

# U.S. EPA REGULATION OF CHEMICAL BIOPESTICIDES

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# BASIS FOR REGULATION

- **Federal Insecticide, Fungicide & Rodenticide Act [FIFRA]**
- **Federal Food Drug & Cosmetic Act [FFDCA]**
- **40 CFR 158.2000 – 156.2084**
- ***40 CFR 152.25(f) – Minimum risk pesticides***
- **Pesticide Registration Manual (Blue Book)**
- **Label Review Manual**
- **Pesticide Registration Notices**

# DEFINITION

- **CHEMICAL BIOPESTICIDES** are naturally occurring substances that control pests by non-toxic mechanisms. Included in the category are pheromones, plant extracts, attractants & repellents

# EXAMPLES

- **LEPIDOPTERA PHEROMONES**
- **OTHER PHEROMONES**
- **ATTRACTANTS/REPELLENTS/PLANT VOLATILES**
- **NATURAL INSECT GROWTH REGULATORS**
- **PLANT GROWTH REGULATORS**
- **“BIOCHEMICAL LIKE” SUBSTANCES**

# ADVANTAGES AS STATED BY EPA

- **USUALLY LESS TOXIC THAN CONVENTIONAL PESTICIDES**
- **NARROW SPECTRUM OF ACTIVITY**
- **USED AT LOWER APPLICATION**
- **NO OR LOW PERSISTENCE IN THE ENVIRONMENT**
- **WHEN USED IN IPM PROGRAMS DECREASE THE USE OF HARD PESTICIDES**

# BIOPESTICIDE AND POLLUTION PREVENTION DIVISION

- **ESTABLISHED IN 1994**
- **PROMOTE THE USE OF SAFER PESTICIDES**
- **BIOPESTICIDES ARE SEEN AS POSING FEWER RISKS**
- **USUALLY REQUIRE LESS DATA, SHORTER REVIEW TIMES TO REGISTER (OFTEN LESS THAN ONE YEAR)**
- **REVIEW COST & TIME-FRAME [ \$1,160 - \$46,200] (3-18 months)**

# MINIMUM RISK PESTICIDES (MRP)

- EXEMPT FROM THE REQUIREMENTS OF FIFRA
- THIRTY-ONE DESIGNATED ACTIVES & ABOUT TWO HUNDRED SPECIFIC INERT INGREDIENTS
- INERT INGREDIENTS MUST BE IDENTIFIED ON LABEL
- CLAIMS CANNOT INCLUDE ANY TO CONTROL OR MITIGATE MICRO-ORGANISMS THAT POSE A THREAT TO HUMAN HEALTH OR CLAIMS TO CONTROL INSECTS OR RODENTS THAT VECTOR SPECIFIC DISEASES.
- REGISTRATION REQUIRED BY THIRTY-SEVEN STATES

# REGULATORY STATUS

## BY FORMULATION TYPE / USE

- **MONITORING/SURVEY**

**Arthropod pheromones, (sole active ingredient) attractants, and MRP are exempt from registration**

- **MASS TRAPPING**

**Arthropod pheromones when used for pest control are exempt from registration**

- **KAIROMONAL USE**

**Chemical biopesticides can be used in pest control strategies to mitigate non-pest species and be exempt from registration**



# REGULATORY STATUS

## BY FORMULATION TYPE / USE

- **DISRUPTION**

- Pheromones, irrespective of formulation require to be **REGISTERED**, but when used on food crops certain lepidopteran pheromones are **EXEMPT** from the requirement of a tolerance.

- **ATTRACT & KILL**

- All “A&K” products require to be registered and will be reviewed outside of BPPD. Although the chemical biopesticide may be exempt from tolerance, the toxicant and the inerts must have a numerical tolerance or an exemption

# DECISION TREE

- **PROPOSED CHEMICAL BIOPESTICIDE PRODUCT**
  - **NO PESTICIDE USE , MONITORING/SURVEY**
  - **PHEROMONES & TRAPS**
  - **MINIMUM RISK PESTICIDES\***

**CAN GO STRAIGHT TO MARKET WITH THE EXCEPTION (\*) THAT SOME STATES REQUIRE STATE REGISTRATIONS FOR MRP PRODUCTS**

# DECISION TREE

- **CHEMICAL BIOPESTICIDE**
  - **INITIAL DECISION TO SEEK REGISTRATION**
  - **CLASSIFICATION REQUEST**
  - **PRE-APPLICATION MEETING**
  - **ADDRESS THE DATA REQUIREMENTS**
  - **SUBMISSION – APPLICATION SCREENED, THEN INTO REVIEW, DEFICIENCIES (IF ANY ADDRESSED)**
  - **APPROVAL AND ISSUANCE OF STAMPED APPROVED LABEL**
  - **OBTAIN STATE REGISTRATIONS**
  - **TO MARKET**

# STRATEGY

- **REGISTER A TECHNICAL ACTIVE INGREDIENT PRODUCT AND THEN AN END-USE PRODUCT**
- **REGISTER ONLY AN END-USE PRODUCT USING THE INTEGRATED SYSTEM PROCEDURE**

# DATA REQUIREMENTS

- **PRODUCT CHEMISTRY**
- **TOXICOLOGY**
- **NON-TARGET, FATE AND EXPRESSION**
- **EFFICACY ONLY REQUIRED BY EPA FOR PRODUCTS TO CONTROL PUBLIC HEALTH PESTS ALWAYS REQUIRED BY THE STATE OF CALIFORNIA**

# SATISFY THE REQUIREMENTS

- **SUBMIT A NEW STUDY - see guidelines**
- **CITE A PREVIOUS STUDY IN EPA FILES**
  - data compensation may be required
- **PUBLIC LITERATURE**
- **REQUEST A WAIVER**
  - scientific rationale
- **DOCUMENT A DATA GAP**



# Your partner in the EPA biochemical registration process

## Biochemical pesticides

**Pheromones:**

- Lepidopteran (SCLP) pheromones
- Other lepidopteran pheromones
- Other pheromones
- Pheromone mimics

**Other semiochemicals**

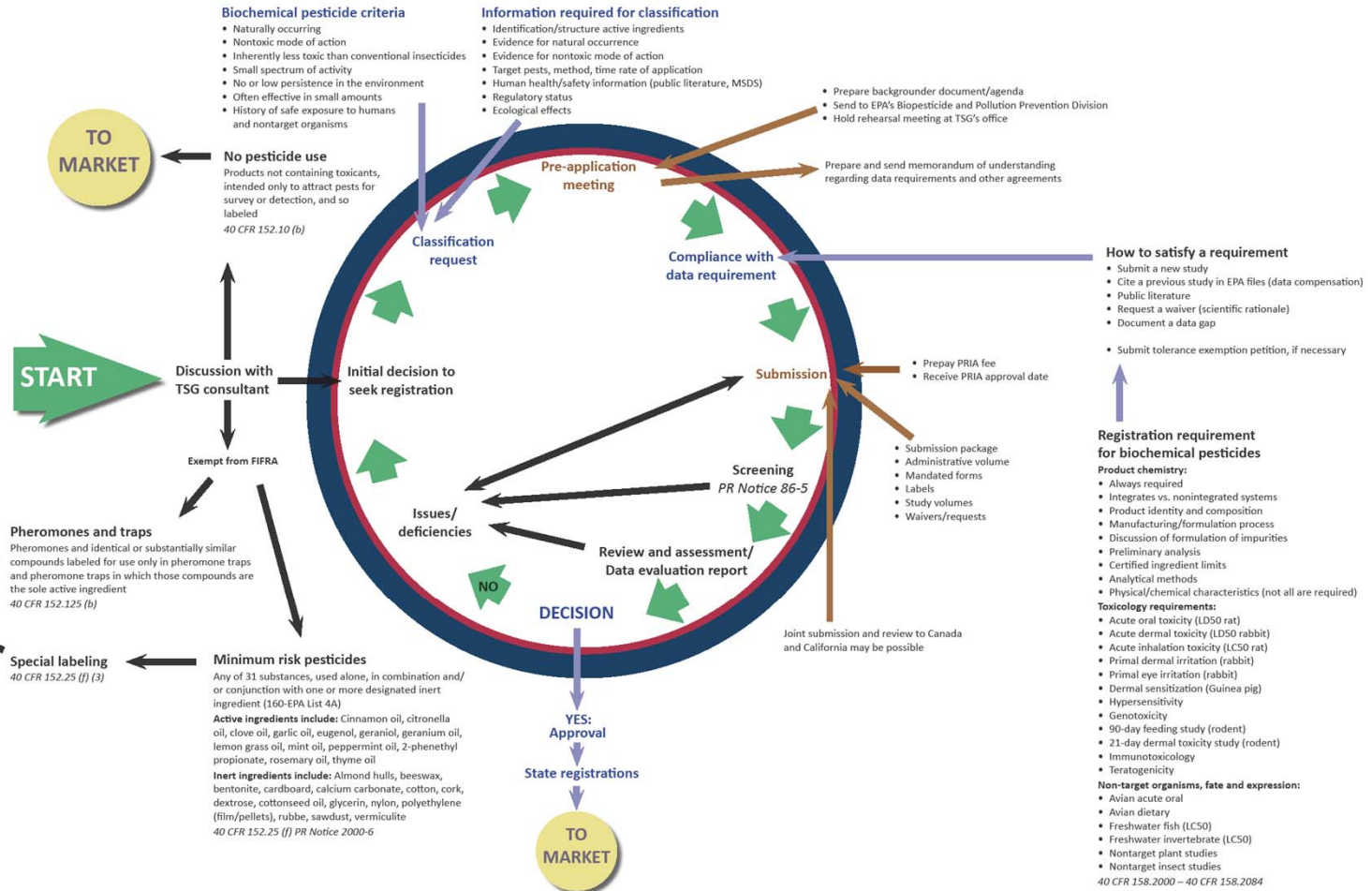
- Attractants
- Repellents
- Plant volatiles
- Direct volatiles
- Essential oils
- Components
- Mixtures
- Single compounds

**Natural IGRs**  
(Azadirachtin, methoprenes, etc.)

**Plant growth regulators**  
(Cytokinin, gibberellic acid, ethylene, etc.)

**"Biochemical-like"**  
(Sodium bisulfate, propylene glycol monoesters)

**TO MARKET**



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