FIFRA: IMPACT ON THE INDUSTRY

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FIFRA: IMPACT ON THE INDUSTRY

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates all pesticides marketed in the United States. Statutory and regulatory requirements of the law naturally affect the industry which manufactures and distributes pesticide products. Congress has expressed interest in just how the administration of the FIFRA is impacting the industry as a whole, and particularly the small businessmen involved in the pesticide distribution chain. This paper addresses this Congressional concern, and will discuss the major impacts of the legislation since the 1972 amendments to date, especially those affecting the competitive atmosphere in the pesticide industry.

PROFILE OF THE INDUSTRY

Over 1.4 billion lbs. of pesticide are produced each year, encompassing some 1400 active ingredients. These 1400 active ingredients are contained in approximately 2500 technical products, which are in turn formulated in approximately 40,000 end-use products.

About 400 registrants produce technical material in a given year which is purchased and formulated into end-use products by about 4200 registrants. Some manufacturers of technical material also formulate their own end-use products. Some 90% of the active pesticide producers depend upon the other 10% for supply of the active ingredients.

The industry can be divided into two groups: those who gather their own data, and those who rely on data developed by others. Almost all data developers are large companies which can afford the long-term testing required under the Act. The bulk of the long-term data which form the basis for all these registrations is developed by the approximately 30 companies which contribute to innovative R&D in pesticides in the U.S. Most of these are large, multi-product firms for which pesticides comprise less than 20%, and in some cases less than 1%, of their total sales. Most formulators are small firms which lack the resources necessary to perform the required tests.

RELEVANT ISSUES

The registration regulations and guidelines impose costs through testing requirements; this overall impact has been considered in the preparation of the regulations implementing the registration, reregistration, and classification regulations, and a cost impact estimate of the proposed guidelines was published in the Federal Register on August 22, 1975. This issue is discussed briefly in the Appendix. However, the primary purpose of this paper is to address the two major issues affecting the ability of firms to register products and the amount of competition within the industry:

Availability of Data for Use and Disclosure -- to what extent can and should data developed in support of registration be shared among registrants and available to the public (this issue centers on Sections 3(c)(1)(D), 3(c)(2) and 10 of the Act).

Data Validity -- what is the quality of the data on file with the Agency, and can an applicant receive a registration for a product identical or similar to one already on the market without a validation of the entire data base.

These two issues are discussed at length in Parts I and II of the following paper. Other impacts of the FIFRA include areas where competition could be either stimulated or impaired by EPA actions: research and development, integrated pest management, application equipment and techniques, packaging, and application (commercial vs. private applicators). These are discussed in Part III. Results of some recent and on-going studies are summarized in the Appendix.

PART I
AVAILABILITY OF DATA FOR USE AND DISCLOSURE

Formulators of end-use products desire to purchase ingredients at reasonable prices. So long as a patent covers an active ingredient pesticide chemical, the developer controls the market and the price. Once the patent expires, however, the formulator could expect that other firms would begin to produce the chemical and thus the resulting competition would lower prices. For several years this was the pattern in the industry; competitors obtained "me-too" registration for technical-grade chemicals* after the patents expired.

The trade secrecy allegations recently raised by the data-developer firms have drastically changed this situation. Although a formulator-applicant who plans to use the technical-grade chemical sold by the data-developer can still obtain registration, a formulator who wishes to obtain technical-grade material from a different source will be stymied because his technical-grade source will be unable to furnish him access to the necessary data and he will not be able to obtain a registration. Thus, an essential question is whether the data developer firm should be able to control the market after his patent has expired by denying access to the data he submitted.

Equally controversial is the closely related issue of whether this data should be available to interested members of the public under FIFRA Section 3(c)(2) and the Freedom of Information Act. How these issues are resolved will, to a large extent, determine how the pesticide industry in this country is to be structured, how much the public will be allowed to know about the possible risks of pesticides, and perhaps how much research will be carried out on new pesticides.

EPA's interest in a speedy resolution of the various sub-issues that make up the use-of-data controversy stems from a desire to be able to conduct the registration and reregistration programs in an efficient manner, and to shift Agency resources now occupied with use-of-data matters to more environmentally-oriented tasks.

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* The basic chemicals sold for manufacturing use are often referred to as technical-grade chemicals, and normally contain some amount of impurities, ranging from less than 1% to, on occasion, 20% or more. The impurities are present because of the high cost and technical difficulty of producing commercial quantities of pure active ingredient.

This Agency believes that the issues should be resolved by Congress. This discussion is intended to describe how the controversy arose, and to indicate likely outcomes in terms of the amount of competition (and the range of public disclosure) with or without legislative changes.

BACKGROUND

The controversy has arisen because of the interaction between the patent law, the patterns of development and marketing of pesticides the various provisions of FIFRA bearing on use and disclosure of data, and the changes in data requirements that have occurred.

Patent law considerations.

A patent may be issued to cover a newly-discovered chemical, a newly-discovered use for a previously-known chemical, or a new method for producing the chemical. New chemicals and new pesticidal uses are the kinds of patents with which we are concerned here.

A patent provides that during the 17-year period commencing with the issuance of the patent, no one other than the patent's owner can "practice" the invention without the owner's permission. The owner may license others to practice the invention.

After the 17-year period expires, the patent law provides no further protection; any firm can practice the invention, without needing the prior consent of the patent-holder. This does not necessarily mean that the patent owner has no remaining advantages; he may have acquired valuable "know-how" that he can still license, and he may have acquired marketing advantages due to his long association with the product. However, he can no longer prohibit unconsented competition in the market.

Developers of new chemicals or new pesticidal uses normally make prompt application for patents, to avoid the possibility of loss of rights through publication or independent invention by another. In the case of pesticide chemicals, the patent normally issues well before the developer has established, through long-term testing, that the chemical is safe and effective enough to be registered under FIFRA. Thus, there may be only 12 or so years of patent protection remaining when the initial FIFRA registration issues.

The great majority of the important agricultural pesticides were patented between 1945 and 1965. (Many of the products were developed as a result of military research begun during World War II.) Patents on many of the major pesticides have thus already expired, and more will expire in the next few years.

Patterns of pesticide development and marketing.

Development of new pesticides is not easy. Discovery of a chemical which is both effective against pests and adequately safe for use occurs only infrequently. The research and development costs are great, and must be absorbed by the sale of successful chemicals.

When a firm does develop a promising new chemical and obtains a FIFRA registration, there is every reason for that firm to promote its sale and use during the remaining period of patent protection. The firm will in most cases aggressively seek to develop and have approved new uses of the pesticide (on crops or pests not originally the subject of registration). Extensive advertising of the product is common.

A technical-grade pesticide chemical normally cannot be applied directly for pest control; it must be dissolved, diluted, or otherwise formulated into a product which is safe to the applicator, effective in pest control, and adapted to desired methods of application. The pesticide's developer may choose to formulate the chemical into end-use products himself; he may decide not to engage in formulation, instead reaping his profit from sale of the technical-grade pesticide to firms specializing in formulating end-use products; or he may choose to do both. Likewise, the patent-owner may choose to license other firms to manufacture and sell the technical-grade chemical. Each of these decisions will be made on the basis of profit maximization.

However, each technical-grade product which is to be sold in commerce (by the developer or his patent licensee), and each formulated product, must be separately registered under FIFRA. Each person who seeks registration must demonstrate that the product he will offer for sale is safe and effective. Unless formulators and license-seekers can obtain FIFRA registration for such products, neither patent licensing nor sale of technical-grade product will be feasible. Thus, the patent owner has a powerful incentive to encourage these other firms to use whatever data is necessary for the registration of their products.

Once the patent expires, however, everything changes. There are many firms which might find it economically attractive to commence production of a technical-grade product on which the patent has lapsed, and to sell it in competition with the original developer. Because these firms often do not maintain research operations, or have other cost advantages over the firms who do, they could in many cases undersell the original developer. And all things being equal, the formulators would prefer to purchase the lower-priced technical-grade chemical.

These potential competitors cannot enter the market until they can obtain FIFRA registration for their proposed products. And there is absolutely no incentive for the developer to consent to the use of his data for supporting these competitive registrations--instead, the incentives point in the opposite direction. Indeed, after patent expiration the chemical's developer may desire to curtail whatever competition already exists in the technical-grade market (from those firms which were the subject of patent licenses granted earlier). On the other hand, the developer has no reason to attempt to curtail the number of registrations of formulated (end-use) products, for each formulator represents an existing or potential customer. The developer merely desires to have control over the supply of the technical-grade chemical.

It is perfectly understandable that a developer firm would desire to lengthen the period of exclusive control of production of the chemical beyond the 17 years the patent law allows. This may be especially true when it is remembered that a portion of the 17-year period may have been lost to pre-registration testing.

One can equally easily understand the lack of enthusiasm over this kind of behavior on the part of the developer's potential competitors, those who desire to enter the technical-grade market. From their standpoint, the developer has obtained his due reward under the patent law; now he wants to start all over in reliance on a different kind of protection, that which can be obtained by denying access to the test data required for FIFRA registration. If a prospective competitor can be required to perform duplicate tests as a condition of market entry, in most cases the potential profits will not justify the expense of this duplicative testing and the developer will retain control over production and price levels.

Early regulatory practices and assumptions.

Some of today's problems concerning use of data can be traced to the practices and attitudes developed by both industry and Government during the period prior to the 1972 amendments.

The system of registering each product individually developed under the 1947 FIFRA, at a time when most of the important agricultural pesticides were still protected by patents owned by the major producing firms. For the reasons noted earlier, these firms were anxious to maximize production and use of their patented technical-grade chemicals, and many registrations were issued for formulated end-use products containing these chemicals. It became routine practice for developer firms to allow formulator applicants to rely on the data already on file concerning the composition of the technical-grade chemical.

(This composition data was not publicly disclosed by USDA, which treated it as trade secret.) USDA officials also routinely considered the other data (that pertaining to safety and efficacy) in support of formulator applications, without authorization of the technical-grade chemical's developer. This is understandable in the context of the times, because it normally would have been safe to assume that the data developer was anxious to have the formulated product registered, and to have the formulator as a customer. Moreover, during the early years of administering the 1947 FIFRA, the testing requirements were not nearly as stringent as they became starting in the mid-1960's. Thus, the data barrier would not have been formidable, even if the data developer objected to other firms' use of existing data.

But as time went on, two things changed: long-term testing requirements were imposed, and the patents began to expire. By the early 1970's, firms which had held the patents could see that their control over production would soon expire. These firms suddenly became very concerned about the use of their test data and composition statements by EPA in support of other firms' registrations.

EPA (like USDA before it) had continued to process registration applications on the assumption that it was proper to rely on any test data in its files. (The 1947 FIFRA, after all, made no mention of this practice, speaking only of the confidentiality of the formulas.)

In fact, under the 1947 FIFRA, products were routinely registered without any scrutiny of the underlying data, if there already existed a product registered for the same use patterns. Other prevalent assumptions at the time were also involved. One was that the potential hazard from a pesticide was associated only with the active ingredient of a product, not with the accompanying impurities. This led to the idea that if one firm's technical-grade product containing a particular active ingredient was safe, so was another firm's technical-grade product containing the same active ingredient.

Application of these various assumptions ultimately led to the registration of various technical-grade products made by firms other than the original developer, both those holding patent licenses and those which entered the market after the patent had expired. Many of these "me-too" registrations of technical-grade products now exist; the registrants have never performed their own tests on these products. All these products will be subject to fresh examination at reregistration.

Development of the present statutory provisions.

In 1971-1972, during the debate over the amendments to FIFRA then under consideration by Congress, the National Agricultural Chemicals Association (NACA) urged adoption of a provision that would have required the data developer's consent before test data could be used to support the registration of a pesticide product. NACA argued that the then-current EPA practice of allowing applicants to rely on data developed by the original registrant was causing pesticide firms to abandon their research and development programs. NACA argued that this trend would be accelerated by the public disclosure provisions of the amendments (which ultimately were enacted without change as §3(c)(2)). NACA did not oppose the disclosure requirements, but argued strongly for the "exclusive use of data" approach. The bill which passed the House in late 1971 contained an "exclusive use" provision, and the same approach was initially favored by the Senate Committee on Agriculture and Forestry. However, the Senate Committee on Commerce strongly opposed it, arguing that "exclusive use" would grant the original data developer a practical monopoly for a period extending well beyond the 17-year patent term. The two Senate committees arrived at a compromise that became law as §3(c)(1)(D). It provided that test data was to be available for use by all applicants (mandatory licensing), but required those applicants who had not obtained the data developer's consent to offer to pay the developer reasonable compensation.

In 1975, §3(c)(1)(D) was amended to provide that the limitations it placed on the Administrator's consideration of data did not apply to data received by EPA (or its predecessors) before 1970.

The 1972 amendments made both the public disclosure provision, §3(c)(2), and the mandatory licensing provision, §3(c)(1)(D), subject to one crucial exception: EPA could neither disclose to the public, nor consider in support of another firm's application, data which "contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential."

It is the meaning of this "trade secrecy" exception, and the interaction of it with §3(c)(1)(D) and §3(c)(2), which has served to frame the present controversy. Congress did not define what kinds of data were to be treated as "trade secrets."

The 1972 FIFRA amendments also put an end to the practice of issuing registrations based on "existing use patterns." FIFRA §3(c)(2) requires that EPA state publicly what data supports each registration action. The compensation provisions of §3(c)(1)(D) likewise assume that EPA will know just which items of data were relied on.

The large pesticide producers (the firms which generated most of the test data in EPA files) have argued, first to EPA and now in court, that the term "trade secrets," as used in FIFRA, encompasses any and all test data which the firms have not voluntarily disclosed to the public and which has competitive value. Most of the data has not been publicly disclosed. And the data does have one kind of competitive value: as long as it is considered "trade secret," other firms wishing to compete with the data developer will be practically excluded from the market because of their inability to obtain registration or reregistration. However, in EPA's opinion, it was this very element of value which was intended to be covered by the reasonable compensation plan of §3(c)(1)(D).

The data developers' primary concern appears to be control over the domestic technical-grade market. However, they have opposed not only use of data by other firms, but also disclosure of the data to the public. The sole argument against public disclosure of test data, insofar as EPA is aware, is the possible usefulness of such data to firms seeking to register products in other countries. (Toxicity data is apt to be most useful in foreign registrations. Data on efficacy and environmental chemistry may be of little use, because of the different weather and soil conditions, pest strains, crop varieties, and application methods prevalent in other countries.) Thus, the value of this data for purposes of preserving market shares in foreign countries must be balanced against the right of this country's citizens to critically examine the toxicity data and other information concerning pesticides used here. The Toxic Substances Control Act, it should be noted, requires that health and Safety data on marketed products must be publicly disclosed.

ISSUES REQUIRING RESOLUTION

1. <u>What safety, efficacy, and environmental chemistry data should be available for use by competitors under FIFRA?</u>

The kinds of hazard-related data that must be submitted or cited by an applicant for reregistration or new registration include short-term, acute toxicity studies; 90-day subacute toxicity studies; and often long-term (normally 2-year) feeding studies designed to show whether prolonged dietary exposure to the product produces cancer or other adverse health effects. Such studies are performed using rats, mice, or other test animals. In some cases, depending on the proposed use

patterns, studies must be done of the effect of the pesticide on fish and wildlife, and on the "environmental chemistry" of the product (its behavior in soil, degradation time, etc.). Efficacy studies, showing that the pesticide is useful against pests but not unduly harmful to desirable life forms, must be furnished. Finally, in the case of products for use on agricultural commodities, or to which livestock or poultry will be exposed, studies must be performed dealing with such things as how the chemical is metabolized (chemically changed) by food plants or feed animals, studies of pesticide residues which result from the product's use, and studies showing the waiting periods which must be employed after use of the pesticide to avoid unacceptably high pesticide residues in food plants, meat, poultry, milk, or eggs.

EPA has taken the position that it was Congress' intent to make this information subject to the mandatory licensing procedure of §3(c)(1)(D), and that Congress did not therefore intend that data of these types should be regarded as trade secrets. 1/* However, most of the major pesticide firms have commenced litigation alleging that this data is trade secret. If these firms are successful, and the test data is held to be immune from the mandatory licensing provisions, true competition in the technical-grade pesticide market in the future will be greatly diminished. The expense and delay incident to duplicative testing may effectively preclude market entry; only those firms which "own" the data, or are able to come to terms with the data owners and obtain permission to rely on the data, will be able to either enter or stay in the market.

If Congress desires not to promptly encourage competition, it need do nothing; the present law will continue in effect, and the cases will wend their way through the courts. During the year or more that the litigation will require, EPA will be able to register only those products which have the blessing of data developers. EPA anticipates that it will prevail in the litigation, but this result cannot be guaranteed.

On the other hand, if Congress desires to resolve the matter promptly in favor of increased competition in the production and sale of technical-grade pesticides on which the patents have expired, it should amend FIFRA §3(c)(1)(D) by deleting the prohibition on the Administrator's consideration of trade secret data. This will facilitate competitive registrations, whether or not the data may be publicly disclosed. 2/

* Footnotes are found at the end of the paper.

2. <u>What safety and efficacy data should be available for examination by the general public?</u>

This Agency firmly believes that Congress, in enacting FIFRA §3(c)(2) in 1972, intended to make it possible for interested members of the public to examine the actual data which is submitted in support of the safety and efficacy of registered pesticides, and therefore to encourage public understanding and criticism of Agency decision-making as well as to increase the knowledge of risks and benefits of pesticide use.

Public disclosure to supporting test data is fully consistent with the licensing-and-compensation scheme of §3(c)(1)(D). Disclosure of data does not in any way diminish the right of a data developer to be paid reasonable compensation for the use of the data by another. In fact, by allowing a prospective user of the data to examine it, disclosure of the data would facilitate data-sharing and would make more likely the negotiation of acceptable compensation terms.

Some have suggested that only summaries of this data should be disclosed. This would not assist those interested in assessing the validity of the data; it is the detailed data which must be examined if public scrutiny is to serve any useful purpose.

EPA's position is that trade secret status should be routinely afforded only to truly secret information concerning manufacturing processes (and, perhaps, to the list of deliberately-added inert ingredients in formulated, end-use products). The remaining data needed to support a registration, including the data describing the toxicity of a product, its environmental behavior, and its efficacy, should be routinely available to the public once registration has been granted. This approach would be consistent with that recently adopted under the Toxic Substances Control Act.

The procedural aspects of data disclosure are nearly as important as the substantive issue of which data may be disclosed. The present law, which requires disclosure of all data except that which is trade secret (but does not define what data <u>is</u> trade secret), encourages judicial review. At present, most of the large data-developing firms are engaged in litigation seeking to enjoin EPA from disclosures of data. Some of these firms are arguing that they are entitled to a complete evidentiary trial in court to establish the facts concerning the confidentiality and the value of each item of data in question. It is EPA's position that the data is publicly available as a matter of law, i.e., that the statute, properly construed, requires disclosure of the data. However, if EPA does not prevail on that issue, full evidentiary hearings will be the result whenever EPA proposes to disclose any item of data against the data developer's desires.

If Congress desires to clarify the matter in favor of disclosure, it should amend FIFRA 10(b) to state that all data pertaining to the properties, safety, behavior, or efficacy of a registered pesticide is publicly available, except for those specific portions of an item of data identified by the submitter as information which, if disclosed, would divulge details of secret manufacturing methods or quality control procedures having competitive value to the data developer.

3. Should information concerning the impurity content of technical-grade pesticide chemicals be available for use by prospective competitors and disclosure to the public?

Some large data-developing firms have recently argued that toxicity test data pertaining to one firm's product (even if it is not trade secret) is simply irrelevant, in a scientific sense, to the question of the safety of another firm's product containing the same active ingredient, because of the possible presence in the second product of toxic impurities. Thus, they allege, Firm B should be required to perform a complete battery of toxicity tests on its product, and should not be granted registration on the basis of tests on Firm A's product. If accepted, this argument would tend to severely limit competition in the technical-grade pesticide market.

Traditionally, toxicity testing has focused on the possible adverse effects of the pesticidally-active ingredient which composes the bulk of a technical-grade chemical. (Most toxicity testing is performed using technical-grade chemical as the substance fed to test animals.) However, this Agency has become increasingly concerned about the possible adverse health effects attributable to the impurities that are present in technical-grade chemicals. These toxic effects may be either of an acute or chronic nature. Certain dioxin compounds (present as impurities in some herbicides unless very careful manufacturing precautions are taken) are among the most acutely toxic substances known, and also have chronic adverse effects. Some nitrosamine compounds, present as impurities in various pesticide products, are highly potent carcinogens, and there are other highly carcinogenic pesticidal impurities. It is likely that this concern with impurities' toxicity will continue to grow as more becomes known about their presence in pesticides.

Because of this concern, EPA has concluded that in the future its registration decisions must take into account the toxicity of possible impurities that may be present in marketed quantities of pesticides. Applicants will be required to state the maximum limits for the various impurities that they will allow to be present in marketed products, and the Agency will base its health evaluations in part on the impurity limits the applicant furnishes. Enforcement action will be taken against firms whose marketed products are found to contain impurities in excess of the limits the applicant prescribed in its application.

The various toxicity studies required for registration differ in their ability to demonstrate the toxicity of impurities. A highly acute toxic impurity may demonstrate its effects even though it is present in a test substance at very low concentrations. On the other hand, the long-term animal feeding studies (especially studies designed to show the possible carcinogenicity of the pesticide) probably are only marginally useful in demonstrating the safety of impurities. For one thing, these tests are, for reasons of economy, designed to produce evidence of possible toxicity by use of relatively small "test populations" of animals; to do this, it is necessary to provide the test animals very high daily dosages of the technical-chemical test substance. But the test substance is, of course, mostly comprised of the active ingredient. Impurities are often present in the test substance at very low concentrations, and therefore a finding that tested animals showed no chronic adverse effects may demonstrate very little about the toxicity of the impurity even though it says a great deal about the safety of the active ingredient. Higher dosages of the impurity might demonstrate that it is indeed chronically toxic.

Moreover, any given sample of a technical-grade chemical, including the lot used as the test substance in long-term feeding studies, may happen to be free of impurities that would be found in other lots of the same firm's technical-grade product. In short, a "negative" long-term feeding study is much more persuasive of the safety of the principal active ingredient than of the innocuousness of the various possible impurities in the marketed product.

Limitations on availability of test facilities, as well as cost considerations, make impracticable the theoretically-desirable requirement of complete testing of impurities. EPA's hazard evaluations of impurities will sometimes have to be made in the absence of hard data, and will have to be based in some cases on the presence or absence of chemical characteristics known to be indicators of hazard.

Assuming that, using modern hazard criteria and evaluation methods, EPA has concluded that Firm A's technical-grade product (with its certified impurity limits) is safe enough to warrant registration or reregistration, how should EPA respond when a potential competitor, Firm B, requests registration for its own technical-grade product containing the same active ingredient? As already noted, Firm A may argue that EPA should deny registration until Firm B has thoroughly tested the new product. There is some merit to this argument, if one assumes that Firm B's product will contain more or different impurities than Firm A's. A new battery of tests just might demonstrate that Firm B's product is more toxic, because of impurity differences.

There are, however, counter-arguments, aside from the obvious limiting effect on competition that required new testing would have. First of all, Firm A's own product may contain impurities that were not present in the test substance used for Firm A's tests; thus, the logic of the alleged need for testing by Firm B would lead one to conclude that Firm A must also perform a complete new set of tests on his current product.

Second, it will be remembered that the safety decision concerning Firm A's product was based on an EPA evaluation of the likely hazard of all the impurities that Firm A indicated might be present in its product as marketed. If EPA could be assured by Firm B that its product's impurity levels would fall within the limits already found safe with respect to Firm A's registered product, the hazard decision would be easy to make. However, Firm B cannot easily make this certification unless it is able to ascertain what those approved limits are and whether its quality control methods allow it to conform to those limits.

Under the present law, EPA cannot routinely disclose information on the formulas of products. Such formula information would be available to Firm B only in the event that Firm A, when queried, is unable to demonstrate that the formula is in fact "secret" or unable to show likely competitive harm in the event of the formula's disclosure. Each such determination must be made individually and can be appealed in court, where Firm A would probably be entitled to a full evidentiary hearing. Because of the startling advances in analytical methodology, most commercially-useful formula information is probably not truly "secret" anymore; but establishing this in court can be an arduous process under present law.

Accordingly, if Congress desires to encourage competition in the production of technical-grade pesticides, it should amend FIFRA §10(b) to make clear that, as a matter of law, EPA may routinely disclose to the public the impurity limits which a firm has stated may be present in commercial quantities of its technical-grade product (or at least those that pertain to any product no longer protected by a U.S. patent).

EPA believes that requiring disclosure of impurity content would also serve the general public's interest in knowing which chemicals reach the environment as a result of pesticide use.

PART II

DATA VALIDITY

Before registering a pesticide, the Administrator is required under §3(c)(5) of the Act to find, among other things, that the product will not pose "unreasonable adverse effects" on man or the environment. In order to apply this standard prior to registration or reregistration, the Agency must determine:

- how much data are required in order to make a §3(c)(5) finding;
- to what depth should those data be reviewed prior to a reregistration decision; and
- in registering a product, is the Administrator making a determination that the active ingredient is not posing an unreasonable adverse effect, or that the individual product -- considering that the environmental burden of that active ingredient is actually posed by the aggregate of all products on the market -- will pose an unreasonable adverse effect. In other words, should the Agency consider the whole hazard of the active ingredient, or consider the incremental hazard of the product for which registration is pending.

All these considerations are important to the competitive situation among pesticide registrants, and particularly to pesticide formulators who do not submit their own data to support product registrations. With full reregistration, and the accompanying data review, being stretched years into the future, the Agency is at a critical juncture in deciding how to treat applications for pesticides which utilize active ingredients that are also found in products already on the market.

If, on the one hand, the Agency requires all the data on the active ingredient, the formulator may find it impossible to comply, since some of the data may never have been generated by any registrant. Meanwhile, since the Act contemplates that registrants already on the market should have time to gather missing data, they enjoy a distinct competitive advantage. Even if a formulator can cite data submitted in the past, it may be that EPA will be unable to validate the data for reregistration purposes for three or more years. Because of the Agency workload, it would not be reasonable to take the data in question out of its scheduled review sequence; but neither is it desirable to inform an applicant that his application cannot be processed for three years. From his standpoint that would be unreasonable.

On the other hand, the Agency could permit new registrations of products utilizing active ingredients already on the market until such time as all products containing the active ingredient are scrutinized during the reregistration process. This option would favor a competitive situation within the industry; further, it can be argued that this option would not jeopardize environmental quality in that it is the active ingredient as a whole from all sources of its use which is or is not posing an unreasonable adverse effect, and thus all products containing that ingredient should be evaluated at the same time. The legality of the latter option has been questioned by one Congressional Committee. The Agency is pursuing development of an approach incorporating conditional registration. This consideration is at the heart of the resolution of the so-called "double standard" problem: should products registered under the 1947 Act have the advantage of remaining on the market while their data base is being verified, when identical or similar products are denied access to the marketplace until the 1972 FIFRA standards are fully met. Congressional affirmation of the Agency position would help break the registration logjam.

BACKGROUND

Why has data validation become an issue and what does it mean in terms of competition?

The original reregistration program was based on the assumption that data on file were accurate and reliable and had been reviewed internally in a thorough manner according to still valid scientific principles. The section 3 regulations thus made a distinction in the data requirements for new registrations and reregistrations in order to ease the administrative burden of reregistering 30,000+ pesticides (by October 1976). While a full range of data would be necessary to support an application for a new registration, a much more limited range of data would be sufficient to support an application for reregistration. It was felt that given a product's prior registration and its use history, the §3(c)(5) safety finding would be adequately met until full compliance with the data requirements could be achieved.

To ensure that reregistration would proceed in an orderly and systematic manner, products were grouped into batches on the basis of similarity of formulation and broad use patterns. At a scheduled time an entire batch would be called in for reregistration. In addition, active ingredients were assigned to one of five categories based on a review of data to determine simply whether data existed to meet the data requirements: Category I, all data requirements filled; Category II, long-term data gaps; Category III, short-term data gaps; Category IV, rebuttable presumption against registration (RPAR) (presume not to reregister); Category V, unreviewed. Because of our assumption that the data were generally reliable, the review did not actually

examine the quality of the data on hand. A preliminary call-in schedule for the batches and a list of active ingredients in the five categories were published in the Federal Register on February 17, 1976.

However, as reregistration began, it became increasingly apparent that the distinction between data requirements for new registrations and reregistrations was creating serious inequities for producers of new products. Registered products could be conditionally reregistered and marketed pending the completion of long-term testing but identical new products could not be registered without full submission of data, some of which have not yet been developed. To alleviate this situation to some extent, the Agency issued a General Statement of Policy - Data Requirements for Registration in the Federal Register on May 27, 1976. This notice provided for the conditional registration of new pesticide products which were identical or substantially similar to currently registered products which had been reviewed and found eligible for a full or conditional reregistration (that is, products with no data gaps or only long-term data gaps). Products not identical or substantially similar to presently registered products still required the complete submission of data prior to registration. Like full and conditional reregistration, conditional new registration relied fundamentally on the reliability of the data in Agency files.

However, early in 1976 new information came to light which questioned the assumptions of the registration and reregistration process. Senate hearings, discussions with GAO and FDA concerning the reliability of certain data submitted to FDA, and a subsequent preliminary report of an independent toxicologist on a sample of pesticide data raised serious doubts about 1) the adequacy of the testing in EPA files, and 2) the completeness of the Agency's own review and follow-up. Since then, in December 1976, the staff of the Senate Subcommittee on Administrative Practice and Procedure has issued a report stating that the Agency has, in fact, been negligent in its public duty by not reviewing all data in depth prior to reregistration.

In August 1976, reregistration was halted because the Agency decided it was now necessary to actually review the data in our files. There are several important consequences of the Agency commitment to this review.

. The May 27, 1976, policy statment is basically inoperable, because all products are back in Category V (unreviewed). New products utilizing chemicals already on the market are thus not eligible for conditional registration, since the supporting data are not reviewed.

. Reregistration will take far longer than was originally anticipated. A recent zero-based program analysis indicates that, at current resource levels, the task will take 10 years or more.

. It is no longer reasonable to have different requirements for registration and reregistration. Policies which would have worked during a short transition period will not be equitable in a lengthy transition. The removal of the distinction between registration and reregistration requirements has also been recently required by a recent Federal District Court injunction.

. Because of the large amounts of efficacy data which are on file, considerable resources would have to be dedicated to complete validation of those tests. EPA believes that except for public health and disinfectant type products, the user community can best judge a product's efficacy, based on local conditions and pest resistance. Because of this and because a manufacturer would not find it in his best interests to go to the expense of registering a product which did not work, public resources can most effectively be put to use in hazard rather than efficacy evaluation of products other than public health/disinfectant uses.

. The length of time necessary for reregistration and the complexities of handling individual registration actions resulting from the trade secret disputes have led the Agency to the conclusion that a new approach for regulating pesticides in this country is in order. Specifically, Agency resources could best be utilized if devoted to intensively reviewing technical products rather than end-use products.

CURRENT PENDING DECISION

Currently registered products may remain registered and on the market pending completion of data review and registration; in this respect, they are not seriously affected by data validation problems. Similar new products are in a much more difficult situation. On the one hand, we could ask registrants of new products utilizing old chemicals to provide all required data. On the other hand, we could just request data corresponding to the difference (e.g., new target pest, new site, new method of application, new formula, etc.) between the new products and those already on the market. The choice of one of these two general options (or some combination of each) will have a significant effect on the structure of the pesticide chemical industry.

IMPACTS OF TWO BASIC OPTIONS

Option 1: Require full data submission or data citation for every application for registration.

. For individual pesticide producers, this means that where long-term data gaps exist new applicants will not be able to register products similar or even identical to those which current registrants are selling for several years. While current registrants are able to continue to market such

products for up to three years while the data gaps are filled, there will be no data for a "new registrant" to cite and it will not be impossible for him to complete required tests should he be willing and able to do so.

- For the industry as a whole, the requirement of full data submission will, to a large extent, preserve the status quo. Those now marketing registered products will continue to do so. But few new competitors, in particular small formulators, will be able to enter the market for at least three years, and probably much longer than that.

- Registrations for minor uses will be impeded.

- The total environmental burden of particular pesticide chemicals may remain substantially the same until assessments of their hazards can be completed. However, current registrants are limited mainly by the elasticity of demand, and their own capital formation abilities, from substantially increasing production and sales. Thus, the environmental burden of a particular pesticide may be more directly affected by marketing strategies than regulatory controls.

- On the other hand, the approach provides the greatest assurance that each product will be assessed for safety thoroughly before entering market.

Option 2: Generally require full data for new chemicals. However, for old chemicals, require only the data pertinent to the incremental differences between the new product registration and those already on the market to achieve conditional registrations. Products thus conditionally registered would have to meet the full requirements of the amended FIFRA when the active ingredient as a whole is evaluated during reregistration.

- "Double standard" would be removed; all products containing the same active ingredient would be treated fairly.

- Competition would thus be served in that a barrier would be removed for registrants of "me too" products and other new products formulated with old active ingredients.

- The interests of the environment can be served in that a) the environmental burden of the chemical may not, it can be argued, be appreciably increased by encouraging competition for the existing market or by legalizing minor uses; and b) the decision as to the environmental safety or being posed can most efficiently and systematically be made on the chemical as a whole.

- The legality of such a conditional registration scheme may be open to question. FIFRA does not specifically provide for conditional registrations; its silence on

this subject could be interpreted to mean that the Agency should not proceed in this direction.

AGENCY POSITION

The Agency believes it is in the best public interest to devote its currently scarce resources to assessing the effects of pesticide chemicals from a generic standpoint rather than laboriously processing thousands of individual product actions. This approach, would

- focus attention on the broad risks and benefits of any pesticide, encompassing all uses and all formulations;
- limit the primary data compensation arena to registrants of technical, rather than end-use, products;
- provide a simple registration mechanism for formulators who utilize an already-registered technical material, in which only data pertinent to the individual product which has not already been submitted to support the technical registration would be required, which would thereby
- free EPA reviewers from complex paper work and record keeping so that resources could be best utilized in assessing the larger risk and benefits issues.

Regardless of whether the Agency maintains the current product-by-product approach, or adopts the generic chemical approach, there will be a transition period of many years before all data are validated and reregistration is accomplished. What to do with new applications during this time is crucial to the competitive situation in the industry. Generally speaking, the Agency subscribes to the philosophy articulated in the second option above, i.e., that it is the incremental hazard which should be assessed during the transition period, and that registrants of like products generally should be treated alike. Our overriding concern will be to answer several fundamental questions:

- will the product pose a risk additional to that posed by products already on the market?
- if so, are data available on the additional hazard?
- has an RPAR or intent to cancel notice been issued on the active ingredient?
- is there a known inert or contaminant problem?
- will public health or the environment benefit by denying the product access to the market place, or would denial simply affect the structure of the industry?

SPECIFIC TREATMENT OF CLASSES OF APPLICATIONS

Application For New Chemical

. Generally, all data required by Section 3 must be present.

-- For exceptional circumstances on a case by case basis -- in reliance on the chemical structure of the pesticide, the exposure expected from use of the pesticide, and short term indicator tests -- a conditional new registration may be granted where one long term study has been completed with negative results and the second is underway.

Application For Old Chemical, Old Use Pattern ("ME-TOO")

. Register product if all requisite data are submitted or cited (with appropriate permission or offer to pay reasonable compensation) for active ingredients not subject to an RPAR or intent to cancel notice.

. Provide a conditional registration when long-term data are missing, so long as registrant provides or cites short-term data (and offers to pay reasonable compensation if applicable) supporting registration of product already on the market which is not subject to an RPAR or intent-to-cancel notice. Full data requirements will have to be met by all like products at the time of reregistration.

. Conditional registration may be granted if active ingredient is an RPAR candidate, since the risk has not been validated and in any event is not greater than that already being posed by like products already on the market.

Application For Old Chemical, New Use Pattern

. Registration will be granted if all required data are submitted or cited (along with permission or offer to pay where applicable).

. Conditional registration will be granted if

-- long term data are missing but all short term data are submitted or cited;

- data supporting the efficacy and safety of the new use, i.e., the incremental difference between the already registered uses and the proposed new use, can support a §3(c)(5) finding;

- if a food crop is added, pertinent data required to support a tolerance under the Federal Food, Drug, and Cosmetic Act must be provided if a tolerance is not already established; and

- the active ingredient is not subject of an RPAR notice or notice of intent to cancel.

- Products utilizing active ingredients which are in the RPAR process will be eligible for conditional registration but the burden of justification for the §3(c)(5) finding for the use will bear more heavily on the applicant.

The Agency believes that this approach would be conducive to eliminating many of the current regulatory and statutory roadblocks to registrations as formulators and other new registrants of products utilizing chemicals already in use could enter the market on the same footing as old registrants. This would eliminate the "double standard" by equalizing registration requirements for products containing the same active ingredient.

POTENTIAL CONGRESSIONAL ACTION

The Congress could either sanction or disagree with the Agency position through a specific statement in the law or the Committee Report regarding Congressional intent on conditional registrations. The Agency would welcome discussion and instruction in this area.

PART III

OTHER IMPACTS

The primary impacts on competition of FIFRA and its administration by EPA were dealt with in the previous two sections. Those were primarly negative impacts, and ways to alleviate those negative effects were described. This section describes five other areas where effects can be identified -- on new product research and development, on integrated pest management, on application technology, on child protective packaging, and on users and applicators.

NEW PRODUCT R & D

How has FIFRA affected new product research and development? A look at history shows that most new product research and development has been done by larger firms. Therefore, although small businesses are not presently a major factor in the innovation of new chemicals, it does not appear that FIFRA has contributed significantly to this situation. 3/

Although some firms have left the pesticide research and development field in recent years, about an equal number have entered the field. High profits and profit potential have kept the industry interested. 4/ There has been some trend to consolidation of business in the larger firms. Since few small firms have ever been in the field, however, this trend is making very little change in the situation. Chemical research and development, synthesis, screening, production, and marketing have always required some substantial size for success.

As suggested by studies conducted by outside organizations for EPA and the investment community, 5/ as well as by EPA's own contacts with the regulated industry, the pesticides industry expects that opportunities for innovators to be fewer in number than in the past, but that a big success will be relatively more spectacular. In addition, the industry will continue to build on its existing research and development base with changes in use patterns and formulations of previously-registered products, and new chemicals within already successful classes of compounds.

One segment of the industry, however, is adversely affected by increasingly stringent regulatory requirements -- those firms currently or potentially pursuing products with inherent limitations on market size. This applies to pesticides for minor crops, to biological controls (predators and pathogens), and to such chemical agents as insect growth regulators, pheremones, attractants, repellants, antimetabolites and antifeeding agents. Many of these products are attractive from an environmental point of view because of their low volume of use, specificity of action to a small number of species, low toxicity to humans and other non-target organisms, and lack of persistence. 6/.

But to determine these desirable characteristics requires testing costs of a magnitude similar to products with much larger production and profit potential. The Agency is able to waive all or part of the $10,000 tolerance petition fee if the applicant can show financial hardship or if waiving of the fee would be in the public interest. Considering product development costs running into the millions of dollars, it cannot be expected that waiving tolerance fees would be much of an inducement to potential developers of such products.

INTEGRATED PEST MANAGEMENT

Integrated Pest Management (IPM) is an approach to pest management that utilizes all suitable techniques and methods in as compatible a manner as possible, to maintain pest population at levels below those causing unacceptable economic or aesthetic injury. It usually employs a means of scouting or monitoring; use of "action thresholds" to trigger treatment; consideration of the dynamic interactions among pests, weather, parasites or predators, and costs of treatment; consideration of a series of strategies; and selection of the most appropriate tools, with high priority given to long-term human health and environmental concerns.

This is an area where opportunity exists for the entry, expansion and prospering of small businesses. The primary responsibility for the development and promotion of IPM lies with USDA, but the Agency's actions could encourage or discourage the growth of IPM. Therefore, it is worthwhile to examine the consequences for small businesses and competition from a growth in IPM.

Characteristics of the IPM Industry

IPM is a knowledge industry. It operates by collecting and analyzing information about crops, pests and their interactions, and providing guidance for actions by the growers or managers of agricultural crops, structures, parks, lawns, rights-of-way, etc. Practitioners come by their knowledge via long experience in the field, by formal training (associate degree to Ph.D.), informal in-house training courses or a combination of these.

There is a high degree of decentralization of the delivery of services, since advice, to be useful, must be tailored to the particular circumstances prevailing at the growers' sites. However, some demonstration projects have utilized centralized data analysis, in order to incorporate weather projections and other data more amenable to a regional approach (eg., the Purdue system for alfalfa, the Michigan State University system for apples, and a model for cotton at the University of California.)

IPM is currently fairly labor intensive because of the reliance on scouts in the fields. Some technology is evolving to reduce this reliance, such as satellite or airplane surveillance for presence of plant pathogens or weed infestations, but there are limits on this development -- there will probably always be a need for scouts in the field, not only for the detailed information they can produce, but to act as an effective human interface between the provider of the information and the grower users. Likewise, there are opportunities for more efficient means of information collection and processing, but IPM represents a small move away from the current trend in capital intensive farming.

In considering the potential acceptability of IPM, it should be noted that the infrastructure and traditions exist in some areas (eg., in California, where private farm advisors have become established, consistent with the high degree of regulation of agricultural activities), but IPM services delivered by private parties would be seen as a new idea in other areas.

There is some set-up cost involved in developing and testing out IPM techniques. This work has primarily been carried out by university and USDA sponsored researchers, but some small firms have been successful in developing their own techniques and adapting those developed with public funds. In addition, some pesticide manufacturers have developed parts of IPM programs as vehicles for the commercialization of their products (such as the information provided by the Zoecon Corporation for effective use of their insect lures.)

These characteristics create an environment particularly suited to small, localized firms, providing services via high-labor and low-capital mechanisms, and dealing in information and innovation.

Experience to Date

Government sponsored or run programs have predominated, reflecting the unique capabilities of the land grant system for developing and proving out new ideas of use to the farmer. Among the scouting and pest management projects examined by APHIS and EPA, the program participants experienced a decline in pesticide use and production costs, and increases in yield and profits, and must therefore be deemed successes. 7/

Studies conducted for EPA's Office of Research and Development on farmers' considerations of risk have indicated the preferability of information, as opposed to insurance or other mechanisms, as a means for reducing growers' uncertainties. 8/ In this context, pest infestation information and other components of IPM programs can be cost effective means for maintaining profits and productivity, while reducing environmental exposure to pesticides.

Results from a Ph.D dissertation from the University of California suggest that the spread of IPM can best be promoted by focusing support on the providers of information (as opposed to the users of the information.) 9/ Governmental policies to encourage an expanded supply of information services might include price subsides to the information providers, training of potential IPM practitioners, or cooperative development of pest management techniques for particular crop/pest situations. Although the limited crop and geographical bounds on that study restrict the ability to generalize from it, it is worth noting, however, that this finding is consistent with the long-established practice of USDA providing area specialists to deal with particular crop production problems.

Over the past few years, numerous pest control advisors or farm management firms have achieved recognized success. 10/ Success is measured not only in their own financial well-being, but in their ability to improve their clients' profit situation.

EPA Mandate

Conduct of the pesticides registration scheme requires EPA to understand IPM well enough to make intelligent regulatory decisions. In addition, Section 20(a) directs EPA to conduct a research program, giving "priority to research to develop biologically integrated alternatives to pest control." Finally, Sec. 4(c) directs EPA to provide information on IPM to those pesticide users requesting it.

EPA Actions

EPA is evolving a statement on its stance and programs on IPM, with particular attention to the research needs and where the research should be conducted. EPA is looking into the development of IPM in urban settings. EPA is also providing materials potentially useful to persons interested in applying IPM to their pest control problems to USDA, for distribution through the Cooperative State Extension Service. IPM will be considered among alternative pest control practices in RPAR, cancellation and suspension decisions. Through its research, information distribution and regulatory actions, EPA intends to help create a climate that is conducive to the further development of a healthy vigorous system of private providers of IPM services.

APPLICATION TECHNOLOGY

The Agency feels that its actions may also have an effect on the portion of the pesticide industry which is concerned with application technology. EPA regulations should stimulate changes in methods of application, since more efficient application can reduce the amount, and therefore the risks, of pesticides applied. This is not a big push, but the pressure is there. The industry seems aware of the need to refine application techniques, and users, of course, are interested.

As an illustration of the potential savings involved, it has been estimated that for a typical application of an agricultural foliar insecticide, 40% of the quantity applied winds up away from the target area through drift, misapplication, volatilization, leaching and surface transport. Another 15%, although falling in the target area, does not land on the target crop. Of the remaining 45%, only 4 % is typically applied near the target insect, and the bulk of that makes no contact with the insect. Thus, less than 1% of the amount applied is absorbed by the insect through contact, inhalation and ingestion. The details are different for different crops and pesticide types, but sizable opportunities exist for reducing the quantity of pesticides applied without sacrificing any benefits through the reduction of drift, improvement of placement within the target area and attracting target pests to pesticide deposits. 11/ Innovations in recent years include ultra-low volume (ULV), microencapsulation and time-release formulations and their attendant application equipment; chemicals and devices for improved baits, lures and traps; and other improvements stemming from an increased understanding of the aeronautical and physical principles underlying pesticide applications. 12/

Any market created for innovations in application methods need not be restricted to large companies. Small firms are as viable a source for new approaches to research, development and production of application equipment as are larger firms.

CHILD PROTECTIVE PACKAGING

The Agency is planning to publish proposed child protective packaging regulations early in 1977. Use of child protective packaging will enable some products to be used in the home that otherwise would not have been available. These are products with an inherent toxicity making them candidates for restricted use.

A recent study showed that the total annualized incremental cost of child protective packaging will be less than $6 million, which is less than 8 cents per container subject to the regulations. This cost should not be a serious problem for manufacturers or formulators, particularly since it means that these products can be kept in the home market. 13/

Developers and vendors of child protective packaging and closures include a variety of large and small firms. The regulations will expand the market for special packaging and both large and small companies will be stimulated to compete on the basis of innovative designs, price, and performance.

USERS AND APPLICATORS

Certification and training of applicators, as a condition on the use of restricted use pesticides, is not expected to deny agricultural users the benefits of such products, nor to make them more dependent on commercial applicators than in the past. The certification and training program has ample provision to allow such agricultural users to qualify as private applicators.

Section 3(c)(5) provides that the Administrator "shall not make any lack of essentiality a criterion for denying registration of any pesticide." This allows multiple products to be introduced to compete for the same use patterns. When considering products for cancellation or suspension, EPA weighs the costs and benefits of the products' uses, particularly the effects on productivity in the affected agricultural sector. A cancellation decision typically has different impacts on agricultural users in different parts of the country, and some minor uses may be adversely affected. Where cancellation occurred, the Agency's judgment was, however, that these disadvantages were outweighed by the advantages of the cancellation. 14/

Some products intended for home use will be available only as restricted use products, although the exact numbers depend on re-registration decisions between now and October 1977. This probably will cause some increased reliance on professional applicators in these instances, creating some benefit to that sector of the industry. Contacts with the professional applicator industry show optimism that classification of pesticides into restricted and general use will be good for business.

APPENDIX
STUDIES

Several studies done in recent months have given the Agency a more accurate idea of the side effects of our actions and some suggestions for how the negative effects might be lessened.

ECONOMIC IMPACT OF REGISTRATION DATA REQUIREMENTS

EPA is in the process of revising the Guidelines for Registering Pesticides, proposed in June 1975. Concurrent with the development of the Guidelines is an assessment of the cost impacts of the testing requirements. EPA estimates on the Guidelines as proposed in 1975 amounted to an incremental one-time cost of $68 million. 15/ Industry's own estimates have been much higher. A recurring problem has been to identify what increased costs are due to data requirements made progressively more stringent in the 1960's and 1970's and which are attributable to the Guidelines themselves. As the Guidelines stood in mid-1976, the incremental one-time costs were roughly estimated at $97 million or $29 million annualized over a 5 year period. As the Guidelines reach the point of re-proposal in 1977, the costs will be summed up and reported.

INCENTIVES AND DISCENTIVES

A study has recently been completed on incentives in the pesticide industry. A working conference took place in October 1976 and EPA received the final report in January 1977. 16/ The study concluded that although action by EPA, USDA, and the industry cannot be expected to bring about a major change in pest control innovation, EPA and others could take some incentive measures to improve the likelihood of pest control research and development. Steps recommended for implementation as soon as possible included specific actions to:

* Decrease regulatory hindrances to research and development
* Reduce the risk of product development by industry
* Increase the availability of minor use pesticides
* Lengthen patent life
* Advertise safety on product labels
* Increase use of integrated pest management
* Increase information and training for pesticide users.

A STUDY OF SMALL BUSINESSES

A study was conducted in 1975 for the Experimental Technology Incentives Program and the Small Business Administration on "The Impact on Small Business Concerns of Government Regulations that Force Technological Change." 17/ Although FIFRA and the FFDCA are laws which bring about technological change, the effects of these statutes were not examined directly in this study. The statutes considered were of the "minimal standard" or "allocation/distribution" type, and not "permission/prohibition" variety which characterizes FIFRA and FFDCA. In spite of the lack of direct applicability of the study to the specifics of the pesticide regulatory situation, some of the findings are worthy of mention:

Among the firms studied, the costs of compliance (per unit of output) with the statutes under consideration rose as size of the firm decreased (reflecting economics of scale,) except for the very smallest firms. This is related to exceptions that are made for smaller firms (in the form of extension, modifications and exemptions), and to flexibility of enforcement. In the opinion of the contractor, flexible enforcement is more common among the older, more established regulatory bodies, but even the "younger, brasher outfits like EPA" have "confronted and accepted the impossibility of total enforcement."

Smaller firms face higher interest changes, less advantageous terms of payment, and less availability of money to finance spending required by regulatory demands than larger firms. There is a tendency to be able to pass through either nearly all or nearly nothing of the costs incurred. The further down the production - distribution chain a company is located, the less likelihood of cost pass-through.

The small firms studied also had non-financial problems with compliance which seem to be shared to some degree with pesticide registrants -- time and paperwork burdens, confusion over regulatory requirements, difficulties in dealing with agency personnel and in the formulation of legislation and regulations.

The study notes the benefits partly off-setting the costs of regulation, citing "a wide range of industries, including many small businesses, (which) receive indirect benefits through sales of materials, equipment, supplies, and services to manufacturers of pollution control equipment and the like."

The report recommends several kinds of action to the Small Business Administration, including intervention and advocacy in the federal legislative and regulatory process; financial assistance via Regulatory Economic Injury Assistance Loans and the like; technical assistance of several types; and programs to foster cooperative action among similarly-affected small businesses.

NEW, INNOVATIVE PESTICIDES

A study on "New, Innovative Pesticides: An Evaluation of Incentives and Disincentives of Commercial Development by Industry," is being conducted for OPP. Tentative findings include the expectation that, over the next ten years, there will be a steady flow of products from the chemical industry for pesticide uses, but that innovative products (such as bacterial, pheromonal and viral pesticides) will not be registered and available in sufficient quantities to dramatically substitute for conventional chemical products, although some are expected to complement the use of chemicals in selected markets. These conclusions are based both on analysis of economic factors and on the views of pesticide users.

By viewing profit as incentive for product development by private industry and risk as disincentive, two limiting factors on the development of innovative products are their generally narrow spectrum (limiting the ultimate market size) and the lack of proprietary protection. Therefore, the government should consider the following changes to encourage develoment of innovative products.

* Means to give some measure of proprietary protection to firms seeking to market naturally-occurring agents.

* Means to reduce risk to the developers, possibly through support for R & D costs and modification of performance liability constraints.

These are preliminary conclusions, but it is worthwhile to note that the measures seen as helpful in encouraging development of innovative products are to some degree in conflict with the promotion of an atmosphere of competition.

CHILD PROTECTIVE PACKAGING

Another recent study looked at the cost of the child protective packaging which will be required later in 1977. 18/ It showed that the total annualized cost will be less than $6 million and less than 8 cents for each container subject to the regulations. The effects of the special packaging regulations were discussed further in the text.

Footnotes

1. Memorandum, March 5, 1976, to Deputy Assistant Administrator for Pesticide Programs from EPA General Counsel.

2. The "data validation" problems will not be solved by this legislative action.

3. Incentives for Research and Development in Pest Control, Volume II, Appendices, 1976, EPA-540/9-77-009, pp. 1-12.

4. The Pesticide Industry -- An Overview, William Blair and Company, July 7, 1975, p. 15.

5. Ibid., and Incentives for Research and Development in Pest Control, op. cit.

6. Contemporary Pest Control Practices and Prospects, Vol.I of Pest Control: An Assessment of Present and Alternative Technologies, National Academy of Sciences, 1975, pp. 340-386.

7. An Evaluation of the Scouting Activities of Pest Management Programs, 1974, EPA-540/9-75-014, pp. 34-38.

8. Crop Insurance and Information Services to Control the Use of Pesticides, draft final report, 1974.

9. The Diffusion of Pest Management Information Technology, Wayne Richard Willey, Ph.D. dissertation in economics, University of California, Berkeley, 1973.

10. Contemporary Pest Control Practices and Prospects, op. cit., p. 397, and volume III, Cotton Pest Control.

11. Production, Distribution, Use and Environmental Impact Potential of Selected Pesticides, 1974, EPA 540/1-74-001, pp. 106-108.

12. Incentives for Research and Development in Pest Control, Volume II, op. cit., pp. 8-12, and Contemporary Pest Control Practices and Prospects, op. cit., 365-380.

13. Economic Impact of Child-Proof Packaging Regulations on the Cost Of Pesticide Containers in the United States, draft screening study, Office of Pesticide Programs, U.S. EPA, 1977.

14. DDT: A Review of Scientific and Economic Aspects of the Decision to Ban Its Use as a Pesticide, prepared for the Committee on Appropriations, U.S. House of Representatives, by the U.S. EPA, July 1975.

15. Incremental Cost Impacts of the 1972 FIFRA, 1976, EPA-540/9-76-002, p. 41.

16. Incentives for Research and Development in Pest Control, volumes I and II, op. cit.

17. September 1975, CAI-800-F-2R.

18. Economic Impact of Child-Proof Packaging Regulations on the Cost of Pesticide Containers in the U.S., op. cit.