me increase in efficiency in obtained, but the increased llection, less than 1 micron oximately doubled the total vever, evaluation of the dust try by the assessment of air-ounts is not an exact science, tion of dust counts with dis-est approximate. In view of s, operation of the micro-flow rate of 0.01 cfm and he resultant particle counts levels of dustiness as speci-get impinger did not appear vere infraction of good judg-rt of the industrial hygienist.

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Industry's Responsibility in the Toxicity Testing, Manufacture, Compounding, and Use of Economic Poisons

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The pesticide chemicals industry recognizes and accepts their responsibility for the effectiveness of the product and for proper safety precautions in manufacture, distribution, and application of the product. A five-stage development program for new products takes full cognizance of the possible toxicity hazards. Safety data for proper labeling and handling procedures are a part of the development.

Introduction

THE BASIC responsibility of the pesticide chemicals industry is to continue the research, the development, and the production of those chemical "tools" of modern agriculture and public health called pesticides, so that the present and the future populations of this country and of the world may have food and shelter and clothing and be allowed to grow and prosper in a healthy environment.

In accepting this basic responsibility the industry also accepts certain other responsibilities. These have to do with the effectiveness of the product and the safety of the product: safety in manufacturing, safety in the channels of distribution, safety in application — and freedom from any unwarranted residue that may be present at the time the crop is harvested.

Plants in the United States are attacked by some 3000 species of insects and equally as many disease agents. Livestock are not directly attacked by nearly so many, but they are seriously attacked by numerous ones including heel fly, horn fly, face fly, botts, lice, mites, mange, and screw worms. Add to this list weeds affecting crops and livestock and, as Assistant Secretary of Agriculture John Baker recently told a committee of Congress, the total loss to American farmers is some $13 billion annually, a sum more than equal to their total net income. This loss occurs even with the widespread use of pesticides.

Now add to this list some 15 billion board feet of saw timber lost because of the attack by the 160 destructive forest insects. This loss is ten times as great as the total loss from forest fires.

As the list mounts, you begin to get the story of the importance of pesticides, the contribution they are making to our economy, and the potential benefits to mankind from their increased use. The pesticide industry is proud of the part it plays in helping to provide the American people with the most wholesome, most abundant, most attractive, and cheapest food on earth.

It is equally as proud of the part it has played in helping the public health official control many of the earth's most destructive diseases.

That we might continue to do our share, we are spending more than 10% of our gross income on research and development. More than 10% of our gross income at the technical level goes back into producing new materials which we hope will be better, more

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effective and cheaper. This is more than is spent by any other industry with the single exception of the pharmaceutical industry.

Development of New Pesticide

There is no rigid pattern of organization or research followed in the development of a new pesticide chemical. There are variations from company to company and from product to product. However, there is a great degree of similarity among all the companies in their procedures for developing new products, since they are all aimed at the same objective, that of establishing the safety and effectiveness of the product under intended conditions of use.

Some companies do most of the research in their own laboratories, covering many scientific disciplines such as chemistry, entomology, physiology, and pharmacology. Other companies contract much of their work out to specialized independent laboratories.

I wish to outline briefly the steps involved in the development of a typical new pesticide chemical, based on the general practices and experiences of a large number of companies.

The development program prior to marketing is basically divided into two major categories — screening and field testing. The industry further divides these two categories into five subcategories as follows: preliminary screening, secondary screening, preliminary field testing, secondary field testing, and full-scale field testing. All these are development stages prior to the sixth stage, which is the actual marketing and commercial use.

A typical industry research program starts with the synthesis of a great many new chemical compounds each year. Each of these syntheses is a small research project in itself, since each is an invention of a new compound. Each chemical is then screened in a special greenhouse to determine whether it possesses pesticidal activity. In addition to internal screening, many companies send samples of newly synthesized compounds to the National Cancer Institute for screening as potential antitumor agents. Some of the companies also send a number of these compounds to the pharmaceutical industry for screening as potentially useful drugs. Of the total cost for a new pesticide, about half is devoted to this initial search.

Only about 3% of the compounds synthesized show enough pesticidal activity to justify further consideration in secondary screening activities. For this phase, the pesticide manufacturer synthesizes a larger quantity of each of the chemicals.

Up until this time the investigations have all been conducted with the assumption that each of these compounds is extremely toxic, and research personnel are cautioned to handle the materials with adequate ventilation and with protective clothing to avoid any exposure. However, at the secondary screening stage, the company is interested in greenhouse testing, and this is necessarily conducted in a manner that creates some limited exposure to research personnel. Accordingly, an estimate of the toxicity of the compound is made. This is an acute, single-dose screening test to permit the company to determine whether it must handle the compound as a highly toxic material or as a relatively nontoxic one. After these studies, the secondary screening takes place, which includes a broader spectrum of test insects, fungi, and plant species; also some estimate of phytotoxicity is made.

There is a high rejection rate at the end of this second phase and only about one of every ten compounds advances to the next stage. At this point, samples of the candidate pesticide leave the confines of the company's research center to be field tested. During this stage of development acute toxicity data are sufficient to permit the manufacturer to recommend appropriate precautions to ensure safe handling, and samples of the candidate pesticides are submitted to one or more land-grant colleges and to the U. S. Department of Agriculture Experiment Stations for actual small plat field testing. Tests are also run on plats on the company's experimental farm. After these tests, a portion of the experimental crop is analyzed for preliminary estimate of residue.

At the end of this phase, the company gives each compound very careful scrutiny. The candidate compounds must meet every qualification of a superior p the investment necessary stage. Chemists and chemi plore all feasible methods determine which is the bes nomical. The company c toxicity studies on test anin formation on the properties and to determine what pr required in the manufactur of it over extended period tests also serve as a basis f amount of residue that wo food crop. Many companie at this stage to the U. S. Service research centers for fish and fowl toxicity. Exp under different weather cor dosage rates, and different undertaken, under a specific arrangement, providing only of crop samples used for Analytical chemists are also development of a sensiti method of analysis to be residue work required for the establishment of toleran ods frequently must be sens per million or less.

On the basis of these re three compounds are usuall variety of reasons. In some is considered too great: in manufacture is too high to attractive; and in others th that the product is no bett ing pesticide. However, if a all the requirements, the co information available to th ment of Agriculture and t Drug Administration, disc grams, and requests expe and/or temporary tolerance proceed with a full-scale gram.

Nearly all compounds ar stage of development even market.

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qualification of a superior pesticide to justify the investment necessary during the next stage. Chemists and chemical engineers explore all feasible methods of synthesis to determine which is the best and most economical. The company conducts subacute toxicity studies on test animals to obtain information on the properties of the chemical and to determine what precautions will be required in the manufacture and application of it over extended periods of time. These tests also serve as a basis for predicting the amount of residue that would be safe on a food crop. Many companies submit samples at this stage to the U. S. Fish and Wildlife Service research centers for determination of fish and fowl toxicity. Expanded field tests under different weather conditions, different dosage rates, and different formulations are undertaken, under a specific crop destruction arrangement, providing only for the retention of crop samples used for residue analyses. Analytical chemists are also engaged in the development of a sensitive and specific method of analysis to be employed in the residue work required for registration and the establishment of tolerance. These methods frequently must be sensitive to 0.1 part per million or less.

On the basis of these results, two out of three compounds are usually dropped for a variety of reasons. In some cases the toxicity is considered too great: in some the cost of manufacture is too high to make the product attractive; and in others the field tests show that the product is no better than an existing pesticide. However, if a compound meets all the requirements, the company makes the information available to the U. S. Department of Agriculture and to the Food and Drug Administration, discusses future programs, and requests experimental permits and/or temporary tolerances so that it can proceed with a full-scale field testing program.

Nearly all compounds arriving at this fifth stage of development eventually reach the market.

Chronic toxicity studies involving the feeding of various levels of the chemical to at least two species of test animals are conducted; and, depending on the use of the product and its properties, a number of other special toxicological studies are also conducted, such as enzyme studies, reproduction studies, and metabolism studies. At the same time, various agricultural experiment stations conduct large full-scale field tests to confirm dosage rates, frequency of application, desired preharvest intervals, and precise residue levels. A specified limited quantity is made available under a USDA experimental permit to qualified growers for application under commercial growing conditions to check performance, phytotoxicity, and other pertinent factors.

The company's analytical chemists also conduct extensive residue analyses at various stages of growth of the crops involved in these field tests to determine the amount of residue which will be present at harvest.

If all the earlier observations are confirmed, the company then forwards these data to the U. S. Department of Agriculture with an application for label registration. If the compound is intended for use on a food crop, data also go to the Food and Drug Administration with a petition for tolerance under the Miller Pesticide Amendment (Section 408 of the Food, Drug, and Cosmetic Act). After government approval, plant construction and commercial use can begin.

From the time a new pesticide is first conceived in the laboratory of the organic chemist to the time it can be marketed, five or more years have elapsed. Regardless of how spectacular the pesticidal activity appears early in the development, the interval from discovery to market cannot be shortened to a period of time less than that necessary to establish safety and effectiveness.

Labeling Requirements

Up to this point my remarks have concerned the elaborate system of checks and balances under which the industry must operate in order to fulfill its basic responsibility. But how is all this translated into a form which the user or consumer of the industry's wares can understand and follow?

By law a pesticide chemical cannot be

marketed in interstate commerce until its label has been registered by the U. S. Department of Agriculture. A careful scrutiny of all the data and other information assembled in the years of development is made by experts in the USDA's Pesticides Regulation Division. The words that appear on the proposed label are also scrutinized, since they must accurately portray the results of all that development in a few short paragraphs — probably the most expensive piece of literature in the world today!

It is therefore most vital that everyone handling or using a pesticide chemical make it a regular habit to read the label on each product carefully and completely and to follow the instructions to the letter. Doing this will ensure satisfactory performance and complete safety.

A pesticide safe-use program is now being offered nationally with the cooperation of the Federal Extension Service and the Farm Department of the National Safety Council. Although safe-use programs have been conducted by this association and other groups for some time, an aggressive, state-wide project was initiated in Florida in 1962 in which all interested state organizations participated on a cooperative basis. This was expanded to a few additional states in 1963 and this year to a national program, using the same basic program aids found to be so successful in the state-wide campaigns.

More than 22,000 copies of a program-planning guide have been distributed to rural youth organizations and other interested active groups in all fifty states.

The campaign is based on the theme "Read and Follow the Label," which is repeated for public consumption through program aids designed to appeal to the eye as well as the ear. The rural youth of America are making this program one of their objectives this year.

Summary

In conclusion, the following main points have been presented:

The industry is keenly aware of its responsibility for pesticides, not only as they are manufactured but also as they are handled, shipped, stored, and used.

Safety testing is incorporated in at least four of the six major areas of product development to ensure safety of the product not only to the handler and/or user but also to the consumer of the crop on which the product is to be applied.

All information regarding the safe handling and use of a pesticide is incorporated on the label of the product, which, by law, must be scrutinized and registered by the U. S. Department of Agriculture before the product can be offered for sale in interstate commerce.

As the Trade Association representing the pesticide chemicals industry, we firmly believe that a strong, wisely administered regulatory program is necessary to accomplish the industry's objectives in its area of responsibility. We strongly support such programs at the state and national level. All the present Federal laws and most of the state laws involving pesticides have been enacted with the support of the industry.

Conversely, we strongly object to legislative proposals, rules, and regulations that harass and hamper the orderly development and marketing procedures which we, as an industry, must surely follow if we are to fulfill our responsibility to furnish health officials and agricultural authorities with the chemical tools they must have in order to fulfill *their* responsibilities.

An atmosphere of scientific objectivity — not emotional hysteria — will greatly assist us to accomplish our tasks, to meet our responsibilities, and to achieve our high objectives in a sensible and wholly creditable manner.

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A brief survey i ments in researc

Introduction

NOISE PRODUCED b tion is now recognized many facets of everyday livi lem is steadily increasing. that high-level noises can hearing, and it has also bee searchers to be a major s many other human ailmen disease, high blood pressur aches, nervous disorders, poo and peptic ulcers have beer All these relationships are cated, and researchers often very basic points. Thus, i have a continuing effort in ards, and legislation to learn effects and to use the avai to the best advantage.

Research

Research on the relatio level to noise exposure a noise control has been car countries[1] during the past There have been no far throughs in this research, b cumulation of information be very useful. Some of th reports that may be of in are listed under references

Standards

A considerable amount done in committees recentl velopment of better stand use in hearing conservatio trol programs.

One pertinent American