2-14-1979

IMPACTS OF AMENDED PESTICIDE STATUTES ON REQUIREMENTS FOR REGISTRATION OF PRODUCTS FOR THE CONTROL OF VOLES IN ORCHARDS

William W. Jacobs
U.S. Environmental Protection Agency

Raymond W. Matheny
U.S. Environmental Protection Agency

IMPACTS OF AMENDED PESTICIDE STATUTES ON REQUIREMENTS FOR REGISTRATION OF PRODUCTS FOR THE CONTROL OF VOLES IN ORCHARDS

William W. Jacobs
Registration Division

and

Raymond W. Matheny
Hazard Evaluation Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
Washington, D. C. 20460

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has recently been amended by the passage of The Federal Pesticide Act of 1978 (Public Law 95-396, passed September 30, 1978). While many aspects of the FIFRA have been amended, the changes of most immediate relevance to those interested in developing data in support of products used in the control of orchard voles are the authorities given the EPA Administrator to grant conditional registrations and to waive efficacy data requirements.

The conditional registration authority under Section 3 (c) (7) of the amended FIFRA permits the marketing of certain pesticide products without the submission and favorable review of the full complement of required supporting data. Depending upon the proposed use pattern, the submission of efficacy data is either waived or mandatory for the granting of a conditional registration. Human and environmental safety requirements are not waived in the conditional registration process, but some of these requirements may be deferred until the time of reregistration for the active ingredient(s) contained in the product. The conditional registration process is designed primarily to quickly process registration applications for traditional and new uses of chemicals currently registered. New chemicals found to be in the public interest may be conditionally registered under Section 3 (c) (7) (C) of the amended FIFRA. Until standard procedures for handling the conditional registration of new chemicals are established, such applications will be dealt with on a case-by-case basis.

Each application proposing use of a currently registered active ingredient or active ingredients will be subject to an "incremental risk assessment". An incremental risk assessment is an evaluation of the increases (if any) in risks posed by the conditional registration of previously registered active ingredients for traditional or new uses. For the purposes of incremental risk assessment, some safety and residue studies may be required prior to conditional registration. Such requirements are most likely to be in force when the proposed use pattern would require the establishment of a tolerance and/or would result in the increased exposure of nontarget populations not placed at risk by currently registered uses of the active ingredients.

Section 3 (c) (5) (D) of the amended FIFRA grants the Administrator the authority to register a pesticide "without determining that its composition is such as to warrant proposed claims of efficacy." Under this authority, the Agency is embarking upon an experimental program in

deregulation. This program entails the waiving of efficacy requirements for many use patterns. Efficacy data requirements will remain in force for pesticides used to control pests which either pose direct threats to human health or pose indirect health threats through their transmittal of diseases. Thus, for vertebrate pesticides, efficacy data requirements remain in force for products used to control species such as commensal rats and mice, potential rabies vectors (e.g. - bats, skunks, raccoons, canids), significant plague vectors, and birds in situations in which the potential for spread of disease is a prime reason for desiring control (e.g. - dispersal or elimination of birds from roosting sites). In addition to these public health uses, risk-benefits analyses will be conducted prior to the conditional registration of all candidate products which contain active ingredients which have been canceled, suspended or subject to Rebuttable Presumption Against Registration (RPAR) proceedings. Exceptions will be made in instances in which the risks identified in the Agency's actions are clearly not posed by the newly proposed use.

Under the efficacy waiver policy described above, the Agency will not review efficacy data and will, therefore, not make a finding of product efficacy for products used to control orchard voles. Efficacy requirements will be waived for this use pattern because the damage caused by voles in orchards is primarily economic. The Agency believes that the regulatory mechanisms built into the marketplace and the university and extension systems are sufficient to insure that ineffective products will not enjoy long market lives.

The efficacy waiver policy is experimental. All or some waived requirements may be enforced at any time by the Administrator if a pattern of product failure is reported. If the caliber of product performance research conducted on orchard vole products in the recent past (c.f. - Byers, 1978; Richmond, et al, 1978; and this symposium) is maintained, users of such products may be adequately protected against consumer fraud in the future.

The procedures for the granting of conditional registrations, the making of incremental risk assessments, and the efficacy waiver policy are outlined in detail in the following document:

> Interim Final Regulation Implementing Section 3 (c) (7) Relating to Conditional Registration (40 CFR 162.18 - 1 through 6)

Copies of this document and additional information may be obtained by writing to:

> Registration Division (TS-767)
> Office of Pesticide Programs
> U. S. Environmental Protection Agency
> 401 M. St. S. W.
> Washington, D. C. 20460

References

Byers, R. E. 1978. Pine vole control studies in Virginia - 1977. In Proc. 2nd Eastern Pine and Meadow Vole Symposium. p. 62-71.

Richmond, M., M. Dunlay and R. Stehn. 1978 Efficacy data for baits prepared as candidate orchard vole control agents. In Proc. 2nd Eastern Pine and Meadow Vole Symposium. p. 52-60.