



Biopesticides and



Office of Pesticide Programs



Biochemical/Pheromone



US Environmental Protection Agency
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division

www.epa.gov/pesticides/biopesticides

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Pesticide Regulation





Biochemical Pesticides

Definition

- (1) Is a **naturally-occurring** substance or structurally-similar and functionally identical to a naturally-occurring substance;
- (2) has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticide, is equivalent to a naturally-occurring substance that has such a history; and
- (3) Has a **non-toxic mode of action** to the target pest(s).





Biochemical Pesticides

- include but are not limited to:
 - (1) Semiochemicals (Insect pheromones and kairomones),
 - (2) Natural plant and insect regulators
 - (3) Naturally-occurring repellents and attractants, and
 - (4) Enzymes





Non-Toxic Modes of Action

- Lures/Attractants/Repellents (Irritants)
- Systemic Acquired Resistance induction
- Growth/developmental changes (IGRs, PGRs)
- Physical modes of action
 - Suffocation (by oils)
 - Dessication (by powders)
 - Coatings





Biochemical Pesticides

160 registered

Semiochemicals (Pheromones) (50)

- (Z)-9-Tricosene (muscalure) attracts house flies

Insect growth regulators (4)

- Azadirachtin – insect growth regulator

Plant growth regulators (21)

- Indole-3-acetic Acid

Herbicides (3)

- Corn gluten meal

Repellents (29)

- P-menthane-3,8-diol

Floral attractants and Plant Volatiles (14)

- 1-Octen-3-ol attractant in electric bug traps

Insect & nematode control (18)

- Soybean oil

Plant pathogen & microbial control (21)

- Sodium bicarbonate





Biochemical Classification Committee

- Formed in 1995
- Decides if a chemical can be a Biochemical Pesticide
 - literature, significant food component?, other uses, etc.
- Decision options:
 - Biochemical Pesticide
 - Not a Biochemical Pesticide but eligible for review using the reduced data set.
 - Conventional Chemical Pesticide
 - Not a pesticide
- 212 entries, many requested by registrants
 - 42 were classified as conventional chemical pesticides
- Pheromones automatically considered to be a Biochemical Pesticide





Exemptions from Regulation

- 152.10 - Products that are not pesticides
 - (b) Products to attract pests for survey or detection
 - (c) Physical Barrier Products (e.g. pruning paint)
- 152.25 - Specific exemptions
 - (b) Pheromones used in pheromone traps
 - Includes substantially similar compounds
 - (d) “Foods” used to attract pests
 - (e) “Natural cedar” chips, panels, etc
 - (f) “Minimal Risk Pesticides” aka “25b list”
- 152.500 – Devices
- Experimental Use Permits
 - Not required for testing on no more than 10 acres of land or 1 surface acre of water
 - Not required for testing arthropod pheromones
 - on up to 250 acres at less than 150 grams ai/acre/year (FR 7 July & 26 Jan 1994)





Biochemical Data Requirements

Data Requirement Regulations 40 CFR 158

- Footnotes in data requirement tables indicate when that data is not required
- Organized into Tiers to indicate when a class of data is not required
 - e.g. exposure studies are not needed if no toxicity is seen in the Tier 1 nontarget tests
- Information from the literature may adequately satisfy the data requirement
- A formal data waiver request may be granted if a valid scientific argument is provided





Registered Pheromone Survey 1995 - 2003

Z-9-dodecenyl acetate

Z,E,9-12-Tetradecadien-1-yl

Z-9-Tetradecen-1-ol

(zz) -11,13 Hexadecadienol

German Cockroach Pheromone

Z-11-hexadecenyl acetate

Data requirements	5 Straight Chain Lepidopteran Pheromones	1 Arthropod Pheromone
Product Chemistry	All data required except 1. Temperature stability 2. UV/light absorption 3. Particle size	
Residue	Directions for Use - Required 15 requirements - Not Required	
Human Health	No data required	
Nontarget Organisms & Environmental Fate	No data required	





Revisions To Data Requirements, 2007

Revised data requirements

- Test notes better describe when studies are needed
- Revised tiering for immunotoxicity
- List physical/chemical properties
- Replaced Hypersensitivity with Dermal sensitization

Deleted data requirements:

– Pheromones exempted:

- All Arthropod exempted from Non-target & Fate data
- Straight chain Lepidopteran exempted from Human Health data

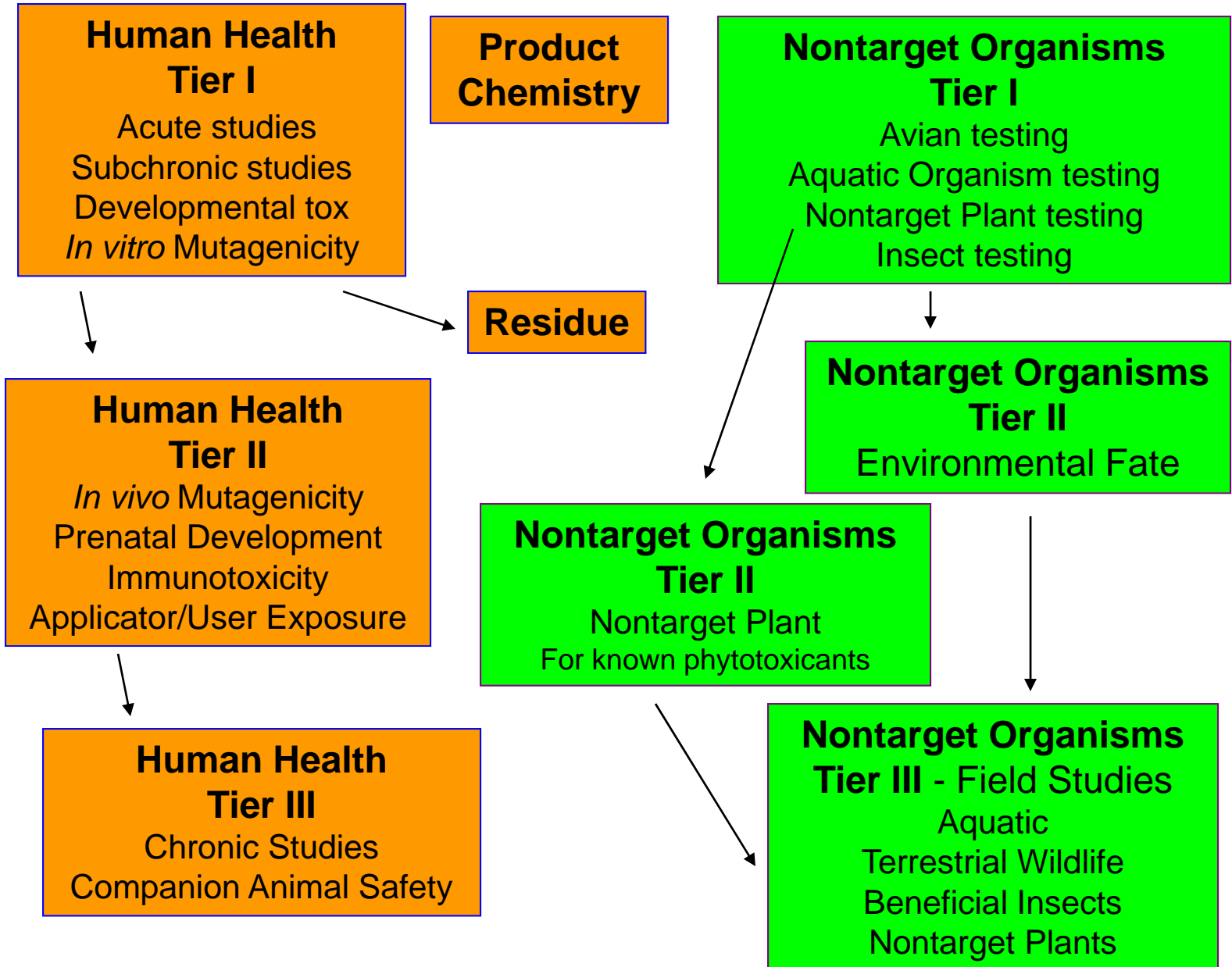


New data requirements (Tiers II & III):

- Applicator/user exposure data
- Prenatal development, 2nd species
- Companion animal safety data
- Reproduction & fertility effects
- Anaerobic metabolism studies
- Seedling emergence and Vegetative vigor

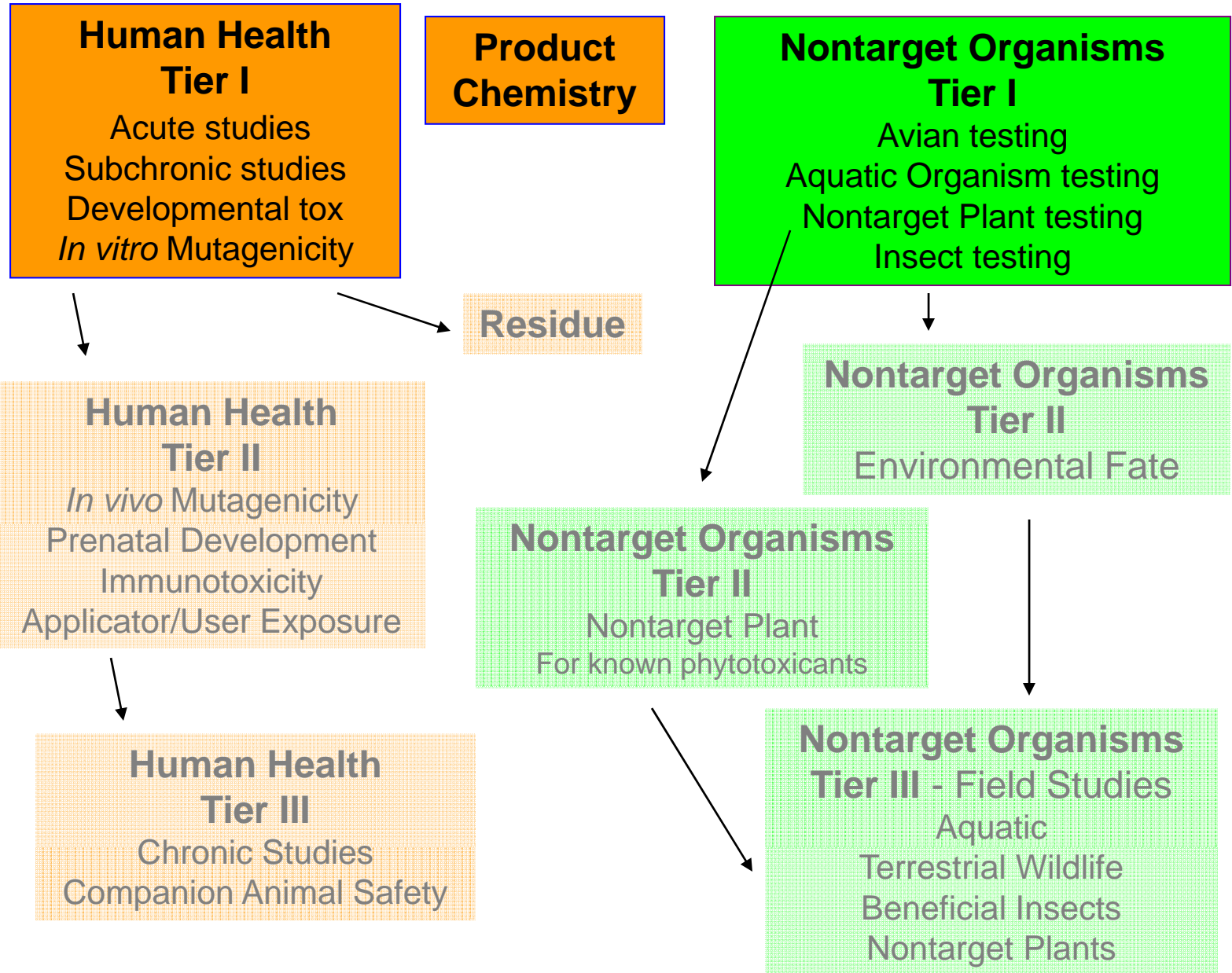


Biochemical Pesticide Data Requirements





Pheromones >150gm/acre Data Requirements





Arthropod Pheromone Data Requirements

<150gm/acre

Human Health Tier I

Acute studies
Subchronic studies
Developmental tox
In vitro Mutagenicity

Product Chemistry

Residue

Human Health Tier II

In vivo Mutagenicity
Prenatal Development
Immunotoxicity
Applicator/User Exposure

Human Health Tier III

Chronic Studies
Companion Animal Safety





Straight Chain Lepidopteran Pheromones

**Product
Chemistry**

<150gm/acre





Pheromones in Traps





Risk Assessment

- Hazard
 - Toxicity, Pathogenicity
- Exposure
 - Biopesticide aspects
 - Scale of use, use patterns, application rates
 - Persistence, degradation, mobility
 - Biochemical pesticides occur naturally in the environment
 - Exposure data required only if toxicity concerns are identified
- Risk
 - Non-targets, humans, domestic animals, endangered species





International Harmonization



- PMRA, Canada has published a regulatory proposal: PRO2007-02, 1 October, 2007, Registration of Low-Risk Biochemicals and Other Non-conventional Pesticides
 - Includes information on Submission Process
 - Presubmission consultation
 - Data requirements
- When finalized it will be combined with PRO2002-2, Guidelines for the Research and Registration of Pest Control Products containing Pheromones and other Semiochemicals.

