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AN OVERVIEW OF ASTM'S ACTIVITIES IN ESTABLISHING STANDARDS FOR VERTEBRATE PEST CONTROL MATERIALS

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The new FEPCA legislation under which all of us now operate, changes the format and program of pesticide registration and use in the United States. One of the events immediately proceeding this law was the establishment of the United States Environmental Protection Agency, and the necessity for that new agency to develop guidelines and standards for the registration and use of pesticides.

Early in 1973, a large number of persons associated with one or more areas of pesticides, and representing the academic world, consumers, and producing companies, assembled in Philadelphia to discuss with the American Society for Testing and Materials the possibility of developing a committee on pesticide standards. The purpose was to determine if there were interests enough to justify establishing a committee.

During this three day meeting, conferees, almost 400 in number, representing all sections of the United States, heard speakers from the National Agricultural Chemical Association, EPA, ASTM Executive staff, and other groups speak to the needs for guidelines and standardizations. The main thrust of the discussion presented by EPA officials was that it was very difficult under administrative hearing procedures and rules governing federal agencies to develop standards and guidelines which might have the authenticity and scientific support to be representative of all aspects of American society in relationship to the use and registration of pesticides. They pointed out that ASTM has a long history of dealing with the difficult standards in a wide variety of situations, the steel industry, the chemical industry, plastics and more recently even medical transplants have been developed under the aegis of ASTM. The officials from ASTM pointed out that unless sufficient interest developed on the part of the conferees in the establishment of a committee, that ASTM could not undertake to do this itself since it is primarily a source of publication of standards and of the development of those standards and that it is supported by voluntary contributions, and dues of its members, both corporate and private, and the sale of its publications.

It was pointed out in the explanation of the functions of ASTM committees that there must be a balance between producers, consumers, and general interest persons. ASTM's bylaws and corporate papers require such a balance to be maintained through a system of intricate procedures that are too lengthy to detail here. ASTM has for more than 75 years maintained a sophisticated system of consensus standards involving many aspects of government and American life. There are several precedents in federal courts which have clearly delineated the fact that, even though the persons making up ASTM committees have positive and definite bias, that the carefully controlled procedure for the development of standards insures that the ultimate product of the society is as unbiased yet as accurate and scientific a set of standards, for whatever field we are discussing, as exists in the country today.

ASTM standards have frequently been upheld in court in such a manner that they can be accepted by federal agencies as standards since they do not represent the bias or feeling of any one particular group or persuasion of individuals. The conferees to this conference held in January 1973, after hearing the presentation, agreed almost unanimously that ASTM should form a committee to develop pesticide standards and guidelines. The conferees then proceeded to formalize the structure of a committee, choosing several well known individuals in the pesticide field as committee officers. The Committee Chairman at the present time is Mr. A. J. Culver, Jr., who is in the EPA laboratory at Corvallis, Oregon. The Vice-chairmen chosen were Mr. John Tapas, Velsicol Corporation, and Dr. Roy Lovvorn of the United States Department of Agriculture. Mr. Paul Schumann of Drew Chemical Corporation was chosen Recording Secretary, and Dr. Dayton Klingman of the Turfgrass Laboratory at Beltsville for the United States Department of Agriculture was chosen as Membership Secretary. The conferees were then asked to delineate their interest and they proceeded to develop several sub-committees along the lines of biological groupings as they relate to pesticides. There is, for instance, a sub-committee on Plant Disease Control Agents, one on Terrestrial Plant Growth Control, one on Anti-bacterial and Anti-viral Agents, one on Nema-tode Control Agents, one on Aquatic Vertebrate Control Agents, chaired by Mr. C. R. Walker of the Bureau of Sport Fisheries & Wildlife, a sub-committee on Pesticide Equipment, one on Safety to Man and the Environment, and one which we will deal with today concerning Terrestrial Vertebrate Control Agents.

Each sub-committee met and chose a temporary chairman and secretary, and developed plans for a second meeting in June, 1973. The June meeting was held in Philadelphia where each sub-committee began to develop its own organization, and to set up a working outline from which protocols would be developed.

Sub-committee E-35.17 Terrestrial Vertebrate Control Agents has as its permanent secretary Mr. Joe Brooks of the New York State Health Department. I was chosen to be the permanent Chairman at this time. The Committee and Sub-committee officers hold office for a period of two years at a term, with the maximum number of terms prescribed in the ASTM bylaws.

The sub-committee that I represent approved a working outline in June 1973, and proceeded to divide into task force groups for the purpose of developing two kinds of standards. One would be the standard method of test for determining the efficacy of a group of pesticides, and the second would be a standard recommended practice for certain critical pesticides already in common use which, because of their length of use were not required originally to register under any particular set of standards. It is felt that certain of these materials have been used for so many years that efficacy testing at this time would be both difficult and impractical, and that the best approach for the use of these materials would be Standard Recommended Practices. Therefore, standard recommended practices would be limited to a very few critical compounds already in public use.

Presently the Pesticide Committee of ASTM which is called E-35, has very good representation from the producer industries and from general interest people who may be regulatory or academic in their background. There are consumers on some of the committees, but the balance is not as good as it will be. Basically, after the committee was formed and the subcommittees were started, the National Agricultural Chemical Association felt that their interests could be best served by not participating formally as a group in ASTM. Several of their member companies participate, but even though NACA was quite active in the formation of the original committee and its purposes, as a group they do not formally participate.

It is recognized that each group working within ASTM or each individual person that is a member of ASTM or is a correspondent, presents a particular biased position (his own or their own bias). There is no attempt made within ASTM to avoid bias, but rather to temper it by subjecting it to the bias of all of the other groups involved. There obviously must be much give and take within a group or session of this kind. Within the operating framework and guidelines of ASTM, it has been possible to develop to rather a high degree of sophistication, standards that are acceptable to the many groups and biases presented.

ASTM's composition and legal status have been touched upon and one of the main points that should be emphasized is the fact that a federal agency may by law, by court decision, adopt all or part of an ASTM standard as its own, because it has been developed in a truly consensus atmosphere.

The question of who can participate in ASTM committees is a very natural one and the answer is, anybody who has an interest may participate. Sub-committee E35.17 has a rather lengthy list of correspondents who, because of one reason or another, are not interested or able to be ASTM members, but who do wish to contribute. Membership is restricted to those people who are technically qualified in the field of vertebrate animal control agents in one way or another, are interested in paying their dues and in participating in all phases of ASTM activity as it relates to this committee.

Our results to date are that the sub-committee has divided into four Task Forces - Rodenticides, Predacides, Avicides, and Terminology. The Rodenticide Task Force is headed by Rex Marsh of the University of California at Davis, and it is presently working on multiple-dose rodenticides in terms of the standard method of tests for efficacy of that type of rodenticide.

The Predacide Task Force is being temporarily headed up by the speaker, and they have developed a standard method of test for the efficacy of acute mammalian predacides, and a standard recommended practice for the use of sodium cyanide as an acute predacide.

The Avian or Avicide Task Force committee is chaired by Mr. Ed Schaffer of the Denver Wildlife Research Laboratory. That Task Force has developed a standard method of test for the efficacy of acute avicides, and a standard recommended practice for the use of strychnine as an acute avicide.

Dr. W. B. Jackson of Bowling Green State University is the Task Force Chairman for the Terminology group and he has a third draft on Terminology well in hand.

It is anticipated that publication may occur within this year, certainly there will be drafts ready for balloting within the committee. It is anticipated further that any standards developed by this sub-committee will be tentative standards subject to automatic review each year. This probably will be continued for a period of two to three years at which time a workable permanent standard should be fairly evident. Each ASTM permanent standard is automatically reviewed every five years for its applicability to changes and advances in technology. There is no question on the part of anyone who has been involved in the development of vertebrate pesticides that some standardization has been sadly needed for a long period of time.

Forty years ago there was no question but that the leadership within this area was primarily within the United States Fish & Wildlife Service. More recently, the development of many curricula in several of our large major United States Universities, and the experience and development of a large group of people working in vertebrate control research has greatly expanded the area of expertise and the scope and concern of several colleges and universities, and other regulatory agencies within the United States. Therefore, it is perfectly evident that a vehicle for working together to solve some common problems as relates to the standardization of testing for vertebrate pesticides is overdue. It is hoped that all interested parties will take the opportunity to participate insofar as they are able. There is no attempt, nor will there be any attempt, to ram standards down the throats of various commercial companies or testing agencies. ASTM's standards will not become mandatory even if accepted by EPA. However, as in other fields, it is anticipated that ASTM's standards may well represent the best concensus standards available for the particular concerns covered under those standards.

I would like to close my talk by reading a quotation from Mr. Henry J. Korp, Deputy Assistant Administrator with the Environmental Protection Agency, as he spoke to the ASTM Committee last October in Chicago.

"The question of test methodology is of particular concern to my office, of course, because of our function in the registration of pesticides. We are charged by law to insure that pesticides meet efficacy and safety requirements prior to registration, and that we may require data from the applicant to demonstrate that his product complies with these requirements. As you all know, the knowledge about pesticides has increased tremendously in the last decade, and from our viewpoint culminated in the amendments to the FIFRA passed by Congress last year. As our knowledge and regulatory responsibility has grown, so have the requirements for registration which must be met by all applicants. As requirements have tightened, we have received some complaints and many good suggestions from applicants. In particular, our office has repeatedly received requests from pesticide manufacturers to provide more definitive guidelines for meeting registration requirements. As you all know, one of our first priorities for 1974 will be the publication of our revised guidelines for registering pesticides in the United States which we are confident will go a long way towards satisfying this need. We are also planning to follow this publication in the future with an appendix to the guidelines which will contain suggested tests methodology. The work of this committee cannot help but be an asset in this effort, and EPA is most encouraged that we and E-35 are all working towards the same goal." He also continued in the same speech to this effect, "Concern has been expressed by industry in the past that standardizing methodology by ASTM in the pesticide area might be another burden associated with the registration process. Let me digress here and say that there seems to be two opposing schools of thought on standardizing test methods. One group feels that there should be a strict standard requirement for conducting the test needed for registration. The other group wants to maintain a laissez-faire attitude toward test requirements and to decide the merits of a company's data on a flexible case-by-case basis. We do not feel either approach is acceptable. We look at standardized methodology first of all as a help, not a hindrance to a prospective registrant. Standards should be developed and recommended, but we do not foresee a particular standard as being a mandatory prerequisite for registration either. We must insure that a manufacturer's data meets the requirements of the act, and we feel that ASTM standards will be assets not burdens to those developing such data. I believe an important function of this committee and EPA will be to solicit the understanding of concerned parties who are not participating in the work of E-35 regarding the intent of this committee's efforts." That is basically the reason why this presentation is being made at your Conference.