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Criteria for Pesticide Registration

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Satisfactory criteria for registration of vertebrate pesticides, other than for commensal rodents, are largely lacking. Even those that are available have not made their way fully through the bureaucratic processes of EPA.

Recognizing the difficulty of standardizing pesticide registration, EPA in 1973 requested that the American Society for Testing and Materials (ASTM) consider establishing a committee on pesticides for the purpose of writing consensus standards, guidelines, and practice statements. The resulting committee of more than 400 biological scientists and chemists from academia, industry, and regulatory agencies has prepared standards on many phylogenetic areas.

Vertebrate pesticides have received attention of more than 50 international vertebrate ecologists since 1973. Testing standards also have been written and accepted for acute (single-dose) and chronic (multiple-dose) rodenticides, gustatory avian repellents, dog repellents, acute predaclides, acute avicides, and general vertebrate testing procedures. Guidelines for use of such compounds as sodium cyanide in M-44s, sodium monofluoracetate, PA-14, and strychnine as an avicide also have been accepted by the several-thousand-member Society. Pesticide testing standards for bats, field rodents, and others are in process.

There is no pressure upon any regulatory agency or chemical company to accept ASTM standards. These standards have, however, been adopted, revised, and used by several agencies, both state and federal. ASTM standards have been accepted in the Federal District Courts as true consensus documents, because ASTM is a private, non-governmental organization; and adoption of standards required a consensus of all members. USEPA has used all or part of some of the ASTM vertebrate pesticide work in their own standards and enforcement proceedings.

Participation in ASTM-E35 Pesticide Committee is open to any qualified person. There are two levels of participation: members and correspondents. Members pay annual administrative fees and must participate in balloting. (Balloting has stringent protective procedures for substantiated negative votes.) Correspondents review the multitudinous drafts and comment as they wish. They have no financial obligation and may not vote on society or committee ballots.

The Vertebrate Subcommittee (E35.17) meets twice a year and is presently chaired by W. B. Jackson. Review of existing standards is mandatory every fifth year, and present tasks include review of earlier standards. The subcommittee also has sponsored four symposia to update the state of the art. Two have been published; one is in press (November 1981), and the other is scheduled for 1982 in conjunction with the California Vertebrate Pest Conference.

The International Standards Organization (ISO), which coordinates closely with the European Plant Protection Organization (EPPO), also sponsors standards.
These tend to be more species oriented than do those of ASTM, but there has been a free exchange of information and interaction between members of the committees.

Basically, ASTM standards presently tend to standardize concepts by family or order rather than dwelling upon generic and specific approaches. This is accomplished by emphasizing that in most vertebrate pesticide testing the target species must be the ultimate test animal. Screening tests with common or readily available species are encouraged; but there is no substitute for the target species, even if it is hard to manage, cage, or feed. The only concession is to species in very short supply, and then the concession is only to numbers of test animals and replicates.

There is strong emphasis upon both laboratory and field testing, despite the fact that costs are greatly increased. Lab scientists always are inconvenienced and annoyed by the uncontrollable variables inherent in limited field observations and full-scale testing, au naturel. However, the most dismal failures in vertebrate pesticides have developed as a result of shortcutting tests under actual environmental conditions, and the scientists in ASTM are on record that laboratory studies alone are inadequate; and extrapolation of test data between life forms or even closely related species is hazardous. The real marketing and safety test of any vertebrate pesticide or device is, "Can the ultimate user solve the existing problem, thereby establishing both efficacy and economics?"

Rather than being a totally negative issue, at least in the vertebrate pesticide testing arena, revised FIFRA has had a generally salubrious effect on improvement of the end product and inherent safety for both human applicators and the environments where the pesticides are to be used. It has had a very negative effect upon efficacy, as was to be expected.

One major area of concern does rear its ugly head, that of the proliferation of personnel or people who have been dubbed "experienced" and qualified by civil service fiat or licensing examinations. The level of real expertise has dropped as a direct result of more emphasis on "environmental awareness" than organic chemistry, animal behavior (in the field), and "hands-on" experience. In prior years it was unthinkable to have public administrators or company managers who would make biological decisions concerning materials they had never used or species or locations with which they were unfamiliar. Today it is commonplace.

Safe and effective use of vertebrate pesticides still is as much an art as it is a science. It is true, yesteryear's art lacked some essential elements of science; but today's science is often bureaucratically correct but with sterile and mediocre effect, because much of the art has been ignored. It only takes one generation of ignorance to completely lose the true capacity to solve problems.

Rather than propose specific criteria, we have chosen to expose you to a process whereby the ideas of many are shared in a truly democratic arena controlled by the best of prevailing science.
LITERATURE CITED

E 551 - 75 Standard test method for efficacy of acute avicides. 1-5.
E 552 - 75 Standard test method for efficacy of acute mammalian predacides. 6-10.
E 554 - 75 Standard guideline for use and development of strychnine as an avicide. 11-13.
E 565 - 76 Standard test method for efficacy of a single-dose rodenticide under laboratory conditions. 16-23.
E 589 - 76 Standard guideline for the use and development of PA-14 avian stressing agent. 24-26.
E 590 - 76 Standard guideline for the use and guideline for the development of sodium monofluoroacetate (compound 1080) as a predacide. 27-41.
E 593 - 77 Standard test method for efficacy of a multiple-dose rodenticide under laboratory conditions. 42-49.
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