TALK TO FIRST INTERNATIONAL WORKING CONFERENCE ON STORED-PRODUCT ENTOMOLOGY

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Good Morning. I am pleased to have been included in a symposium of this fine conference and to have the opportunity to discuss with the international representation here, even though briefly, the pesticide registration requirements in the United States. I think it is quite important that the rationale for our requirements be understood not only by our foreign friends but that it be better understood by our own consumers.

Like most things in our lives, pesticide registration requirements have come about in a truly evolutionary manner. Many years ago the main concern about a pesticidal product was that consumer got what he paid for - that is, did the product, in fact, dispel or destroy the pest for which it was intended. Then as more products developed, the realization that toxicity was involved became clearer and requirements included considerations of safety, particularly for the user. This evolved into the first Federal Insecticide, Fungicide, Rodenticide Act in 1947, known as the FIFRA, which in effect said that pesticidal products which are shipped interstate must be examined for efficacy and human safety and, fulfilling certain requirements will be registered.

And, again, like other aspects of our lives, technology caused vast changes in pest control. As the population has grown, with an accompanying need to expand crop yield, agricultural uses, including pest control on stored-products, have vastly increased. The pest control arsenal afforded by modern technology abounded to meet the demand. And certainly, these pest control agents have contributed unquestioned benefits to our society.

However, this same technology gave us certain warnings of adverse effects from these agents--their immediate toxicity, their persistence, their degradation products, their mobility, their accumulation in the food chain. These warnings caused alarm, and continue to do so, both in the scientific community and in the public at large. Although regulatory requirements became somewhat more stringent as the arsenal of products grew and the technology of analysis expanded, the existing law, even through several amendments, did not seem to provide the mechanism for making and implementing the prudent judgments necessary to avoid irremediable damage to the environment in which we seek to exist. Thus, it was that the FIFRA was entirely amended in 1972 by the Federal Environmental Pesticide Control Act - known as the FEPCA.

One of the more intriguing aspects of pesticides is that

the material must intentionally be released into the environment if it is to achieve its beneficial effect. Once so released, its later movement and effects are extremely difficult to control. This is considerably different from most situations in which contaminants are released because they have no residual economic value and are merely being thrown away.

In the case of pesticides, it costs money and produces benefits to intentionally place these substances in the environment. They are of no agricultural value until they are so utilized. This circumstance, therefore, makes uniquely important the role of registration in their control. For it is evident that reduction in the amount of these chemicals reaching man and his environment may be accomplished only through two mechanisms: first, by reduced use of pesticides in general, which can be accomplished only with full cognizance and regard for cost/yield relations and through development of new technologies of pest management, or second, by proper use directions and close control to assure use consistent with such directions in the application of present pesticides.

In this new version of the FIFRA, Congress tried to recognize the need for careful judgment in setting the requirements for registration of pesticides, which, in turn, defines the labels under which the pesticides are used -- by stating in the law -- that in performing its function and in its normal and recognized method of application -- the pesticide shall not create unreasonable adverse effects on the environment -- and here is the important phrase -- taking into account the economic, social and environmental costs and benefits of its use. The imposition of this cost/benefit perspective to pesticide regulation complicates an already difficult problem. What it means to us, however, is that our decisions must be reached by using the "rule of reason" as a component part of our guidelines -- in other words, how can a pesticide be used as a useful tool and be given proper directions for use so that it does not create problems and still does the job it was intended to do. We will continually be called upon to consider carefully the trade offs between food production, food contamination, human health, disease control, environmental safety, worker safety, and pest elimination. The choice of pesticides and their regulation will, therefore, be based upon our best evaluation of benefit to hazard -- not on the basis of toxicity of compounds alone.

However, by the passage of this new FIFRA, the law was changed from a labeling program to a truly regulatory program. For the first time use of a pesticide in any manner inconsistent with its directions for use becomes an illegal act, punishable by civil and criminal penalties. For the first time, too, pesticides will be classified for general or restricted use, with those in the restricted category limited to use by certified applicators or by any other restrictions deemed appropriate by the EPA Administrator. Intrastate products as well as those shipped interstate are now subject to registration. In short, this new Act affords significantly strengthened powers to control the fate of pesticide chemicals.

So, where are we in implementing this new law? Congress recognized that the changes incorporated in this package were major. It, therefore, gave the Agency two years to effect new regulations for implementation. The two years are up on October 21, 1974 - ten days from today.

Many facets of the new act are in effect. However, we are a little behind in regulations for registration. It is my understanding that the proposed regulations for registration will appear in the Federal Register next Wednesday. These regulations outline in some depth the requirements for data that must be submitted to support the registration of a product. Soon to follow we will publish a document called, "Registration Guidelines". This loose-leaf publication is intended to amplify the regulations by detailing suggested methods of obtaining these data.

It is purposely being made a supplementary document in order that it may be periodically updated as methodology and analytic techniques change.

The Section 3 Regulations, together with the Guidelines, are the basic requirements for registration and, in turn, for the development of the label and labeling, which, of course, is the end product of registration. These documents will also delineate the requirements for data to support tolerances. For, as you know, a tolerance or an exemption from tolerance must be established for pesticides used on food or feed products in order for the pesticide to be registered.

In general, it may be said that these requirements will be somewhat more stringent than in years past. We are asking to know something about the manufacturing process of the pesticide, for we have found that this can often be indicative of possible contaminants in the pesticide that are sometimes more harmful than the active ingredients. We are also requiring more information on the inert ingredients, particularly as related to the amounts that may be a part of any residue.

Most persons are fairly familiar with the efficacy requirements so I won't repeat them now. However, as I have indicated, in examining the effectiveness of a product, considerable more emphasis will be placed on our knowledge of its environmental chemistry. We are considerably concerned with the life of the product - is it persistent in soil, water, plants, food? Does it translocate? Is it compatible with other chemicals? What is the rate of dissipation? What is the mechanism of degradation? -- Is there photodecomposition in soil, water, air? Is there metabolism from the presence of microorganisms? What are the metabolites? Are the metabolites harmful? What is the propensity of the chemical to accumulate in the food chain? What are the most likely routes into the food chain?

Obviously, some of these requirements are not applicable to pesticides used in stored-products. On the other hand, they may be quite significant in the pesticides used in food handling establishments - such as restaurants, bakeries, mills, canneries, etc. - where the pesticide is not used directly on the food products,

but where aerial residues or residues on working surfaces may get into the pertinent foods. We are continually trying to develop methods for detecting and analyzing the tolerances for such possible residues.

Of course, we continue to require extensive toxicity data to show that the directed use of the product would not be injurious to exposed man or beneficial animals when warnings and cautions are carefully followed. Naturally, the extent of toxicological data required will vary with the nature and proposed use of the product - those for a compound to be used on a food product will be much more than a compound much less likely to get into the food chain. However, we must always consider the safety of persons handling the products and, therefore, we nearly always require acute mammalian studies. Not only by the oral route but also by the dermal and inhalation routes. Particularly is the latter important in cases where the pesticide is used as a spray or fog or dust. For broader applications, toxicity data on fish, wild birds, and even shellfish may be required.

As the possibilities for further contact or ingestion become greater, the more subacute studies are necessary. Here again, more extensive oral, dermal, and inhalation tests must be done. And in food applications where residues, may be considered non-negligible, chronic studies are required - these include genetic studies, teratogenic, mutagenic, etc. If the pesticide is used on animal feed - generally we require reproduction studies. And, of course, great emphasis is now being placed on pathological examination for carcinogenic effects.

All of these data requirements lead to one end. Can the product be effectively used for the purpose intended with no adverse effects on man or his environment if used in accordance with directions? This, then, means that the final product of registration is the label. And with this new Act each label must be marked "General" or "Restricted". Those safe enough for everyone to use will be marked "General". The most hazardous materials, in terms of potential harm to the applicator or to the environment will be used only by those who have demonstrated competence to handle these products properly. Those products will be labelled "Restricted" and will be obtainable only by such competent persons. These provisions, will, we anticipate, minimize misuse, overuse, accidental spills, and improper disposal of pesticide products. The regulations covering the state plans for training and certification of competent applicators is scheduled for publication in the very near future - possibly November 1.

A couple of other features should be discussed in connection with pesticide registration.

One is state registration. As most of you know, states have been permitted to register pesticides independently prior to enactment of the new FIFRA. They are still doing so and will be allowed to continue until our Section 3 Regulations are published. Under the new FIFRA, states which have capability approved by the EPA will be able to register pesticides but only those required

for a special local need. It is evident from the law that Congress intended the Federal Government to monitor pesticides closely because not only does EPA have to examine all present state registrations and consider them for federal registration but EPA must also review each "special need" registration in the future and approve or cause the product to be taken off the market.

It is estimated that there are approximately 15,000 state registered products, mostly in California, Florida, New York, and Washington. Since it will be possible to convert these to federal registrations immediately, EPA has authorized these registrations to remain in effect until each can be reviewed federally, providing the registrant has signified an intent to have the product federally registered. As may be seen, the workload of re-registering, and classifying, our presently registered 34,000 products, plus the 15,000 additional from the states, together with the normal applications constitutes a tremendous task for the next two years.

The other feature that should be mentioned is the matter of experimental use permits. Such permits have always been authorized. But Section 5 of the new FIFRA is much more specific about the procedure and use. The purpose of such a permit is to allow the prospective registrant a full opportunity to test his product within limitations in the realities of actual use conditions - To gather data preparatory to registration. Here, again, we have to reconcile use of pesticides in the environment, about which we do not have full knowledge, with our need to stimulate development of new products. That means we must exercise prudent judgment to minimize the use but not stymie the enthusiasm of the registrant. Regulations for Section 5 are in the last stages of review for publication as final rules, hopefully by November 1.

In conclusion, I want to express our confidence that we are taking the right steps to minimize the adverse effects of pesticide products and through our regulatory involvement and through helping fund activities such as integrated pest management research, we will insure wiser use and fewer mishaps, thus improving the quality of our earth, air, and water resources. But I would be remiss not to say that in this mission we receive much assistance from USDA. Dr. Lyman Henderson, our genial convener, helped greatly in the development of definitions for pesticidal use in food handling establishments and the directions for using crack and crevice treatment in these plants. Right now, USDA is working closely with us to develop means to expedite the gathering of supporting data for minor crop registrations.

EPA and USDA have entered into interagency agreements at the national level to best utilize the capabilities of each agency in analysis of environmental impacts, economic and production effects, and problem solutions. This conference provides an opportunity to better delineate potential avenues of mutual effort. If we in EPA and USDA do not mutually mesh our respective mandates to the benefit of man and the environment, our society as a whole can only stand to be the loser.