesticide on food or feed requires a tolerance or exemption from the requirement of a tolerance
 - Toxicity profiles and allergenicity assessment are used to determine safety of pesticide residues
 - FDA enforces tolerance violations



Research Needs for PIPs and MPCAs

- **Environmental fate of dsRNA – degradation and persistence**
 - **dsRNA from plant tissues**
 - **dsRNA from microbes (viable and heat killed)**
 - **dsRNA from sprayable products – stabilized**
 - **In both soil and aquatic systems**
 - **<http://www.epa.gov/scipoly/sap/meetings/2014/january/012814minutes.pdf>**



Research Needs for PIPs and MPCAs (cont'd)

- **Methods development to identify proper endpoints for non-target organism (NTO) effects from dsRNA / RNAi**
 - **Subchronic and chronic testing of dsRNA**
 - **Life cycle studies / latency**
 - **Dosing levels**
 - **Consumption vs absorption**
- **Bioinformatics assessment of RNAi constructs**
 - **Can dsRNA construct sequence information aid predictability of NTO effects?**



Research Needs for PIPs and MPCAs (cont'd)

- **Impacts of gene flow on native or feral plant populations**
 - **Modeling or empirical data relative to transgene introgression & impact**
 - **Not crop to crop gene flow**
- **Persistence of PIP plants in the environment**
 - **Impact of PIP plants on native ecosystems and agriculture via persistence**



Questions and Comments

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