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EPA Registration Requirements for Orchard Rodenticides and The Manufacturer's Development Considerations

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Data requirements for the registration of pesticides in the United States, and other countries, have been increasing steadily over the past 25 years. Requirements have increased fastest during the past 5 years.

Passage of the 1972 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) enacted through the Federal Environmental Pesticide Control Act (FEPCA) in Public Law 92-516 was part of a wave of environmental legislation which completely overhauled Federal environmental regulatory authority. In 1970 Congress passed the Clean Air Act and in 1972, along with amendments to FIFRA, Congress enacted substantial amendments to the Federal Water Pollution Control Act. While Federal regulation of pesticides first began in 1910 and was substantially expanded in 1947, the 1972 amendments completely restructured the Federal pesticide regulatory scheme and refined the thrust. FIFRA was changed "from a labeling law into a comprehensive statute which will henceforth more closely control the manufacture, distribution and use of pesticides."

On July 3, 1975 the Environmental Protection Agency published the revision of procedures for registering pesticides and established procedures for their classification in the Federal Register. This and the Registration Guidelines catalogue the specific requirements which currently apply to registration requirements. The requirements presented here are those pertaining to the registration of a rodenticide for use in orchards.

General chemistry requirements are first and basic to any pesticide registration. The active ingredient chemical must be identified along with the percentage and composition of impurities. Physical properties including specification of appearance, odor, melting point, solubility in water and organic solvents, vapor pressure and particle size are required. Analytical methods must be described for the identification of the neat material and the active ingredient in final products. The manufacturing process must be described including starting materials and their purity, intermediate materials and their purity, and resultant impurities.

Very definative label requirements are specified, but will not be reviewed here. The Confidential Statement of Formulas and Offer to Pay Statement need not be reviewed; suffice to say they are required.

Basic toxicity data are required for all pesticides. Acute oral LD_{50}'s are required for albino rats and dogs using technical material. This is also required for each target species (in orchards pine voles, *Pitymys pinetorum*, and meadow voles, *Microtus pennsylvanicus*), for the technical material and final formulations. Acute oral LD_{50}'s are also required for a number of non-target mammals. Studies are also required on the final formulation to provide human safety data relative to exposure. An inhalation LC_{50} using the technical material is required in rats or dogs. For skin irritation a patch test is required and this is usually on rabbits. An acute dermal LD_{50} is required in rabbits or another mammal. Eye irritation is required and here the rabbit is used most often. For fish and wildlife a LD_{50} is required in bluegills, rainbow trout, fathead minnows, and channel catfish. And last, a dietary LC_{50} is required in bobwhite quail and mallard ducks.

Registration of rodenticides requires data on potential of secondary hazards. To satisfy this requirement, cats and dogs are fed mice poisoned with 3 times the dosage of poison found to be their acute oral LD_{100}. The cats and dogs must not be harmed by these feedings.

Efficacy requirements are clearly specified. The first test is dosage titration on each species to be claimed. After the level of active ingredient required in the bait to effectively kill the pest rodent has been established, paired preference trials are conducted against each target species using individually caged animals. Ninety percent efficacy is required (18/20) to pass. Next, tank tests are run using each target species, and again 90% efficacy must be achieved. Then each final formulation must be tested on each species using the tank test. Again 90% efficacy is required, and if the test is passed, then field trials are required. Two to 5 field trials are required on each species to be claimed in each of the 5 U.S. geographical regions in which the product is to be sold.

A manufacturer must do this work, and much additional work, to develop a rodenticide for use against commensal rodents before considering its development for use in orchards. The market for an orchard rodenticide alone would not justify the development costs of $1-to-2 million and 3 to 5 years of work. After a rodenticide has been successfully developed for use against commensal rodents, other major considerations confront the manufacturer in determining whether or not to develop the rodenticide for orchards or other crop uses.

Successful development of an effective, practical formulation and an appropriate application method must be established before a rodenticide would be approved for development for use in orchards. A formulation must be developed which is acceptable to and effective against pine mice and meadow voles. Apple slices would meet this criterion. However, the bait must also be practical to use, and apple slices certainly are not the most practical. When a formulation is developed, an appropriate application method is needed. Bait stations would be most appropriate because that baiting method would be acceptable to EPA since it would avoid contamination of the eco-system.

Development of a tissue residue tolerance is expensive and time consuming. The first step is radioisotope residue determinations. Assuming some residues are detected, an analytical method must be developed for determining the material chemically. Then a petition must be filed

for temporary tolerance. The additional work required depends on results of various tests conducted. Fate in the environment tests required include a battery of tests, most of which are conducted with radioactive technical materials. These tests include basic soil metabolism, abbreviated soil metabolism, soil metabolism, soil persistance, leaching, hydrolysis and photodegradation studies. Teratogenic, oncogenic and mutagenic studies may be required using technical material in rats. Depending on other results, acute LC_{50}'s may be required using both the technical and formulated materials on shrimp, crabs, and oysters. A chronic dog study is required. Acute oral LD_{50}'s are required in mallard ducks and bobwhite quail, and reproduction studies on bobwhite quail, mallard ducks and 3 generations in rats. Chronic fish (fathead minnow), invertebrate reproduction and dog metabolite studies may be required unless the toxicity of metabolites is low. These studies, depending on how many are required, would cost an additional $1/2-to-1 million and about 4 years of work. Because of this, a manufacturer is not likely to develop a rodenticide for orchard use unless the intention is to develop the material for other crops also.

The classification of products referred to above is based on certain toxicological data. Classification category I is a restricted classification, and the label must carry the statement "For retail sale to and application only by Certified Applicators or persons under their direct supervision." Categories II, III and IV are general use classifications and may be sold as the classification implies.