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THE NEED FOR PRACTICAL AND OBJECTIVE TEST PROTOCOLS FOR BIRD DAMAGE CONTROL CHEMICALS

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The registration and reregistration process for vertebrate pesticides is difficult at best and is becoming more complicated and time consuming each year, particularly for bird-damage control chemicals. Although much of the information that is required for U.S. registrations (such as toxicology, general chemistry, and analytical methodology) is beyond our purview at this seminar, there are some areas where research and management personnel can have a favorable impact on present and future requirements of the Environmental Protection Agency (EPA). I am speaking in particular of the methodology used to determine the laboratory and field efficacy of bird damage control chemicals.

Because bird damage control is a rather new science, and still in a formative stage, there is very little available in the literature or in unpublished reports that details suitable methodology for appraising efficacy under relatively standardized conditions. Although EPA and trade organizations have developed a number of protocols to evaluate the efficacy of rodenticides, few exist specifically for bird control agents. This situation is both beneficial and detrimental. It is beneficial in that there is much room for the development of solid and objective protocols by individuals in private and public organizations. Because there are few previous standards to rebut or invalidate, new protocols should meet with some degree of immediate acceptance if based on sound principles. The existing situation also has many drawbacks, however, because without previous test protocols to relate to, the burden of proof as to the adequacy of a test protocol falls on the person(s) developing the protocol. The way is obviously not open to the indiscriminate development of untested or unreliable protocols but only to those solidly based on fact and which result iin objective appraisals.

Test protocols serve varied audiences, each viewing a protocol from a particular and often biased point of view. To the producer, they are a mechanism for obtaining data that can be used to determine the safety and efficacy of a pesticide and eventually its marketability and profit potential. Producers obviously are concerned about getting a product to market with a minimum expenditure of time and money and yet be assured of a product's safety and eventual success.

Users, on the other hand, are primarily concerned with efficacy at a reasonable product cost and with a reasonable degree of safety in its use. Their interests are not in how the data were obtained, but whether they can use the product to satisfactorily solve a problem without unreasonable (direct or indirect) hazards.

Regulatory agencies (state and federal) share many of the users' concerns, since it is their responsibility to verify that the producer's claims are suitably documented and that any hazards associated with use of the pesticide are adequately explained. Their responsibility, however, also includes the areas of quality control and surveillance to insure that the product continues to measure up to claims made for it and that it is not misused. Often, this requires that registered products be reevaluated under existing test protocols. Thus, it is necessary that protocols used in the development process be standardized, so that they can be used by others to determine efficacy. It also is necessary for the user to adhere to use directions, since misuse can lead to tighter restrictions on its use or, in some instances, removal of the product from the market.

Finally, the environmental or conservation audience also has a substantial interest in most registered vertebrate pesticides. This group is primarily interested in the human and wildlife hazards associated with the product and its uses. Many of the current Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulations have resulted from the concern of this group; and although they have no direct responsibilities in the development and use of pesticides, they definitely influence the registration process.

It should be apparent from the foregoing that the process of developing a vertebrate pesticide is the concern of different audiences and that test protocols that are developed must be rigorous and objective, yet practical enough to satisfy the variety of interests associated with the development process.

In January 1973, the American Society of Testing Materials (ASTM), at the urging of the EPA and other public and private organizations, established a committee to develop test protocols for pesticides. The committee (E-35 Pesticides) subsequently was divided into a number of subcommittees to address the development of test protocols, methods, or uses for a number of specific areas, one being vertebrate pesticides (E-35.17), The transition has not been easy for ASTM, because biological test methods are not as exacting as the non-biological or mechanical test methods that ASTM was experienced in developing; and a considerable amount of flexibility has had to be exercised. The E-35.17 subcommittee was subsequently broken into task forces covering the three major areas of concern -- birds, predators, and rodents. Each of these task forces has the responsibility to develop objective and practical test protocols, which when accepted by the subcommittee are then submitted through a progressive balloting process that eventually involves the entire Society. Protocols which are accepted by the Society are then published and become ASTM Standards.

Regulatory agencies are not necessarily required to accept or use these protocols, but the weight and influence they have can be substantial, particularly if a high degree of quality is maintained. This influence is largely because ASTM operates through a concensus process which involves the review of "experts" from many fields. The membership of E-35.17, for example, is about 40 individuals, and includes representatives from a number of state and federal agencies, chemical companies, pest control operators, and others of varied interest. Because an ASTM Standard has to be accepted with no substantial dissent, it presents a position that does not represent any one interest group, but rather one that contains the best that each group has to offer.

The reasons that I prepared this presentation were twofold: first, to inform you of the need for the development of practical and objective test protocols for use in determining the efficacy of bird control agents; and second, to urge your support and help in developing these protocols. The efforts that are expended in protocol development now and during the next few years, by ASTM or other groups, may set forth the requirements that we all might have to live with in the future. It appears that the best interests of the developer, the user, the regulator, and the public (who are the ultimate beneficiary of control programs) will be represented by ensuring that the protocols which are developed are as realistic, simple, and objective as possible.

With continued and enhanced support from individuals concerned with the development of vertebrate control agents, test protocols, with which everyone can live, can be developed to fulfill the needs and desires of developers, users, regulatory agencies, and other interested parties.

DISCUSSION

Besser: You listed 4 protocols that have been developed and mentioned a fifth on perches that had just come up. What areas do you rate for priority six and seven?

SCHAFER There is a need for methods that can be used for efficacy determinations of compounds currently being used (i.e., perch repellents, perch toxicants) that were registered before the existence of EPA. Such compounds were registered with very little data and now need to be reregistered. Test procedures need to be set up and to be evaluated that are accepted by the majority of the scientific community. EPA does not have to accept ASTM Standards; they can accept other standards or no standards; however, because of the scientific expertise that goes into ASTM Standards, they tend to be readily accepted.

Producers need test protocols, too. For example I know of no set testing procedure that has been developed in the past for stickey repellents. Standards will have to be developed.

EPA, by legislative mandate, regulates pesticides by verifying efficacy, safety, and through quality control checks. Test protocols are necessary to provide a basis for EPA registration and regulatory activities.

Besser: I take it that protocols are needed in many areas. Do you hesitate to rate one above the other?

SCHAFER Probably the biggest area is that of field evaluation of efficacy. Not only is it the hardest one to get a handle on, but different types of control agents require different evaluation procedures. Protocols must be subject to modification and need to be adapted to specific circumstances.

Stickley: The term "protocol" seems strange. Can you give an example of what you consider an adequate protocol?

SCHAFER A protocol is nothing more than a standard procedure for evaluating something under a set of conditions that can be duplicated by somebody else,

Stickley: For example, look at Avitrol.

SCHAFER We need basic guides for field evaluation. For example, refer to ASTM E 551-75. This is very general and not addressed to specific toxicants. It was our attempt to communicate some of general areas we felt necessary.

Besser: Al is an expert field biologist. What you're asking for is Al 's input into this protocol.

SCHAFER All research workers should have a real interest in being included in putting test protocols together. Similarly, PCOs and other users need to be concerned if they are to continue having products they can use.