University of Nebraska - Lincoln
DigitalCommons@University of Nebraska - Lincoln

Great Plains Wildlife Damage Control Workshop Proceedings | Wildlife Damage Management, Internet Center for

12-3-1985

# PESTICIDE REGISTRATION IN THE UNITED STATES

Dale A. Wade
*Texas Agricultural Extension Service, San Angelo, TX*

Follow this and additional works at: http://digitalcommons.unl.edu/gpwdcwp

Part of the Environmental Health and Protection Commons

Wade, Dale A., "PESTICIDE REGISTRATION IN THE UNITED STATES" (1985). *Great Plains Wildlife Damage Control Workshop Proceedings.* Paper 168.
http://digitalcommons.unl.edu/gpwdcwp/168

This Article is brought to you for free and open access by the Wildlife Damage Management, Internet Center for at DigitalCommons@University of Nebraska - Lincoln. It has been accepted for inclusion in Great Plains Wildlife Damage Control Workshop Proceedings by an authorized administrator of DigitalCommons@University of Nebraska - Lincoln.

# PESTICIDE REGISTRATION IN THE UNITED STATES

**Dale A. Wade**, Texas Agricultural Extension Service, San Angelo, TX 76901

**Abstract:** This review provides an abbreviated history of pesticide regulation in the United States, with a summary of the current registration process and exceptions under the authority of the Environmental Protection Agency and the Federal Environmental Pesticide Control Act of 1972, as amended. Issues related to registration are briefly described.

## Summary of Pesticide Regulation in the United States

**Regulation of pesticides** and their use in the United States began with passage of the Federal Insecticide Act in 1910 which authorized the U.S. Department of Agriculture (USDA) as the regulatory agency although relatively limited control of insecticide use was actually exercised by the USDA under this authority. With passage of the Federal Food, Drug and Cosmetic Act in 1938, the Food and Drug Administration (FDA) became involved and some additional constraints were imposed. The perceived need for more stringent regulation of pesticide use led to passage of the Federal Insecticide, Fungicide and Rodeaticide Act of 1947 (FIFRA-1947) which provided a significantly greater degree of control. However, registration of pesticides under this Act and the authority of the USDA did not require extensive and detailed data on pesticide toxicology, safety, effectiveness, exposure of nontarget species and potential hazards as a consequence of pesticide use. Various amendments to FIFRA-1947 followed, with the USDA continuing as the regulatory agency until December 1970 when the U.S. Environmental Protection Agency (EPA) was created by President Nixon's Administrative Reorganization Plan. Creation of the EPA was quite likely heavily influenced by the President's Council an Environmental Quality (CEQ) which had been created in January 1970 under the National Environmental Policy Act to advise the President on all matters relating to the environment and natural resources.

Upon creation of the EPA in 1970, all USDA authority under FIFRA and the FDA responsibilities regarding pesticide residues on raw agricultural products were transferred to this new agency. However, it was not until passage of the Federal Environmental Pesticide Control Act in October 1972 (FEPCA-1972) that major increases in pesticide regulation began. FEPCA-1972, now more commonly referred to as FIFRA-1972, has been amended several times since 1972 and has caused dramatic change in pesticide regulation. Major differences between FIFRA-1947 (as amended) and FIFRA-1972 (as amended) include, among others, the following:

1. All pesticide used in the U.S. must be registered and approved for use by the EPA.
2. Pesticides believed to cause adverse effects or hazards in the environment may be cancelled and suspended by the EPA administrator.
3. Pesticide applicator certification programs are required.
4. Restricted use pesticides may be applied only by or under the supervision of certified applicators.
5. Misuse of pesticides may be punished by civil and criminal penalties.
6. Enforcement of pesticide regulations is substantially increased.
?. Experimental Use Permits are required for evaluation of potential pesticides in field use conditions.
8. Emergency and special local needs uses of pesticides are closely regulated.

In addition to FIFRA-1972 (as amended), more recent laws affecting pesticide regulations include the National Environmental Policy Act, the Endangered Species Act, the Toxic Substance Control Act, the Solid Wastes Disposal Act, the Clean Air Act, the Clean Water Act and others. The consequence of FIFRA-1972 and the numerous other laws which apply is that pesticides are far more rigidly regulated than ever before in U.S. history. Some feel that current regulations are much too stringent while others believe they are too lenient. Whatever the case, there is now a complex set of procedures and data requirements which must be met under FIFRA-1972 before a pesticide can be registered for use in the U.S.

## Current Procedures for FIFRA-Section 3 Registration of Pesticides

Persons not familiar with current pesticide registration procedures in the U.S. often raise questions and may be highly critical of and frustrated by interminable delays of a registration in which they have interest. Those involved is efforts to secure such registrations may be equally critical of seemingly endless data requirements imposed by the EPA and some state agencies. Relatively few people are fully aware of data requirements that are now mandatory and that, under the authority of the EPA and FIFRA-1972, as amended, pesticide registration has became an extremely complex and costly process. This is particularly true of any pesticide used for control of vertebrate animals, for which the research studies to develop essential data may easily cast millions of dollars and require several years to complete. Table 1 lists the information and data categories which are included in the current review process for a full Section 3 registration by the EPA.

In addition, more detailed and extensive information may be required if a potential hazard is believed to exist to one or more endangered or threatened species from pesticide use. Figure 1 illustrates the steps followed by the EPA where such a hazard is presumed to exist Figure 2 illustrates the major steps followed by the U.S. Fish and Wildlife Service (USFWS) and its Office of Endangered Species (OES) in completing a Section 7 consultation required by the Endangered Species Act of 1973. The Section 7 consultation and resulting biological opinion issued by the USFWS are required and utilized by the EPA in its deliberations.

A pesticide registration application that survives the procedures described may be then granted registration by the EPA, subject to use restrictions which are imposed for protection of humans, nontarget animals and the environment from adverse effects.

Following registration by the EPA under Section 3 of FIFRA-1972, the registration must be submitted for review to the pesticide regulatory agency in the state where its use is intended. Additional data requirements and/or use restrictions may be imposed by the state agency prior to granting a state registration and label for pesticide use.

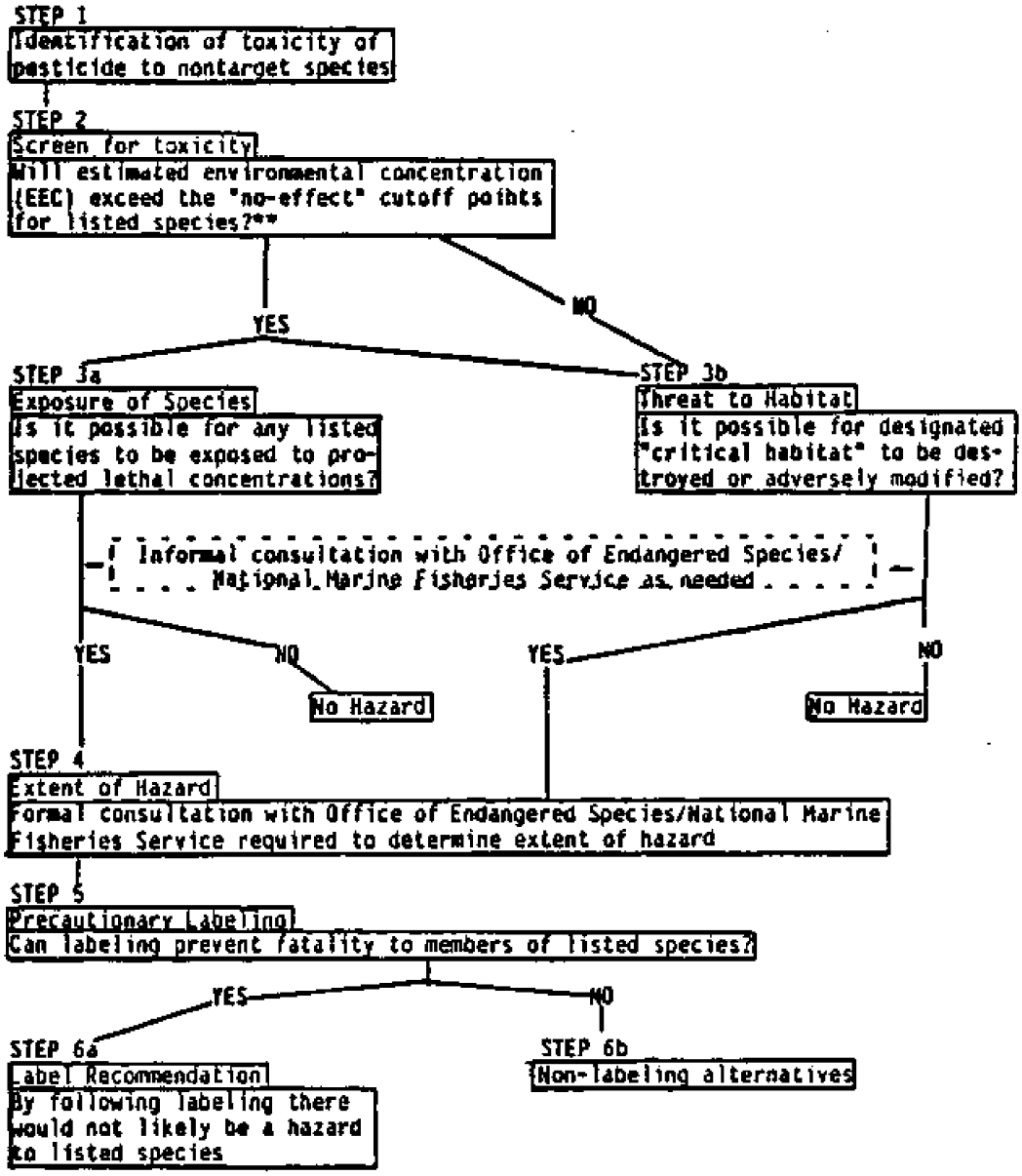
## Current Exceptions to Section 3 Registrations

Exceptions to a full Section 3 registration, which may be granted by the EPA under FIFRA-1972, include a conditional Section 3 registration which permits pesticide use while certain essential data are developed. Other exceptions are experimental use to develop required data under Section 5, emergency use to protect humans and animals under Section 18, and use for "special local needs" within a state under Section 24. However, the relative leniency exhibitied by the EPA during the first decade following passage of PIPRA-1972 to permit use of pesticides under these exceptions has declined; in general, applicants are now being required to supply data for full Section 3 registrations for pesticides which they desire to use. Section 5 experimental use permits may be granted by the EPA to develop

**Table 1. EPA Standard Review Format for Section 3 Registration Submissions.**

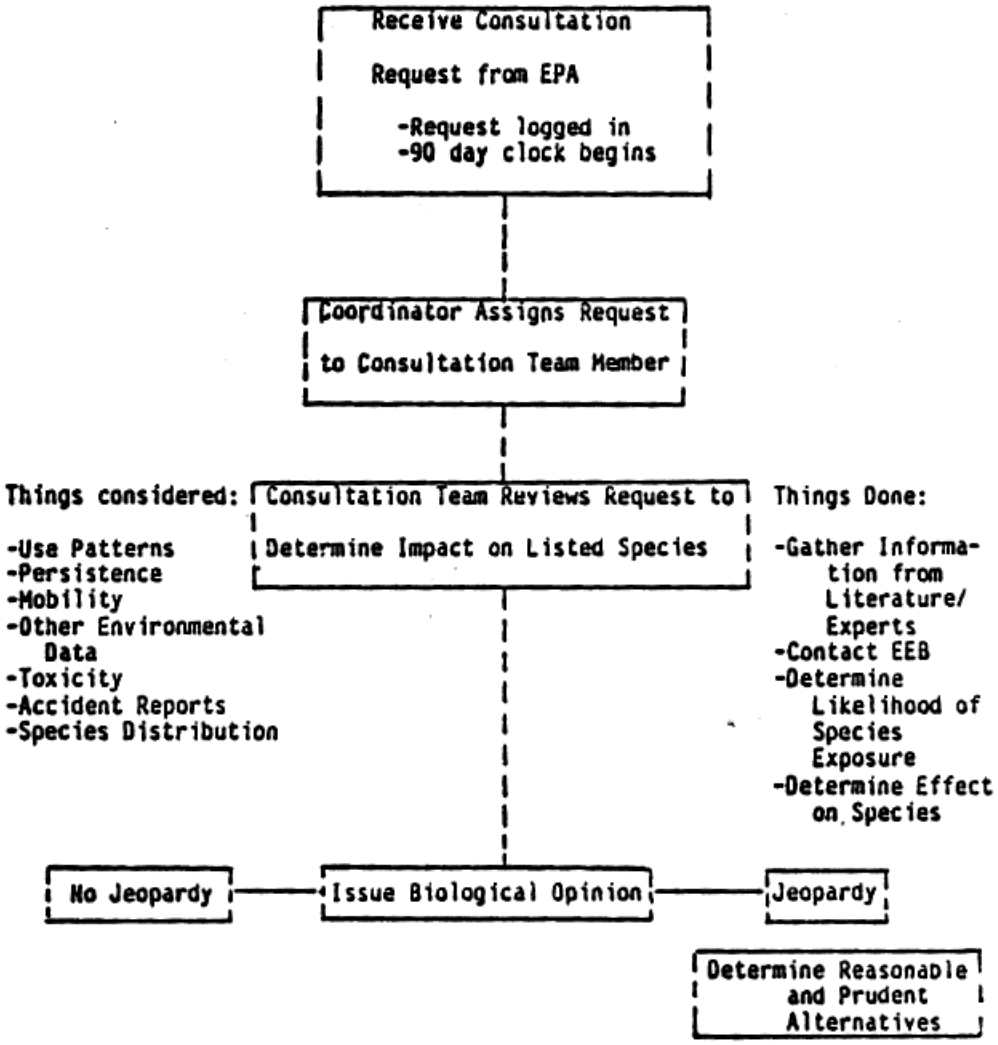
| | |
|---|---|
| Pesticide Name | |
| 100 | Pesticide Label Information |
| 100.1 | Pesticide Use |
| 100.2 | Formulation Information |
| 100.3 | Application Methods, Directions, |
| 100.4 | Target Organism(s) |
| 100.5 | Precautionary Labeling |
| 101 | Physical and Chemical Properties |
| 101.1 | Chemical Name |
| 101.2 | Structural Formula |
| 101.3 | Common Name |
| 101.4 | Trade Name |
| 101.5 | Molecular Weight |
| 101.6 | Physical State (Color, Odor, Taste, etc.) |
| 101.7 | Solubility (include temperature) Water Organic Solvents |
| 102 | Behavior in the Environment |
| 102.1 | Soil |
| 102.2 | Water |
| 102.3 | Plant |
| 102.4 | Animal |
| 102.5 | Microorganisms |
| 103 | Toxicological Properties |
| 103.1 | References from Toxicology Branch |
| 103.2 | Minimum Requirements |
| 103.2.2 | Avian Dietary $LC_{50}$'s |
| 103.2.3 | Fish Acute $LC_{50}$'s |
| 103.2.4 | Aquatic Invertebrate $LC_{50}$ |
| 103.3 | Additional Terrestrial Laboratory Tests |
| 103.3.1 | Avian Reproduction Studies |
| 103.3.2 | Terrestrial Phytotoxicity |
| 103.3.3 | Toxicity to Beneficial Insects |
| 103.3.4 | Cholinesterase-Inhibition |
| 103.3.5 | Toxicity to Reptiles and Amphibians |
| 103.3.6 | Toxicity to Wild Mammals |
| 103.3.7 | Other |
| 103.4 | Additional Aquatic Laboratory Tests |
| 103.4.1 | Toxicity to Estuarine and Marine Animals |
| 103.4.2 | Embryo-Larvae and Life Cycle Studies |
| 103.4.3 | Oyster Shell Deposition Studies |
| 103.4.4 | Toxicity and Residue Studies |
| 103.4.5 | Aquatic Phytotoxicity |
| 103.4.6 | Other |
| 103.5 | Field Tests |
| 103.5.1 | Aerial Drift Studies |
| 103.5.2 | Simulated Large and Small Pen Field Tests |
| 103.5.3 | Aquatic Field Tests |
| 103.5.4 | Terrestrial Field Tests |
| 103.5.5 | Secondary Toxicity |
| 103.5.6 | Other |
| 104 | Hazard Assessment |
| 104.1 | Discussion |
| 104.2 | Likelihood of Adverse Effects to Non-target Organisms |
| 104.3 | Endangered Species Considerations |
| 104.4 | Adequacy of Toxicity Data |
| 104.5 | Additional Data Required |
| 105 | Classification |
| 106 | RPAR Criteria |
| 107 | Conclusions |
| 107.1 | Environmental Fate and Toxicology Acknowledgement |
| 107.2 | Classification Labeling |
| 107.3 | Environmental Hazards Labeling |
| 107.4 | Data Adequacy Conclusions |
| 107.5 | Data Requests |
| 107.6 | Special Notes |
| 107.7 | Recommendations |
| Appendix: | Classification Calculations, RPAR Calculations, Validation Sheets, Endangered Species Formal Consultation Package, Data References, etc. |

**Figure 1. Evaluating risk to endangered/threatend* species from pesticide registration actions by the EPA.**




*also referred to as listed species
**1/5th the lowest mammalian acute oral $LD_{10}$ or $LC_{10}$; 1/5th the lowest avian subacute dietary $LC_{10}$; 1/10 the lowest aquatic acute $LC_{10}$. Where $LC_{10}$, or $LD_{10}$ are not available, 1/10th the mammalian $LD_{50}$ or $LC_{50}$, 1/10 the avian

**Figure 2. U.S. Fish and Wildlife Service Flow Chart - Section 7 Consultation - Pesticides.**



essential data. Currently, EPA administrators appear to have takes the position that requests for pesticide uses for conditional, emergency and special local needs have been excessive and that data for Section 3 registrations should be provided is most cases.

## Issues Related to Pesticide Registration

**Aside** from specific data requirements there are other causes fundamental to the time, effort sad costs required to secure a registration These may include opposition for personal or other reasons by specific interest groups. Some of the reasons described by individuals or interest groups are listed below:

1. Animals were here first, have the same rights as people and should have equal protection.
Z. Animas should not be killed but should be allowed to die naturally.
3. Animals should be guaranteed a humane and painless death.
4. Animal control to prevent damage is both wrong and unnecessary.
5. Animal control disrupts the "Balance of Nature."
6. Chemicals are synthetics produced by man and are "bad" for the environment.
7. Chemicals "upset the ecology."
8. Chemical control of animals is wrong.
9. Chemicals cause disease in animals and/or people (eg. cancer).
10. "Chemicals" are not necessary.
11. People should not eat meat; therefore, chemicals should not be use to protect domestic animals.
12. "Natural organic" foods are safer and better for people than those produced by use of fertilizers and pesticides.

In addition to those persons or groups directly opposed to animal control (with or without chemical methods), individuals and/or groups within the agricultural and pesticide industries may oppose certain registrations. In some instances, this may reflect an intent to reduce market competition for agricultural or other products. In other cases, companies may oppose registration of pesticide formulations which would be competitive to their products. As a consequence, interesting alliances to oppose specific registrations sometimes occur.

Opposition to pesticides frequently leads to political and/or administrative efforts to prevent a registration, to increase use restrictions, to prevent or limit marketing, to prevent or limit uses at state or local levels, to increase the costs of a pesticide, to prevent marketing of products which have pesticides used in their production, and to generate public opposition to the pesticides, their uses and the products therefrom. As a consequence, registrations have become far more difficult to accomplish; therefore, for many pesticides used in small quantities the costs are prohibitive to the manufacturer and/or formulator. The registered pesticides commonly used now and in the past for control of wild vertebrate animals provide examples of "minor use" pesticides which are used in relatively small quantities sad of *the complex* and expensive registration process. In addition, the "Guidelines for Pesticide Registration" (EPA 1985) are both voluminous and instructive in this regard.

Some people may be interested in the rationales for and positions taken in support of or in opposition to various pesticides. For those with interest, a review of the voluminous EPA hearing records and literature related to use of Compound 1080, strychnine and sodium cyanide for control of vertebrate animals in the U.S. will provide graphic examples. Additional references listed below provide a variety of perspectives on these issues.

## Selected References


Cain, S. A., 3. A. Kadlec, D. L. Allen, R A. Cooley, M. H. Hornocker, and F. H. Wag-ner. 1971. Predator Control-1971, Report to the President's Council on Environmental Quality and the U.S. Department of the Interior by the Advisory Committee on Predator Control, University of Michigan Press, Ann Arbor, 207 pp.

Carson, R L. 1%2. *Silent Spring.* Houghton Mifflin Co., Boston, 368 pp.

Dietz, D. H. 1984. Keynote Address-politics of pesticides. Pages 2-4 *in:* Proceedings, Eleventh Vertebrate Pat Conference, D. O. Clark (Ed.), University of California, Davis.

Hood, G. A. 1978. Vertebrate control chemicals: current status of registrations, rebuttable presumptions against registrations, and effects on users. Pages 170-175 *in:* Proceedings, Eighth Vertebrate Pest Conference, W. E. Howard and R. E. Marsh (Eds.) University of California, Davis.

Howard. W. E. 1979. Political and sociological aspects of wildlife damage control. Pages 147-165 *in:* Proceedings, Fourth Great Plains Wildlife Damage Control Workshop, F. R Henderson (Ed.), Kansas State University, Manhattan.

Howard, W. E. and R H. Schmidt. 1984. Biological rationale for 1080 as a predacide. Pages 139-145 *in:* Proceedings, Eleventh Vertebrate Pest Conference, D. O. Clark (Ed.). University of California, Davis.

Leopold, A. S., S. A. Cain, C. M. Cottam, I. N. Gabrielson and T. L. Kimball 1964. Predator and rodent control in the United States. Traps. N. Am, Wildl, Conf. 29:27-49.

MacInryre, A. A. 1982. The politics of nonincremental domestic change: major reform in federal pesticide and predator control policy. Ph.D. dissertation, University of California, Davis, 876 pp.

U.S. Environmental Protection Agency. 1985. Guidelines For Pesticide Registration, U.S.E.P.A., Washington, D. C.

U.S. Fish and Wildlife Service. 1979. Department of the Interior, Final Environmental Impact Statement, Mammalian Predator Damage Management for Livestock Protection in the Western United States, U.S. Dept of Interior, Washington, D.C., 789 pp.

Wade, D. A. 1975. Political factors in animal damage control Proceedings: Advancements in Pesticides, Helena, Montana, reprinted in California Livestock News, Vol. XLX (11):12-19, November 1975.

Wade, D. A. and S. L. Beasom. 1979. The effects of environmental-political factors on predator research. Pages 294-303 in: Vertebrate Pest Control and Management Materials, ASTM STP 680, J. R Beck (Ed.), American Society for Testing and Materials.

Western Regional Coordinating Committee (WRCC-26). 1980. A Response to Secretary of Interior Andrus' Policy Statement Pertaining to the Animal Damage Control Program. Utah State University, Logan, February 15, 1980, 91 pp.