A Historical Overview of United States Pesticides Regulatory Programs

The Evolution of Pesticide Programs

Pesticide Registration

How to seek registration for a pesticide in the United States

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The Evolution of Pesticide Programs

The First Pesticides

- **The first pesticides were inorganic substances that were found to have pest control properties. Some of the early pesticides were:**
- **Sulfur**
- **Salt**
- **Metals**
  - **Arsenic**
  - **Copper**
  - **Lead**
  - **Mercury**

1910 Federal Insecticide Act

- **Chemicals were sold to consumers with the promise of pest control.**
- **Consumers had no way of knowing if the product would work. The Federal Insecticide Act was to protect consumers from products that would not work and required information for pesticide labels.**

1939 – DDT Identified as an Insecticide

- **DDT was the first of synthetic chemical used as an insecticide.**
- **Used to control malaria and typhus.**
  - **Typhus is a bacterial disease (*Rickettsia prowazekii*)**
  - **The vector is for typhus lice. Control is achieved by spraying clothes**
  - **Malaria spread by mosquitoes. Control achieved by spray of walls of homes and broadcast spray.**

Typhus Spray

1947 - Law Changes

- **Fungicides added**
- **Herbicides added**
- **Rodenticides added**
- **The new title "Federal Insecticide, Fungicide and Rodenticide Act"**
- **Regulates product content and labeling**
- **The U.S. Department of Agriculture and Food and Drug Administration implement.**

Spraying Jones Beach, New York with DDT

Advertisement

Concern About Pesticides in Food

- **Section added to the law regulating foods to prohibit carcinogenic substances from being added to food (Delaney Clause)**
- **November 1959 – Cranberry Food Scare**
  - **Cranberry growers applied a herbicide – aminotriazole to the crop before Thanksgiving. Fresh cranberries were removed from the market.**
- **http://www.theatlantic.com/past/docs/issues/95dec/lead/hencran.htm**

Harm? From Pesticides?

Discussion about Hazards of Pesticides

- **Publication of Silent Spring in 1963**
- **Chapters highlight different pest eradication programs.**
- **Wide area spray programs including programs for biting insects (mosquitos and gnats), cotton pests, shade tree pests, were identified as causing harm to the environment.**

Clear Lake California

Clear Lake Gnat

The Clear Lake Gnat - Chaoborus astictopus
Family Chaoboridae

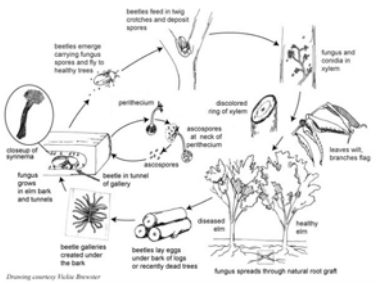
Gnat Problems

- **Drivers could not see.**
- **Drivers had to stop every 0.5 kilometer to clean windows.**
- **Swarms so large that piles accumulated under street lights.**
- **Tourists did not want to go to Clear Lake**
- **DDD used for gnat from 1949-1957**
- **Silent Spring uses Clear Lake as example**

American Elm Trees
Central Park, New York

Dutch Elm Disease

Life Cycle of Dutch Elm Disease



Disease Spread

- Bark Beetle is the disease vector
- Bark Beetle was controlled with DDT or dieldrin.
- Mentioned in Silent Spring (page 105-115).
- Spraying declined rapidly after 1962.
- Control now by cutting off branches and some fungicides.

Earth Day

- First Earth Day, April 22, 1970
- Brought 20 million Americans out into the spring sunshine for peaceful demonstrations in favor of environmental reform
- One million people participated in New York City Earth Day celebration.
- Richard Nixon was President (also opened relations with China).

EPA and FEPCA

- The U.S. Environmental Protection Agency (EPA) was formed on December 2, 1970
  - Takes over pesticide regulatory responsibility from the U.S. Department of Agriculture and the U.S. Food and Drug Administration
- FIFRA was essentially rewritten in 1972 when it was amended by the Federal Environmental Pesticide Control Act (FEPCA).

Real and Potential Risks and No Legal Framework for Action

- Hazards from pesticides included harm to children (phosphorous rat and roach bait resulted in smoking stool syndrome)
- Agriculture would be using more potent insecticides – switch from DDT to cholinesterase inhibiting chemicals.
- FEPCA provides legal additional legal authority to regulate pesticides.
- DDT banned in 1973.

FEPCA Changes

- Changed how pesticides were managed.
- Old law set requirements for content and label of pesticides.
- New law intended to achieve a balance between pesticide risks and benefits.
- Risks to people, wildlife, natural resources to be balanced with the benefits.
- Collect information concerning pesticide production.

FEPCA - Changes

- All pesticides must be registered with EPA-National government.
  - Before FEPCA pesticides could be registered without the approval . States were asked to deny applications (example Lindane-HCB vaporizer)
- Use control.
  - Restricted use pesticides
  - Label must be followed
  - Penalties
- Ways to ban pesticides (cancellation and suspension) streamlined.

FEPCA Changes

- **Defined state roles in regulating pesticides**
- **States could set standards for pesticides users. (7 USC 136i)**
- **States could register pesticides for local needs.**
- **States regulate pesticides.**
- **States may not allow activities prohibited by National Government**

Summary of Key Changes

- **Laws add pesticide use control.**
- **Pesticide manufacture reported.**
- **EPA has the authority to allow only trained persons to use hazardous pesticides.**
- **Some pesticides products restricted to trained users and child resistant packing.**
- **States train and license pesticide users**
- **Penalties for violations of law.**

Examples of Application of Changes

- Suspension of 2,4,5-T
  - Used to suppress the growth of broadleaf weeds in conifer trees.
  - 2,4,5-T was part of chemical mix in Agent Orange, used to defoliate Vietnam.
  - No time to allow for cancellation before spray season (order issued February 28, 1979)
- Prohibition of Predator Poisons (Executive Order). Predator poisons like strychnine, 1080 (sodium fluoroacetate)

More Changes over Time

- **Authority added in 1978 for States to be the lead in enforcing pesticides laws.**
- **Food Quality Protection Act 1996 ended carcinogen prohibition in food. Replaced with "reasonable certainty of no harm".**
- **Pesticides Registration Improvement Acts 2003, 2007 and 2012 increased fees for EPA to provide resources for pesticide registration programs; including staff.**

Pesticide Law Evolution

- **1910 – Consumer protection from mislabeled and fraudulent products**
- **1972 – Product control and also pesticide use control.**
- **1978-2012 – Changes to improve pesticide registration procedures, define state roles.**

Executive Changes

- Coordinated Framework for Regulation of Biotechnology
- Started by the Presidents Office of Science and Technology Policy in 1986.
- Three key points:
  - Focus on the product, not the process
  - Regulation must be on verifiable scientific grounds
  - Laws were sufficient to regulate biotechnology

Regulating Biotechnology

- Three agencies, the U.S. Department of Agriculture, the Food and Drug Administration, and the U.S. Environmental Protection Agency participate in the "Coordinated Framework".

The U.S. Department of Agriculture

A program within the Animal and Plant Health Inspection Services (APHIS) regulates biotechnology. The term biotechnology to mean the use of recombinant DNA technology, or genetic engineering (GE) to modify living organisms. APHIS regulates certain GE organisms that may pose a risk to plant or animal health.

Food and Drug Administration

FDA regulates all food additives under the authority of the Federal Food, Drug and Cosmetic Act. Where novel genes have been introduced or used to produce a novel plant variety

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/biotechnology/ucm096095.htm

EPA Biotechnology Authority

- FIFRA provides the legal requirements for EPA's registration process for all pesticides. With regard to biotechnology, EPA's jurisdiction covers regulation of the new substance and DNA in the plant when it is pesticidal in nature. For example, the substance produced by a plant that has been genetically modified to resist disease or insects.

Plant Pesticides

- Plant Incorporated Protectants (generally insecticides with Bt)
- Viral Coat Protein (disease resistance – papaya ringspot virus)

Summary

- Pesticide regulation has evolved from regulating the content and labeling of products (1910 and 1947).
- Focus changed in 1972 from regulating content and labeling to more reporting and control over use.
- Biotechnology requirements developed by Executive Branch (1986)

Pesticide Registration

How to seek registration for a pesticide in the United States

What is a pesticide?

The term ''pesticide'' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer.

What is a pest?

The term ''pest'' means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals).

EPA Registration Manual

- This manual is an important resource to link to the laws, rules, policies and procedures concerning pesticides registration.
- It is identified in your Reference and Web Addresses supplement as Key Reference 3

Obtaining a Registration for a Pesticide Product

- **An applicant who wishes to obtain a registration for its own pesticide product is responsible for the following:**
- **forms,**
- **proposed product labeling,**
- **technical and scientific data that meet the data requirements related to the specific product the applicant intends to produce, and**
- **A statement of how the applicant will comply with any data compensation requirements.**

Three EPA Programs with Pesticides Registration

EPA has 3 separate programs dealing with pesticides registration.

Conventional Pesticides

Conventional Pesticides which are generally synthetic chemicals used for pest control are handled by the Registration Division

Biopesticides

Biopesticides include:

•Microbial pesticides (Bacillus thuringiensis)

•Plant incorporated protectants (Bt cotton, corn, soybeans)

•Semiochemicals such as pheromones.

•These are handled by the Biopesticides and Pollution Prevention Division

Antimicrobial Pesticides

- **Disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or**
- **Protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.**

These are handled by the Antimicrobial Division.

Process

Determine how the pesticide will be used. This is called "use pattern" and data requirements will be determined by they type of pesticide and the "use pattern".

Major Pesticide Use Patterns 1

Food Crops

Nonfood Uses

- **Terrestrial**
- **Aquatic**
- **Greenhouse**

Major Pesticide Use Patterns Slide2

- Forestry
- Domestic Outdoor
- Domestic Indoor

Propose Directions for Use

- **How much will be used?**
- **When will it be used? How often?**
- **How will it be applied?**
- **Where will it be applied?**
- **See the directions for use (Chapter 11) of the link to the Label Review Manual – Key Reference 4**

Data Requirements

Once the type of pesticide, the pesticide use pattern, and proposed direction for use are developed the data requirements can be reviewed.

Data may be required for the technical grade active ingredient or radio-labeled pure active ingredient, or typical end-use product .

Pre-Meeting with EPA

Once a chemical, use pattern and directions for use are proposed, the next step would be to have a pre-registration meeting. The Agency welcomes requests for a pre-registration meeting. This type of meeting can provide useful guidance regarding information needed for registration. Applicants are encouraged to contact the appropriate branch assigned to the active ingredient in their product before submitting an application for registration.

Who Can Register a Pesticide?

Any person or corporation can register a pesticide. Registrants are responsible for their pesticide and pesticide labeling that are required by FIFRA and EPA regulations.

Registrant Responsibilities Slide 1

- ensure that each production facility is registered and has an establishment number (and ensure that any contractor facility they use is registered) (40 CFR 167.20);
- maintain a U.S. mailing address (40 CFR 152.122(a));
- notify EPA of name and/or address;

Registrant Responsibilities Slide 2

- notify EPA if the authorized agent changes (40 CFR 152.122(b));
- provide information on any adverse effects of a pesticide that have not been previously submitted to the Agency in accordance with FIFRA section 6(a)(2) (40 CFR 152.125);
- ensure that their product labeling is in compliance with FIFRA (FIFRA 2(q) and 40 CFR Part 156);

Registrant Responsibilities Slide 3

- ensure that supplemental distributor products and their distributor product labeling are in compliance with FIFRA (40 CFR Part 152.132);
- obtain permission to transfer registration of a product and/or data to another person (40 CFR 152.135); and
- pay the annual pesticide registration maintenance fees.

Designated Agent in the U.S.

An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing. (40 CFR 152.50)

Templates for Data Submission

- To facilitate review of data, EPA has developed templates for data submission. These templates are on the web.
- Key reference 5 provides a link to Templates for submitting data to EPA.

Information on Pesticide Requirements

•Pesticides Laws: Title 7 of the United States Code, Chapter 136

•Pesticides Rules: Title 40 of the Code of Federal Regulations, Parts 150 through 180.

•Pesticide Registration Manual

•Pesticide Inspector's Manual

•American Association of Pesticide Control Officials (AAPCO) Website

Summary

- **All pesticides must be registered prior to sale in the United States**
- **How the pesticide is to be used determines much of the data requirements**
- **A meeting with EPA is important to verify registration requirements.**
- **Data must be submitted in the format required by EPA.**

References, Acknowledgements and Web Addresses

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- DDT Historical Use
- http://www.epa.gov/pesticides/factsheets/chemicals/ddt-brief-history-status.htm
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- Dutch Elm Disease introduced into the United States around 1930. DDT used to control beetle vector.
- http://kids.britannica.com/comptons/art-141590/An-English-elm-shows-effects-of-Dutch-elm-disease
- American elm trees in Central Park - photo © Mike Rollinger on Flickr http://crawford.tardigrade.net/bugs/BugofMonth38.html
- Clear Lake Gnat Information – From Lake County Vector Control District
- http://www.lcvcd.org/Insects/LCVCD-Clear%20Lake%20Gnat.pdf

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- http://www.theatlantic.com/past/docs/issues/95dec/lead/hencran.htm
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- Lindane Vaporizer Review from Pre-Federal Environmental Pesticide Control Act of 1972
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References, Acknowledgements and Web Addresses

- Key Reference 1
- Link to Title 7, United States Code, Chapter 136 – The Law Concerning Pesticideshttp://www.epa.gov/opprd001/registrationmanual/FIFRA.pdf
- Key Reference 2
- Link to EPA Rules Concerning Pesticides
- http://www.gpo.gov/fdsys/pkg/CFR-2003-title40-vol21/pdf/CFR-2003-title40-vol21.pdf
- Website Link to PDF file establishing the Coordinated Framework for Biotechnology
- http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
- Link to the U.S. Department of Agriculture, Biotechnology Review Services website
- http://www.aphis.usda.gov/biotechnology/
- Link to the U.S. Food and Drug Administration's Biotechnology website.
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- Link to the U.S. Environmental Protection Agency's Biotechnology Website
- http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm
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- American Association of Pesticide Control Officials Letter to the Secretary of the United States Department of Agriculture for continued funding of pesticide recordkeeping inspections
- http://www.aapco.org/documents/VilsackLtr_USDArcdkeepingProg093011.pdf
- Articles on Kauai County Pesticide Bill
- http://www.nytimes.com/2013/10/08/business/fight-over-genetically-altered-crops-flares-in-hawaii.html?_r=0
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- Key Reference 3
- Registration of Pesticides – EPA Registration Manual
- http://www.epa.gov/pesticides/bluebook/chapter1.html#registrant

References, Acknowledgements and Web Addresses

- EPA Index to Pesticide Use Sites and Use Patterns –
- This Pesticide Use Site Index will help a company (or other applicant) apply to EPA to register their pesticide products, by making it easier for them to identify data requirements needed to register a pesticide product. This Index provides information on pesticide use sites and pesticide major use patterns, key information needed to complete the registration process.
- Each pesticide use site is specific to the pesticide, and identifies what the pesticide will be used on or within. For example, the use site identifies crops the pesticide will be used on, or identifies within what non-crop site or thing the pesticide will be used, such as in a building, barn, or airplane. The company applying to register their pesticide is then directed to one or more major use patterns depending on the pesticide use site.
- A major use pattern is a broad designation used in the tables of technical data requirements (defined by law in 40 CFR part 158), to identify which of the requirements might be pertinent to the pesticide use site. The major use pattern is designed to make it easier for those wishing to register a pesticide, to find their data requirements without needing cumbersome tables containing all pesticide use sites. See below, for more information about the tables.

References, Acknowledgements and Web Addresses

- http://www.epa.gov/pesticides/regulating/usesite/
- Link to data requirements
- CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radio-labeled; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.
- http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=74f368ecab3015819dcd73ce072cccb3&rgn=div6&view=text&node=40:25.0.1.1.9.12&idno=40
- Key Reference 4
- Link to Label Review Manual, - Directions for Use
- http://www.epa.gov/oppfead1/labeling/lrm/
- Key Reference 5
- Link to Templates for Submitting Data
- http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist.htm#series-830
- Key Reference 6