ECONOMIC ANALYSIS OF THE PROPOSED CHANGE IN DATA REQUIREMENTS RULE FOR CONVENTIONAL PESTICIDES

Prepared by:

BIOLOGICAL AND ECONOMIC ANALYSIS DIVISION
OFFICE OF PESTICIDE PROGRAMS

U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20640

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1 EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) is proposing to update and revise the data requirements for the registration of conventional pesticide products that are listed in part 158 of title 40 of the Code of Federal Regulations (CFR). This document evaluates the potential benefits and costs expected to result from the revisions presented in the proposed rule, and two alternatives to the proposal.

Federal law requires that before selling or distributing a pesticide in the United States, a person or company must obtain registration, or license, from the EPA. Before registering a new pesticide or *new use* for a registered pesticide, EPA must first ensure that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment. Where pesticides may be used on food or feed crops, EPA also sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods. To make such determinations, EPA requires applicants to provide EPA with the data and other information necessary.

Since the data requirements in 40 CFR part 158 were first codified in 1984, information needed to support the registration of a pesticide chemical has evolved as the general scientific understanding of the potential hazards posed by pesticides has grown. Over the years, updated data requirements were developed by EPA using a process that involved public participation and extensive involvement by the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP). Most of the data requirements contained in this proposal have been applied on a case-by-case basis to support individual applications, or imposed via Data Call-In (DCI) on all registrants of similar products. Although the data requirements imposed have progressed as scientific understanding and concerns have evolved, the codified data requirements in part 158 have not been updated to keep pace.

This proposal involves changes to the codified data requirements that pertain to product chemistry, toxicology, residue chemistry, applicator exposure, post-application exposure, nontarget terrestrial and aquatic organisms, nontarget plant protection, and environmental fate. Coupled with updating the data requirements in part 158, EPA is proposing to add a few new data requirements, reformat the presentation of the requirements in part 158, and to make a few revisions to its general procedures and policies associated with data submission.

By codifying existing data requirements which are currently applied on a case-by-case basis, the pesticide industry, along with other partners in the regulated community, attain a better understanding and are better prepared for the pesticide registration process. In addition, the proposed revisions to part 158 are expected to increase EPA's ability to meet statutory requirements, make more informed regulatory and licensing decisions, enhance efficiencies in the licensing and decision-making process, improve understanding and expectations with regard to the data needed for pesticide registrations, improve the availability of more complete and reliable data, improve the Agency's ability to prepare good quality risk assessments, enhance the consideration of risk mitigation measures, and provide better protection to humans and the environment. These improvements in EPA's abilities will benefit a large number of parties, including the regulated industry, pesticide users, the general public, other federal, state, and foreign governments, and others who are affected by or interested in pesticide use or regulation.

To evaluate the potential annual cost to the conventional pesticide industry under the three options, the Agency examined the historical information of actual pesticide registration actions between 1996 and 2002. This included information regarding the type and frequency of the various pesticide registration actions that are possible, the related applicability of the various data requirements to those actions, and information about the applicants involved in those actions. This information formed the basis for the analysis presented in this document, i.e., to estimate the potential annual impacts on industry assuming an average annual number of future pesticide registration actions and the type and frequency of future pesticide registration actions.

EPA identified a total of 120 individual firms as being involved in one or more of the 986 total pesticide registration actions that occurred during 1996 and 2002. EPA estimated an annual average of 141 pesticide registration actions, and created an economic profile of the affected industry using a large random sample of 1,000 pesticide registrants.

Proposed approach: Decision criteria determination of data requirement: The estimated annual cost under this approach is about $51 million, with an estimated average additional cost of $420,000 per firm per year.

Low-cost option: Codification of Current Practice: The estimated annual cost under this alternate approach is about $48 million, with an estimated average additional cost of $400,000 per firm per year.

High-cost option: Require Data 100% of the Time: The estimated annual cost under this alternate approach is about $69 million, with an estimated average additional cost of $575,000 per firm per year.

The analysis of the potential impacts of the proposed rule on small businesses suggests that the proposed rule will not have a significant impact on a substantial number of small entities because only 1.6% of the potentially impacted firms are expected to experience a cost increase representing 3% or more of gross sales. Only 2.4 % are likely to experience a cost increase representing 1% or more of gross sales. (See Section 4).

Using the currently codified requirements as the baseline for estimating the potential impact of the proposed rule, the total annual impact to the pesticide industry is estimated to be about $51 million. Of this estimated total annual impact, about $28.7 million per year represents the cost of new data requirements that were imposed over the years but were not specified in the existing CFR, and about $21.7 million represents the cost of modified or expanded existing data requirements (i.e., data requirements for certain tests and use patterns in the CFR that are changing from conditionally required (CR) to required (R)). As they have been applied to an increasing number of registrations, these data requirements have become more regularly required. As a result, included in the total cost estimate is about $1.9 million that is attributable to newly imposed requirements. The costs of the newly imposed requirements represents the increase costs over current practices, and therefore provide the estimated practical impact of this proposed rule to the pesticide industry.

The Agency also conducted two sensitivity analyses for the proposed rule impact analysis using: 1) low average laboratory cost estimates with data requirement frequencies as estimated for the proposed rule, and 2) high average laboratory costs with data requirement frequency of 100% required. The estimated total annual costs for the proposed rule using the low average laboratory cost estimates is $44.7 million, and the estimated total annual costs for the proposed rule using the high average laboratory cost estimates is $74.6 million. (See Appendix B).

Since the likely impact of this proposed rule on businesses overall is expected to be small, the Agency believes that a deleterious effect on the availability of pesticides to users is unlikely. On balance, the Agency believes that the costs of the rule are justified by the benefits from enhanced protection of human health and the environment.

2 PROBLEM STATEMENT

2.1 Overview of Pesticide Usage, Exposure, Effects and Regulation

Each year, large quantities of pesticides are released into the environment. In 2001, an estimated 4.97 billion pounds of active ingredient (a.i.) were used in the United States (U.S.EPA "Pesticides Industry Sales and Usage Report, 2000 and 2001 Market Estimates"). Of this, 1.2 billion pounds a.i. were predominately used as conventional pesticides in agricultural, industrial, commercial, government and house and garden uses. The remaining pounds are made up of other chemicals such as specialty biocides, chlorine/hypochlorites, and wood preservatives. Agricultural uses of pesticides account for about 76 percent of the total conventional pesticide use in the U.S., 675 million pounds a.i. in 2001.

Use of pesticides in agriculture may result in residues in feed and food products produced on farms, leading to human exposure through the food supply. Use can also lead to groundwater contamination, or direct exposure to humans and the environment. Groundwater is vulnerable to contamination by pesticides from ordinary usage, leaks, spills and disposal. Groundwater is used for drinking water by nearly half of the U.S. population. In some rural areas, it is the only source of drinking water (OPP, February 1990). Farm use also potentially exposes applicators and farm families. Pesticides are used on a majority of the 2.2 million commercial farms in the U.S. Farm field workers, numbering 8.8 million in the U.S. in 2002, may be subject to a high degree of exposure to pesticides, primarily through dermal contact with residues on plant surfaces (Agricultural Statistics, USDA, 2003).

People who use pesticides are directly exposed, primarily through dermal contact or inhalation. The industrial/commercial/governmental sector is the second-ranked user of pesticides in the U.S., accounting for about 13 percent of the total use of conventional active ingredients (111 million pounds in 2001) (U.S.EPA "Pesticides Industry Sales and Usage Report, 2000 and 2001 Market Estimates"). There are an estimated 422,000 total commercial applicators in the U.S. (U.S.EPA "Pesticides Industry Sales and Usage Report, 2000 and 2001 Market Estimates").

Home and garden usage of pesticides equals about seven percent of total conventional usage on an active ingredient basis, 78 million pounds in 2001 (U.S.EPA "Pesticides Industry Sales and Usage Report, 2000 and 2001 Market Estimates"). Pesticides are biological poisons, intended to kill or repel biological entities. The mode of action is seldom entirely specific as to the time, place and target of the chemical activity. Pesticides are often acutely toxic to animals, plants and other lower life forms and at the same time are likely to be acutely, if not chronically, toxic to at least some part of the biota (flora and fauna of a region) that is non-target. The long-term effects of chronic exposure of human, animal and other living organisms to pesticides are uncertain. There are many possibilities for chemical/toxicological interactions between pesticides and living organisms, particularly those resulting from long-term, low-dosage exposure.

2.2 Nature of Market Failures Inherent from Pesticide Producer and User Behavior

Economic theory suggests that regulatory intervention is justified in the presence of market failures. For example, in the case of pesticide residues on food, the two most salient sources of failure are externalities and asymmetric information. Externalities arise because some of the costs (e.g. groundwater contamination and environmental damage) associated with pesticide residues are external to those benefiting from the pesticides (pesticide producers and users, and consumers of food). The asymmetric information problem arises because consumers cannot easily determine the level of pesticide residue on food. Even if the level were readily apparent, the nature of the risks posed by these residues is not well understood.

3 ANALYSIS OF OPTIONS CONSIDERED FOR THE PROPOSED RULE

Executive Order 12866 directs agencies initiating rule making activities to conduct a regulatory impact analysis and submit it to the Office of Management and Budget (OMB) prior to publication of the proposed rule. The executive order calls for EPA to characterize the costs and benefits of the proposed regulation and to make comparisons of them with the costs and benefits of other approaches. The proposed approach should be the one that maximizes net social benefits. The purpose of this section of the report is to integrate the results of the impact analysis into a benefit/cost framework and to report on the analysis required by the Executive Order.

This analysis is conducted pursuant to EPA's guidance on conducting regulatory economic analyses (EPA, 2000).

EPA considered alternative approaches for data requirements before arriving at the Agency's preferred approach in the proposed rule. The proposed approach and two alternative approaches are summarized and compared below. The pros and cons of each of the two alternatives relative to the proposed approach are also discussed below. The goal is to arrive at a structure and process for data requirements so that EPA receives sufficient data to inform the decision for any registration action, while minimizing the impacts on pesticide registrants. These impacts include the direct cost of generating the data as well as less tangible costs brought about by uncertainty in registration requirements. The three approaches are as follows.

3.1 Proposed Option: Decision Criteria Determination of Data Requirement

Benefits

The Agency is updating its regulations by codifying current data requirements that are not currently listed in part 158 of Title 40 of the Code of Federal Regulations (CFR), which are intended to provide EPA with data and other information necessary for the registration of a conventional pesticide chemical. EPA regulates pesticides under the FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and FFDCA (Federal Food, Drug and Cosmetic Act). FIFRA requires that an applicant demonstrates to the Agency's satisfaction that, among other things, the pesticide product, when used in accordance with label instructions, will not cause "unreasonable adverse affects" on humans and the environment. FFDCA requires a reasonable certainty of no harm from pesticide residues in food. Reducing these adverse effects reduces the externalities of pesticide use on the environment and the effects of asymmetrical information on consumers of food. The proposed rule by requiring additional data enhances EPA's ability to make sound regulatory decisions and prevent the registration of pesticide products that may have unreasonable adverse externalities on the environment as well as protect consumers of food from unreasonable risks, of which they would not be aware. Coupled with updating data requirements, EPA proposes to add a few new studies, increase the requirements of a few existing studies, reformat the requirements, and revise its general procedures and policies associated with data submission. By codifying these data requirements which are currently applied on a case-by-case basis and adding few additional new requirements (such as immunotoxicity testing) , the pesticide industry, along with other partners in the regulated community, attain a better understanding and are better prepared for the pesticide registration process.

In essence, the data requirements identify the questions that the registrant will need to answer regarding the safety of a pesticide product before the Agency can register it. The data requirements address both components of a risk assessment, i.e., what hazards does the pesticide present, and what level of exposure. The answer to one question may inform the kind of information needed in others. For example, a pesticide that is persistent and toxicologically potent may require more extensive exposure and environmental fate data to help establish an acceptable level of exposure. If there is negligible exposure then there may be generally less need for extensive hazard data since any conceivable risk would be low.

Until 1984, data requirements were based on longstanding requirements initially put in place when pesticides were regulated by U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). However, because virtually all of EPA's decisions relating to the registration of pesticides or the establishment of tolerances depend on Agency evaluation of scientific studies, EPA has throughout the years developed standardized data requirements and test guidelines, and established evaluation procedures and peer review processes to ensure the quality and consistency of scientific studies.

Since the data requirements in part 158 were first codified in 1984, information needed to support the registration of a pesticide chemical has evolved as the general scientific

understanding of the potential hazards posed by pesticides has grown. Over the years, updated data requirements were developed by EPA using a process that involved public participation and extensive involvement by the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP). Most of the data requirements being codified under this proposed approach have been applied on a case-by-case basis to support individual applications, or imposed via Data Call-In (DCI) notices on all registrants of similar products. Although the data requirements imposed have progressed as scientific understanding and concerns have evolved, the codified data requirements have not been updated to keep pace.

The proposed approach outlines to applicants the data that would appear to add significant information and value to the decision, while ensuring that the registration meets or exceeds statutory safety standards. By codifying these data requirements which are currently applied on a case-by-case basis and adding few additional new requirements, like immunotoxicity testing, the Agency will be able to predict the potential risks of pesticides to humans and the environment more accurately. Other benefits are increased efficiency due to better understanding of what the requirements are.

Costs

One potential impact of higher data costs for registering a pesticide is that fewer products may be registered in a given time period as more time and money may be required to develop the data to support a registration. Additionally, the types of products that are developed, and for what uses, may be affected. Higher costs may encourage registrants to effectively raise the threshold for potential revenue expected from a pesticide use before they would pursue its registration, which may mean that research into pesticides for "minor uses" (e.g., crops with small acreage or very specific pests) may be reduced. The Agency, in conjunction with USDA, does have a program (IR-4) that seeks to promote research and development in these areas through various incentive measures, including support for data generation.

Another impact with raising costs of regulation is higher prices, which decrease consumer surplus. The amount of the cost that pesticide producers can pass on to the users of pesticides depends on the price elasticity of demand pesticide products. Where there are good alternative pesticides or means of pest control, the pesticide producer would not be able to pass much of the higher costs to users of pesticides, but where there are no good substitutes, the pesticide producer would be able to pass on most of the costs.

The estimated incremental costs of this option for conventional pesticides are about $51 million. Detailed analysis is shown in Appendix F.

3.2 Low-Cost Option: Codification of Current Practice

Benefits

This approach reflects codifying the Agency's current practice. The data required under the current practice relies on the data requirements in the existing Part 158 as modified by current policies and practices, including DCI's. Entities seeking registration of a pesticide have

to submit applications based on requirements in the current CFR and then wait for the Agency to determine the additional data needed that is not currently in the CFR for each pesticide registration action on a case-by-case basis. EPA considers all of the possible tests used to support pesticide registrations, and only require those tests that would appear to add significant information and value to the decision, while ensuring that the registration meets or exceeds statutory safety standards.

Like the proposed option, this option would be more efficient in terms of process than no new rule at all, because most of the data requirements would be known in advance, thus saving delays in generating data. In terms of data requirements, this option is similar to the proposed approach except it does not include a few new requirements, such as immunotoxicity testing, which the Agency has not currently imposed. EPA believes that the newly imposed requirements (that are in the proposed approach, but not in this low-cost option) are needed to make informed decisions on pesticide registration, are worth their cost, and would reduce the externalities to the environment and risks to consumers of food, of which they are not aware, more than this low-cost option.

Costs

The estimated cost of this approach to industry (additional data requirements compared to what is required in the current CFR) is about $48 million. Detailed analysis is shown in Appendix F.

3.3 High-Cost Option: Requirement of the Additional "R" (Required) Data 100% of the Time

Benefits

Another alternative approach the Agency analyzed would be to require all "R" data 100 percent of the time for any new requirements proposed. "R" in the proposed and low cost approach means it is required unless certain conditions are met, so it could be less than 100% since it would not apply to pesticides that trigger those conditions. This approach would result in higher costs to pesticide registrants and the Agency than the proposed approach, but would ensure availability of this information.

Like the proposed approach, this option by requiring even more data may reduce the adverse externalities of pesticides and unknown risks to consumers of food slightly more than the proposed approach. However, the benefits of this additional data are speculative, because if certain conditions are met, then this additional data (over and above what the proposed option requires) would help inform registrations decisions very little. Furthermore, if higher the cost of registering pesticides results in fewer products being registered, overall risk may not be increased since newer products are often safer than the older pesticides they may replace or partly replace.

Like the proposed option, this option would be more efficient in terms of process than no new rule at all, because most of the data requirements would be known in advance, thus saving

delays in generating data. In terms of data requirements, this approach would result in higher costs to pesticide registrants and the Agency than the proposed approach, but would ensure availability of this information. EPA believes that the cost of requiring the data 100% of time for all registrations would be too high to warrant the modest benefits of marginally valuable information. Additionally, EPA expects that registrants would request waivers of many tests under this approach, resulting in inefficiency and uncertainty similar to that described under the case-by-case approach of the current practice. EPA believes that this high cost approach would raise the cost of registering a pesticide substantially, resulting in fewer products being registered for minor uses, which already have a relative shortage of pest control options due to the limited market incentive to registrants

Costs

EPA believes that the cost of requiring the data 100% of time for all registrations would be too high to warrant the modest benefits of marginally valuable information. Additionally, EPA expects that registrants would request waivers of many tests under this approach, resulting in inefficiency and uncertainty similar to that described under the case-by-case approach of the current practice. EPA believes that this high cost approach would raise the cost of registering a pesticide substantially, resulting in fewer products being registered for minor uses, which already have a relative shortage of pest control options due to the limited market incentive to registrants.

The estimated cost of this approach is $69 million. Detailed analysis is shown in Appendix F.

4 ECONOMIC ANALYSIS OF THE PROPOSED CHANGES IN THE DATA REQUIREMENTS RULE FOR CONVENTIONAL PESTICIDES

4.1 Background for Proposed Rule

EPA is proposing to revise parts of its regulations prescribing data requirements for the registration of pesticide products. The regulations governing data requirements have not been comprehensively revised since 1984. This proposal is one in a series of revisions aimed at updating EPA's regulations governing pesticide data requirements. This proposal pertains to the data requirements for conventional pesticides – pesticides that are not classified as antimicrobial(including wood preservatives) or biopesticides.. EPA is proposing revisions to the data requirements in the fields of toxicology, residue chemistry, applicator exposure, post-application exposure, non-target terrestrial and aquatic organisms, non-target plant protection, environmental fate and product chemistry.

4.2 Reason for the Proposed Rule

The data requirements specified in Part 158 of Title 40 of the Code of Federal Regulations (CFR) are intended to provide EPA with data and other information generally necessary for the registration of pesticide products, including "conventional" pesticide chemicals.

Since the data requirements set out in Part 158 were first published in 1984, information generally found to be needed to support the registration of a pesticide chemical has expanded or has been refined as experience with pesticides and the science underlying the data requirements has advanced. Further, as a result of the Food Quality Protection Act (FQPA) of 1996, EPA must now address additional human health risk issues associated with the use of pesticides, such as aggregate and cumulative risk. Additional data are required to perform these assessments.

The proposed revisions are expected to improve EPA's ability to make timely decisions about the likely human health and environmental effects of pesticide products. These new data requirements are intended to help EPA better protect people (including sensitive populations), wildlife, and the environment. Coupled with revising data requirements, EPA proposes to reformat the tables and make some revisions to its general procedures and policies associated with data submission. EPA believes that the proposed changes to these regulations will provide the pesticide industry and other partners in the regulated community a better understanding of the requirements and allow them to better prepare for the pesticide registration process, thus reducing delays.

4.3 Overview of the Costs of the Proposed Rule

The direct costs of the proposed rule are to the pesticide registrant community. EPA estimated the likely expenditures to be incurred by regulated entities, which may be an acceptable first-order approximation of the true cost given the magnitude of the rule.

The impact of the proposed rule on the regulated community is primarily defined as the increase in registration costs to registrants associated with developing and submitting required data and the burden on EPA to process and review this data. Over the years, in specific situations, EPA has imposed new data requirements that are not specified in the existing CFR. Over time, as they have been applied to an increasing number of registration actions, these data requirements have become more regularly required to meet specific needs and are now being codified in this rule. The cost of these new data requirements represent most of the cost of the proposed rule (about $28.9 million per year). In addition, the data requirements for certain tests and use patterns in the CFR are changing from conditionally required (CR) to required (R). These changes would increase the frequency at which certain tests are required. The incremental cost of these changes are part of the cost of the rule (about $21.6 million per year). These impacts are explained in more detail in Sections 3 and 4.

This analysis estimates the annual cost only, because all years have the same expected (average) annual cost. There are no large costs in the beginning followed by smaller costs in the future. Furthermore, since the benefits of proposed rule could not be quantified, there was no need to compare costs and benefits in a common denominator such as present value or annualized costs to account for different time frames. Since the costs are the same each year, the annualized value of the present value of the costs over a period of years at any interest rate is equal to the constant annual costs.

The total estimated annual incremental cost to the conventional pesticide industry of increased data requirements for registering conventional pesticide products is projected to be

about $51 million. This estimate is based on an examination of historical registration actions from 1996-2002. During this period 120 firms would have incurred average increased data costs of approximately $420,000 per firm per year if the proposed rule had been in effect.

An analysis of the rule's impact on small businesses suggests that the proposed rule will not have a significant impact on a substantial number of small entities because, out of an estimated 1373 small firms potentially affected by the rule, only about 23 firms are expected to experience a cost increase representing 3% or more of gross sales. Only 2.4 %, approximately 35 firms out of about 1373 small conventional pesticide firms, are likely to experience a cost increase representing 1% or more of gross sales (see Section 6).

These estimates are based on an analysis of registration costs and do not include reregistration because by the time this rule is promulgated and effective, it is anticipated that virtually all requirements for reregistration will have been met.

In general, the data requirements in Part 158 could apply to new pesticides submitted for registration, to new uses of currently registered pesticides, and to existing chemicals whose databases are subject to Agency review to determine if they continue to meet registration standards. For these existing chemicals, Part 158 data requirements are potentially relevant to three review programs.

Reregistration (mandated in 1988) and tolerance reassessment (mandated in 1996) are well underway. Data requirements under those programs have largely been imposed on registrants of existing chemicals, and the data have been submitted. EPA anticipates that by the time this proposed rule is promulgated, few of the data requirements will remain to be imposed for existing chemicals. Only those requirements that are “new” or “newly codified” (e.g., developmental neurotoxicity, immunotoxicity, sediment testing) have not been broadly required and may be imposed in the future. Data requirements for existing chemicals are imposed under the Agency's Data Call-In (DCI) program.

In those rare cases when such data will be needed for the remaining reregistration or tolerance reassessment after promulgation of this rule, EPA will articulate the specific burden and costs associated with each DCI in support of the appropriate Information Collection Request (ICR) approvals under the Paperwork Reduction Act (PRA). Since the approval process for the PRA requires that EPA characterize the information collection burdens and costs incurred by registrants to comply with a DCI, a complete estimate of the burden and costs for the DCIs will be provided at that time. EPA believes that the public process associated with the PRA approval for the ICRs is a reasonable way to account for the data costs without double counting burden. Accordingly, in this proposal EPA has not included the potential burden or costs of the proposed data requirements on registrants of existing chemicals.

A third program, registration review, mandated in 1996, requires that EPA establish a program for the periodic review of existing chemicals (the goal is every 15 years). Any data requirements to be levied under that program will also be imposed under a DCI. At this time, EPA is developing a proposed rule to establish procedures for the registration review program. Once promulgated, the expanded data requirements in this proposed rule are expected to apply to

all chemicals subject to registration review (i.e., all existing chemicals), depending on the conditions expressed in both final rules (this Part 158 revision and the future registration review rule). At this time EPA has not determined how the registration review program will function. Once the registration review program is better defined, the Agency will be able to provide estimates of the burden/cost related to that program, including the burden/costs related to data requirements that might apply during registration review.

Accordingly, EPA intends to describe the burden and costs of potential data requirements at the time the registration review rule is proposed, and ultimately, to more accurately and fully characterize the individual DCI burden and costs during the public process associated with PRA approval.

4.4 Statutory Authority

Two primary statutes provide EPA the authority to regulate pesticides – the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). The Food Quality Protection Act (FQPA) amended FIFRA and FFDCA.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

As the standard for registration of a pesticide, FIFRA sec. 3(c)(5) requires, among other things, that a pesticide, when used in accordance with widespread and commonly recognized practices, will not generally cause unreasonable adverse effects on the environment. FIFRA sec. 2(bb) defines "unreasonable adverse effects on the environment" as "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)." This standard also applies to the reregistration of existing pesticide products under section 4, and Agency approval of any experimental use of unregistered pesticides under section 5.

FIFRA is a licensing statute, under which regulatory decisions on the registrability of an individual product are based upon data specific to the product and its uses. EPA is authorized to require the submission of data it needs to make the registration decision in the context of any individual application for registration, amended registration, or reregistration. EPA may also impose a data requirement after registration in order to maintain the registration, using specific Data Call-In (DCI) authority of FIFRA sec. 3(c)(2)(B).

In order for the Agency to make registration decisions, FIFRA sec. 3(c)(2) gives EPA broad authority, before and after registration, to require specific testing by registrants and applicants and submission of the resulting data to the Agency (7 U.S.C. §§136a-c). 40 CFR Part 158 sets forth general requirements for data submission. Also, on a case-by-case basis, EPA has exercised authority to require data in addition to that specified in Part 158. Registrants and applicants are under a continuing obligation to

provide EPA with adequate information about their products to demonstrate that the products meet the statutory standard for registration.

The Federal Food, Drug and Cosmetic Act (FFDCA)

In addition to the requirements of FIFRA, FFDCA sec. 408, requires that any pesticide whose use may result, directly or indirectly, in residues on food (including animal feed), must have a tolerance (maximum legal residue level) or an exemption from tolerance. A tolerance (or exemption) is needed for residues of all ingredients in a pesticide product, both active and inert, as well as any transformation products (i.e., metabolites and/or degradates) of the pesticide chemical. A food that bears residues not covered by a tolerance or exemption is considered adulterated under FFDCA, may not be shipped in interstate commerce, and is subject to seizure.

The Food Quality Protection Act (FQPA)

On August 3, 1996, FQPA was enacted, amending both FIFRA and FFDCA. The new standard for establishing a tolerance or exemption under FFDCA sec. 408(b) is that pesticide residues must conform to a “reasonable certainty of no harm" standard with respect to the general population, and to infants and children specifically. To determine whether a tolerance meets this standard, EPA must take into account aggregate exposure to the pesticide chemical residue, (dietary, non-dietary, and non-occupational exposure), cumulative risks from multiple related chemicals with a common mode of action, and other factors enumerated in section 408(b)(2)(C) for infants and children and in section 408(b)(2)(D).

FFDCA section 408(b)(2)(A)(ii) calls for additional scientific analyses which have not routinely been a part of the Agency's risk assessment procedures, such as evaluating multiple pathway aggregate exposures from dietary and non-dietary sources. Although this provision is primarily directed at food use pesticides, the Agency may apply a similar approach to actions involving non-dietary use pesticides that may pose significant non-dietary risks to infants and children.

4.5 Description of Data Requirements

The data requirements for pesticide registration are organized by data category (discipline). The specific data required within each data category depends primarily on the exposure presented and toxic characteristics of the pesticide.

Data Requirements by Data Category (data discipline)

When an applicant applies for registration of a conventional pesticide product, the applicant must submit data in support of that registration application. The following seven categories of data may be required (Table 4.1), depending on the type of product being registered. The tests are generally performed on the active ingredient, but may also be necessary for contaminants or degradates.

Table 4.1: Data Categories and Descriptions

Data Category	Description
Toxicology	Tests of acute, subchronic, and chronic toxicity and other human health concerns, such as carcinogenicity may be required to determine whether the product may pose a hazard to humans.
Human Exposure	Because people may be exposed to the product both during application of the product and after application, information about possible oral, dermal, and inhalation exposure as well as information on how the product is used are required for registration.
Residue Chemistry	To determine whether the chemical may be found in plants, livestock, and fish that may be used for food, a variety of information is required, including a proposed tolerance in food.
Product Chemistry	Tests of product identity and composition, delineation of methods of analysis, and tests of physical and chemical properties are required to characterize the product.
Ecological Effects	Tests of the effects of the active ingredient or a typical pesticide product on aquatic and terrestrial vertebrates, invertebrates, and plants are required to determine whether the product poses an ecological risk to organisms that may come in contact with the product.
Environmental Fate	Information on a pesticide 's transport and dissipation in water, air, and soil may be required to determine whether the components of the product persist in the environment and where it is likely to concentrate.
Non-target Plant Protection	Testing of a pesticide's effects on non-target terrestrial and aquatic plant species may be required on plants of concern including crop plants or non-target plants such as endangered plants, or plants important to fish and wildlife for food and cover.

Data Requirements by Type of Registration Action

Data requirements are generally levied as a result of a potential registration action. They usually differ depending on the type of registration being sought (e.g., whether the product contains an active ingredient not previously registered or whether the pesticide is identical to or substantially similar to an existing product). The types of registration that generally trigger data requirements are grouped in the following categories (Table 4.2):

Table 4.2: Types of Registration Actions and Descriptions

Type of Registration	Description
New active ingredient	An application for registration of a new product that contains an active ingredient that is not included in any currently registered product.
Major New Use	An application for a new product that includes the addition of a use pattern that is not currently registered for one or more active ingredient(s) contained in the product. The proposed use pattern is significantly different from any pattern registered for an existing use.
Major New Use Amendment	An amendment of a registration of a product that includes the addition of a use pattern that is not currently registered for one or more active ingredient(s) contained in the product. The proposed use pattern is significantly different from any pattern registered for an existing use.

4.6 Description of Proposed Regulation

Organizational changes include expanding the number of subparts. Currently Part 158 is divided into four subparts:

1. Subpart A, General Provisions;
2. Subpart B, How to Use Data Tables;
3. Subpart C, Product Chemistry Data Requirements; and
4. Subpart D, Data Requirements Tables.

EPA proposes to reorganize Part 158 to more closely correspond with the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Harmonized Guidelines, primarily by creating a series of new subparts to replace subpart D. Each subpart will address an individual scientific discipline or data type.

Since 1984, when Part 158 was first promulgated, EPA's data requirements have evolved along with the general scientific understanding of the potential hazards posed by pesticides. Most of the data requirements contained in this new proposal have been applied on a case-by-case basis to support individual applications.

In this proposed rule, EPA is proposing new and revised data requirements that encompass three categories of requirements:

1. EPA is proposing "new requirements," never before imposed on any registrant.
2. EPA is proposing "newly codified requirements," which have been applied on a case-by-case basis, but are not contained in the CFR.
3. EPA is proposing revisions to "existing requirements."

Types of Revisions Being Proposed

Some of these changes are clarifications or housekeeping changes without cost or burden, others have the effect of increasing or decreasing the burden of the data requirement. The types of changes may be broadly categorized as follows:

<u>Potentially substantive changes</u>

- *Addition of a requirement.*
- *Elimination of a requirement*, sometimes with substitution of a new requirement. For example, EPA is wholly eliminating the requirement for seed germination testing. By contrast, the existing requirement for a battery of mutagenicity studies is being eliminated in favor of a specific set of mutagenicity studies.
- *Change to the number or type of species that must be tested*. For example, EPA proposes to require acute avian toxicity testing on an additional passerine species in some instances and to require that certain toxicity studies be conducted routinely with two species instead of one.
- *A change in the conditional nature of the test requirement*. For example, EPA is

proposing to change a number of requirements from conditionally required to fully required, or vice versa. In some cases, this is a minor change in the frequency (and burden) of the requirement. In other cases, the change may represent a substantial increase in frequency of requirement.

- *A change to the use patterns to which a data requirement applies*. EPA is proposing to increase the number of use pattern descriptors from 9 to 15. An example would be a proposed expansion of conditionally requiring certain studies for greenhouse and indoor use patterns, for example, avian oral toxicity requirements.
- *A change to the test substance to be used*. Typical test substances include the technical grade of active ingredient (TGAI), the manufacturing use product, the end use product, or a "typical end use product." For example, EPA proposes to require primary eye and primary dermal irritation and dermal sensitization testing using the TGAI in addition to the end use product.
- *A clarification in the notes describing the test*. For example, EPA is proposing a test note that requires analytical methods for residue chemistry and environmental fate to be validated by an independent laboratory.

Technical changes having no substantive effect

Technical changes include the relocation of a data requirement, a change to the title of a data requirement, subdividing an existing requirement to create two separate entries, and merging two data requirements into a single entry. These changes would not increase or decrease the burden of the data requirement.

4.7 Profile of the Regulated Community

The market structure of the basic producing industry can be described as a moderately to highly concentrated oligopoly, with only about 20 basic producers of common U.S. pesticides. Relatively few firms produce the bulk of product, and a few products tend to dominate national, regional, and local markets for individual site/pest combinations. Individual firms tend to significantly influence supply and prices in the markets in which they compete. A detailed profile for the conventional pesticide industry, including information on product classes for firms registering conventional pesticides is presented in Appendix D, Exhibit D-1 through D-12.

General Pesticide Industry Description

Pesticides are important products that play a significant role in many aspects of the economy. They are used by diverse economic sectors such as agriculture, industry, and residential. Pesticides reduce or eliminate undesirable weeds, insects, animals, fungi, and bacteria and are used to preserve wood and regulate plant growth. All of these pesticide uses produce desirable outcomes such as increased agricultural productivity and improved human health. However, due to their nature, their use also implies some environmental and health risks (U.S. EPA, 1999c).

Pesticide products themselves fall into several categories: conventional pesticides, specialty and niche pesticides, and antimicrobial pesticides. Conventional pesticides are

those products that are commonly available to users as herbicides (weed killers), insecticides ("bug" killers), and fungicides (fungus killers), as well as some special classifications such as fumigants used to sterilize soil to remove pathogens. The vast majority of pesticides used in the U.S. fall into the category of conventional pesticides.

4.7.1 Registrant Population

EPA's Pesticide Regulatory Action Tracking System (PRATS) is used by EPA to track and manage registration activities. Each registration action is assigned an action code that defines the specific type of registration action. The PRATS database provides a list of pesticide registration actions submitted by each applicant or registrant, including the dates applications were received by EPA and when the Agency responded to each application. For this analysis, the Agency used a subset of the PRATS data set with registration action codes relevant to Part 158 submitted for conventional chemicals from 1996 through 2002. The action codes relevant to Part 158 are shown in Table 4.3 below. The PRATS database in this analysis includes 986 registration actions associated with 120 entities. The average number of registration actions per year are 141 as shown below in Table 4.3.

Table 4.3: Average Number of Registration Actions per Year

Action Code	Description of Registration Action	Average Number of Actions per Year[1]
100	Application for Registration - New Chemical, Food or Feed	12[2]
115	Application for Registration - New Chemical, Non-Food or Non-Feed Use	5[2]
175	Application for Registration - Old Chemical, New Use: Non-Food or Non-Feed Use	26
180	Application for Registration - Old Chemical, New Use: Food or Feed Use	7
315	Amendment - New Use: Non-Food or Non-Feed	14
330	Amendment - Old Chemical: New Use: Food or Feed	77
Total Actions per year		**141**

Source: PRATS 1996-2002.

[1] Based upon the number of pesticide manufacturers subject to product registration action codes of interest from January 1, 1996 to December 31, 2002.

[2] For these actions, only the first action per active ingredient was counted in the PRATS data, since test results for these actions can be reused for registrations with the same active ingredient. For the purpose of the individual company analysis, it was assumed that the first company to invoke one of these actions bore the entire cost of fulfilling the data requirements even if other companies later invoked the same action with the same active ingredient.

4.7.2 Registrant Financial Data

Since the PRATS database contains historical data, it is a sound indicator of the types of entities that undertook registration actions. However, the PRATS population may not be representative of the entities that will undertake registration actions in the future since it only captures entities that have made requests during the sample time period. Other entities may, of course, do so in the future. Therefore, EPA also compiled a profile of a larger population of entities, from the Pesticide Products Information System (PPIS), some of which conceivably will undertake registration actions in the future.

PPIS contains information on all pesticide products registered in the United States, including, registrant names and addresses, chemical ingredients, toxicity categories, product names, distributor brand names, site/pest uses, pesticidal types, formulation codes, and registration status. PPIS does not contain information on specific registration actions.

Neither PRATS nor PPIS contains information on the size or financial characteristics of the entities. Therefore, it was necessary to collect data from an additional source. EPA used the Dun and Bradstreet (D&B) Market Spectrum database to obtain firm size and financial data for our analysis of the impacts of the proposed rule on individual entities. D&B is a comprehensive source of financial information on entities, including firm locations, sales, and primary business classifications under North American Industrial Classification System code (NAICS).

In order to link entities in the PRATS and PPIS data sets with the D&B database, EPA identified each entity's Data Universal Numbering System (DUNS) number. The D&B DUNS Number is a unique identifier for a business entity, which can also be linked to the corporate family structure.

EPA used the DUNS number for each firm to query the D&B database to retrieve the ultimate parent firm name, as well as the ultimate parent firm's annual sales, total employees, and primary NAICS code. The ultimate parent firm is defined as a corporation that owns more than 50 percent of another corporation. The parent firm may also be a subsidiary of another corporation. All financial information in this profile is summarized at the domestic ultimate parent firm level. The domestic ultimate parent is the highest level within the firm's structure in the United States. EPA evaluated the impacts of the proposed rule at this corporate level to capture the annual sales of the firm. As shown in Table 4.4, using seven years of PRATS data, 120 entities were identified. EPA was then able to identify 81% of the parent firms of these entities. Ninety-five of these parent entities provided D&B with revenue information, but one small and one large entity reported number of employees but not revenue data to D&B. Twenty three companies did not have sufficient D&B financial data.

Using the PPIS data, a set of 1,804 unique pesticide registrants were identified as having one or more Section 3 or Section 24(c) pesticide registrations. For Small Business Administration (SBA) - defined small businesses, a random sample of 1,000 unique pesticide registrants was used to develop the economic profile. Of unique parent companies, 57% were identified having sufficient financial information at the global DUNS number level to be included in the analysis.

Only those firms that would have experienced an incremental impact if the rule had been in effect during the sample period 1996-2002 were selected from the PRATS data, whereas, the PPIS data includes all conventional pesticide firms.

Table 4.4: Summary of Data Sets Used in Economic Profile of Entities Affected by the Part 158 Rule

Data Set	Entities in Sample	% of Entities With Ultimate Parent Firm Identified	Entities Without Sufficient D&B Financial Data	Ultimate Parent Entities With Revenue Information	Entities With Employment Information But No Revenue Data
PRATS	120	81%	23	95	2
PPIS	1804	57%	N/A	565	N/A

Source: Dun & Bradstreet 2002.

D&B reports the 6-digit NAICS code for each firm. The less refined 3-digit NAICS code, which is derived from the 6-digit code, is more useful in summarizing the types of businesses included in the data set. Table 4.5 shows that 51 percent of the parent entities from the PRATS data set are primarily identified as Chemical Manufacturing (NAICS 325). Some subsectors represented in this population are:

- pesticide and other agricultural chemical manufacturing (325320);
- pharmaceutical preparation manufacturing (325412); and
- all other basic inorganic chemical manufacturing (325199).

Table 4.5: Primary Industry Sectors Represented in the PRATS Data Set

NAICS Code[1]	Sector Description	Number of Parent Companies[2]
325	Chemical Manufacturing	46
424	Merchant Wholesalers, Nondurable Goods	27
423	Merchant Wholesalers, Durable Goods	4
339	Miscellaneous Manufacturing	2
531	Real Estate	2
541	Professional, Scientific and Technical Services	2
561	Administrative and Support Services	2
711	Performing Arts, Spectator Sports and Related Industries	2
	Others	4

Source: PRATS 2003, Dun & Bradstreet 2003.

[1] Government entities are excluded from the analysis.

[2] Seven parent companies reported data without a NAICS code to Dun & Bradstreet (D&B) and 23 companies were not found in D&B, yielding a total of 30 companies without a NAICS code. The seven companies with D&B data but no NAICS code were assumed to be associated with NAICS code 325320 - 'Pesticide and Other Agricultural Chemical Manufacturing' for the analysis.

Table 4.6 provides the same information for the PPIS sample. Here 107 entities, or 30 percent, are primarily identified as Chemical Manufacturing (NAICS 325).

Table 4.6: Primary Industry Sectors Represented in the PPIS Data Set

NAICS Code	Sector Description	Number of Parent Entities
325	Chemical Manufacturing	107
422	Wholesale Trade - Nondurable goods	45
311	Food Manufacturing	12
561	Administrative and Support Services	10
541	Professional, Scientific and Technical Services	8
421	Wholesale Trade - Durable goods	5
333	Machinery Manufacturing	4
	Other	27
133 parent firms did not report a NAICS code to Dun & Bradstreet.		

Source: PPIS 2001, Dun & Bradstreet 2002.

Revenues

Market data indicate that sales of conventional pesticide active ingredients total over $11 billion per year (EPA Sales and Usage Report 1998 & 1999). Extrapolating this to the population of conventional pesticide firms producing AI's (20), and adjusting for the number of identified suppliers, results in average sales of $579 million. In other words, each of the major pesticide producers has an average of approximately 5 percent of the estimated industry total annual sales. Market data also indicate that the core number of conventional active ingredients is about 891. Therefore, each active ingredient represents an average revenue of $12 million.

Since 1992 the pesticide industry has undergone a period of consolidation. Many firms have merged or been purchased, decreasing the number of firms producing active ingredients. This has affected the concentration of active ingredient producers as a few large competitors are emerging in each sector. For example, the herbicides market had a concentration of 45 percent (market share held by top three competitors) in 1999, and it is estimated that the concentration will continue to increase. (Frost & Sullivan, 2000).

Consolidation Through Mergers and Acquisitions

Conventional pesticide producers have experienced a period of consolidation in the past few years, as several major producers of active ingredients have either merged or been acquired. The following is a list of the mergers and acquisitions that recently occurred or are underway.

Mergers and Acquisitions

- Novartis with Astra Zeneca
- AgrEvo and Rhone Poulenc to form Aventis
- Monsanto acquired DeKalb
- Dupont bought Pioneer Hi-Bred seed company
- Zeneca with Astra
- BASF acquired American Cyanamid

5 ECONOMIC IMPACTS ON PESTICIDE REGISTRANTS DUE TO CHANGES IN DATA REQUIREMENTS

Summary of Findings

To simplify and clarify the process of applying for a pesticide registration, EPA proposes to revise part of its regulations pertaining to data requirements for the registration of conventional pesticide products. As mentioned in section 2, the Agency is proposing revisions to the data requirements that pertain to product chemistry, toxicology, residue chemistry, applicator exposure, post-application exposure, non-target terrestrial and aquatic organisms, non-target plant protection, and environmental fate. Some new data requirements, not currently specified in Part 158, are being added and some are being dropped. In addition, conditions under which studies are required are being updated, i.e., use patterns are being expanded; test substances are being revised; and other changes have been made to the conditions under which certain studies are required.

The total cost of changes in data requirements for the conventional pesticide industry is estimated to be approximately $51 million per year in 2003 dollars.

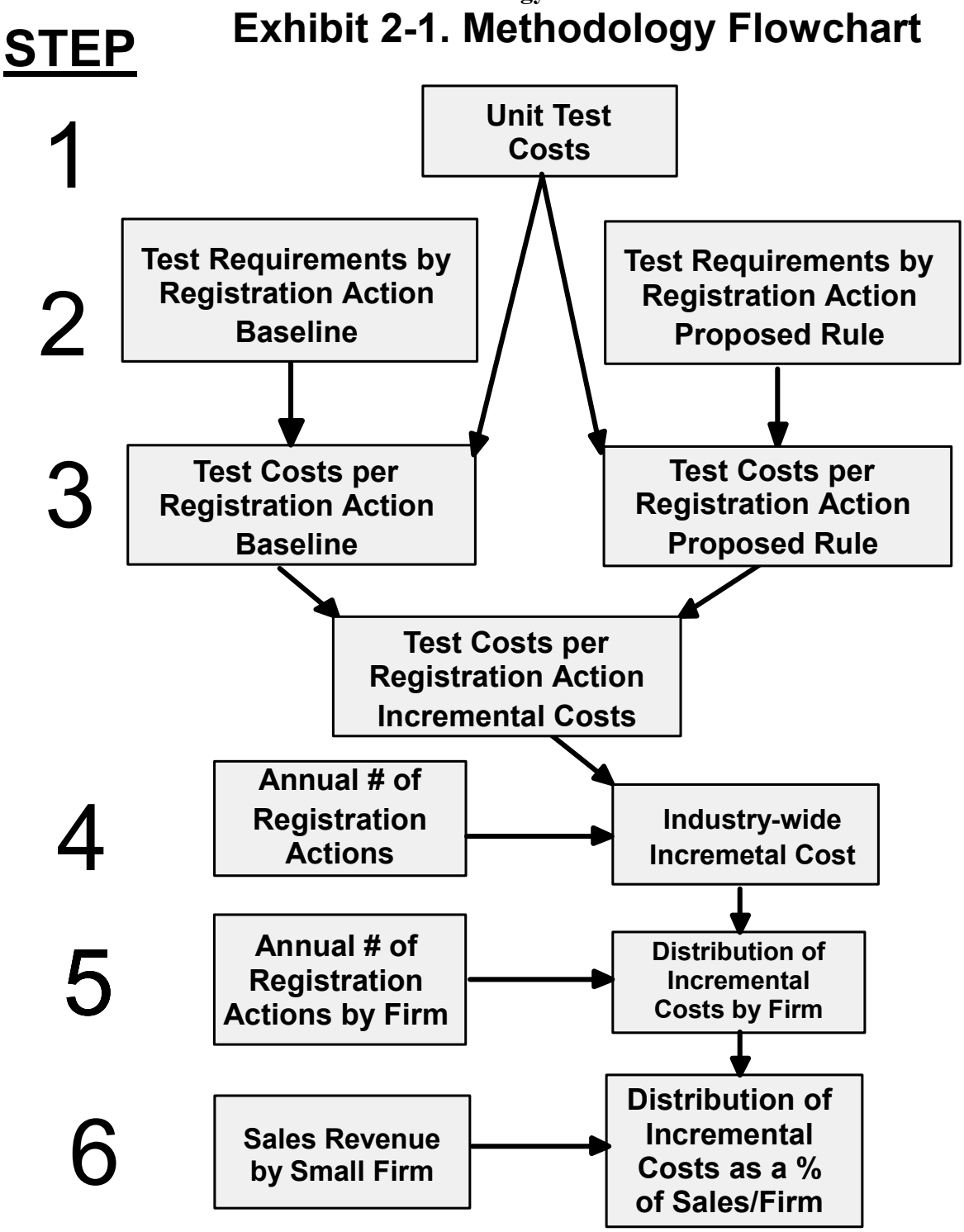
Overview of Methodology

The proposed data requirements for Part 158 were compared to the baseline, the data requirements currently codified in 40 CFR Part 158. These comparisons were conducted for each type of registration action. A registration action is either the registration of a pesticide product or an amendment to an existing registration. When a registrant submits an application to register or amend a product, EPA assigns an action code, which identifies the type of registration action. The incremental costs of each type of registration action due to the proposed changes were then multiplied by the number of each type of registration action, in order to estimate the expected total industry impact and the impacts per firm. This analysis was done in the following six steps:

Step 1. Determine the unit test costs of each data requirement
Step 2. Determine the data requirements per registration action
Step 3. Determine the incremental costs per registration action
Step 4. Determine the incremental industry-wide impacts
Step 5. Determine the incremental impact per firm
Step 6. Determine the incremental impact per small firm as a percent of sales

Chart 5.1 is a flow chart describing the methodology. The unit test costs (Step 1) are multiplied by the data requirements (Step 2) for both the baseline and proposed rule to estimate the test costs per registration action (Step 3). The incremental test costs per registration action are the difference in the test costs per registration action between the baseline and the proposed rule. The incremental costs per registration action are multiplied by the number of registration actions for the industry to get the industry-wide incremental impacts (Step 4) and the number of registration actions by each firm to get the distribution of incremental impacts per firm (Step 5). The incremental costs per small firm are divided by the entities' sales revenue to get the distribution of incremental impacts per small firm as a percent of sales revenue (Step 6–SBREFA analysis–Section 6).

Chart 5.1 Methodology Flowchart



5.1 Unit Test Costs (Step 1)

In order to provide the data required for a registration, registrants must submit or cite test results or other information to satisfy the data requirements. The test costs are the costs of complying with the specific data requirements, which depend on the type of product and use pattern.

EPA contacted a number of laboratories to obtain cost data for different test requirements conducted by testing labs. Laboratories were asked to identify the method, range, analytical, and fixed cost for each guideline based on a set of predetermined protocols. If for any test the component costs were not available, the laboratories were asked to provide a total cost. Understanding that the lab costs could vary considerably based on the study protocol chosen by the lab, we established two protocols, a high cost protocol and a low cost protocol, for each guideline in order to bracket the costs. To establish the protocols, we initially identified the various study design options for each study based on the Office of Pesticide Prevention and Toxic Substances (OPPTS) guidelines.

The Agency collected low and high cost estimates from actual testing labs for each guideline. For each data requirement, the Agency averaged the low cost estimates and high cost estimates provided by the various laboratories (see Appendix A: Test Cost Data Used to Calculate Guideline Costs for Part 158). The estimated low costs of complying with individual tests range from $2,000 (product use information and description of human activity) to $1,000,000 (field testing for non-aquatic non-target organisms). The estimated high costs of conducting individual tests range from $3,180 (honey bee acute contact LD_{50}) to an estimated $2,000,000 (groundwater monitoring and field testing for aquatic non-target organisms).

5.2 Data Requirements Per Registration Action (Step 2)

A registration action is a decision on an application from a registrant to register a product containing a new active ingredient or another type of new product, to add new uses to existing products, or to amend existing products. The data required for a registration action depends on several factors as described in section 2. In this section data requirements are summarized in terms of the following variables:

A. Data Category (Data Discipline)
B. Use Pattern
C. Type of Registration Action

A. Data Category

The data requirements (as described in detail in Section 2.6) of the proposed rule are organized into the following seven data categories or disciplines:

Toxicology
Human Exposure
Residue Chemistry
Product Chemistry

Ecological Effects
Environmental Fate
Non-target Plant Protection

B. Use Pattern

Within each of the seven data requirement categories listed above, a number of individual tests may be necessary. One of the factors that defines whether an particular test will be required for a product is how the product will be used, known as the pesticide's use pattern. Fifteen general use patterns are proposed to replace the nine use patterns found in the current CFR.

C. Type of Registration Action

The specific data required depend partly on the type of registration action. The following types of registration actions are affected by the proposed rule:

New active ingredient
Major new use
Substantive amendment

Registration actions are tracked in an EPA database called PRATS (Pesticide Registration Action Tracking System). Each registration action is assigned an action code that defines the specific type of registration action. Appendix E contains a list of PRATS action codes relevant to this analysis. For each general type of registration action listed above, there are several specific types of registration actions identified by action codes, which define specific data requirements more exactly than the general type registration action.

There are two ways to satisfy data requirements: data may be newly developed for a registration action, or data previously submitted for an existing product may be cited for a new registration action. This analysis considers only the costs of generating and submitting new data.

5.3 Incremental Costs and Impact Per Registration Action (Step 3)

The incremental costs are the differences in test costs between the baseline test costs, i.e., the tests described in current Part 158, and the cost of tests as required under the proposed rule.

Changes Included in Estimating Incremental Costs:

Newly imposed: The costs of new tests and increased frequency of data requirements that are not currently being imposed are shown in Appendix A as "Newly Imposed". They are a subset of the newly codified new tests and expanded use pattern data requirements. A sample of the newly imposed studies for non-food pesticides are shown below in Table 3.1.

Newly codified new tests: Test requirements that are not currently included in 40 CFR Part 158 are not in the baseline, even though they may be currently required in practice. Therefore, the incremental costs include the cost of all tests in the proposed rule that are not now codified in the CFR.

Table 5.1: Cost of Newly imposed Test requirements for Non-Food Active Ingredient

Guideline #	Newly Imposed Test Requirements for Non-Food Active Ingredient	Test Cost	% of Time Test is Required	Average Test Cost
850.2100	Avian Oral Toxicity	$10,100	100%	$10,100
835.4100	Aerobic Soil	$94,375	1%	$944
835.6200	Aquatic field	$267,250	1%	$2,673
870.7800	Immunotoxicity	$54,648	100%	$54,648
870.3700	Developmental Toxicity	$76,844	25%	$19,211
	Subtotal			**$87,576**

Newly codified expanded use pattern: In some cases, the proposed rule increases the frequency of data required in the tests currently in 40 CFR Part 158. Examples include:

Data not currently required will be required in the proposed rule for certain use patterns.
Data currently conditionally required would be routinely required by the proposed rule for certain use site categories.
Some current footnotes specifying when data are required have been changed in a manner that expands the application of the data requirement.

Estimation of Incremental Costs

"EPA is continuing its current system of identifying the applicability of data requirements in the data tables. Because of the variety of chemicals and use patterns, and because EPA must retain flexibility to tailor data requirements to its needs, it uses only qualitative descriptors in the tables. These are used for convenience to make the table format feasible, but serve only as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

The table descriptors (NR (not required), R (required), and CR (conditionally required) can be viewed as markers along a spectrum of the likelihood that the data requirement applies. The use of R does not necessarily indicate that a study is always required, but that it is more likely to be required than not. The use of CR means a study is less likely to be required. If percentages were to be assigned, R typically represents the range of 50-100% and CR represents up to 50%. EPA welcomes comment on ways to characterize the data requirements that would better serve applicant needs

The unit test costs of new tests are multiplied by the percentage of times each test is likely to be required for a particular action on a yearly basis. The Agency determined the percentages by using The Office of Pesticide Programs (OPP) database which contains the listing of all registration test data submitted to the Agency. This database was analyzed and EPA scientists used their expert judgment to estimate the percent of time the tests are required for the proposed rule and the baseline. (See Exhibits B.1 through B.6 of Appendix B).

In cases where the frequency of a test requirement would change under the proposal, the incremental cost of a registration action is estimated by multiplying the change in frequency (percent of time test is required) by the unit test cost.

5.4 Industry-Wide Impacts (Step 4)

In order to calculate the impact on the whole industry, the incremental costs for each type of registration action (Step 3) is multiplied by the average number of registration actions per year (shown in the row below the action codes in Exhibits B.1 - B.6). Also, in order to estimate the number of times each new test is likely to be required per year, the percentage of each type of registration action is multiplied by the average annual number of that type of registration action. These amounts are summed for all registration actions and multiplied by the unit test costs as shown in the right hand columns in Exhibits B.1 - B.6. The total annual industry incremental impact based on an average of 141 registration actions per year is estimated to be about $51 million. The average incremental impact per registration action is about $358,000.

5.5 Average Annual Cost per Firm (Step 5)

According to the PRATS database, 120 firms would have experienced incremental impacts from the proposed rule during the 7-year period, 1996-2002. A total annual impact of $51 million represents an average impact per firm of $420,000.

6 SMALL BUSINESS IMPACTS (STEP 6)

This section describes the method for defining and identifying the small entities affected by the rule, followed by an analysis of the number and percentage of entities incurring economic impacts. The incremental costs of registration actions for each small conventional pesticide firm is estimated and compared to its annual sales revenue to determine the incremental impact as a percent of sales revenue.

6.1 Regulatory Overview

The Regulatory Flexibility Act (RFA) of 1980 and its 1996 amendment, the Small Business Regulatory Enforcement Fairness Act (SBREFA) require that special consideration be given to the effects of proposed regulations on small business entities. The regulations require that a determination be made as to whether the proposed regulation will have a significant impact on a substantial number of small entities. EPA measured the economic impact by the annual compliance costs as a percentage of sales to assess the small business impacts.

6.2 Categorization of Small Businesses

The Small Business Act authorizes the Small Business Administration (SBA) to establish the definition of a small business. The SBA has set size standards under the North American Industrial Classification System (NAICS), using various thresholds on employee number and revenue amount, which vary by NAICS code. In determining the size of a firm, the SBA applies its standards to the parent level of a business entity.[1] The SBA also bases its determinations on the primary industry of the firm. In this analysis, the firm's primary NAICS code is assumed to be its primary industry, and the definition of small business is determined by the SBA based on

[1] Specifically, the SBA treats a firm that has a substantial portion of its assets and/or liabilities shared with a predecessor entity as part of that predecessor entity.

maximum number of employees or sales for small businesses in each industry sector, as defined by a 6-digit NAICS code. For example, entities defined as Pesticide and Other Agricultural Chemical Manufacturing (325320) are small if they employ 500 or fewer people; Pharmaceutical Preparation Manufacturing (325412) entities are small if they employ 750 or fewer people. Other entities are defined by sales. For example, Testing Laboratories (541380) are small entities if they have annual sales of $5.0 million or less.

6.2.1 Estimation of the Number of Small Businesses

As discussed in Section 4.7, EPA used the following databases to estimate the number of businesses registering pesticides:

PRATS, which tracks registration actions.
PPIS, which includes all registered pesticide products and their registrants.
D&B (Dunn & Bradstreet), which includes financial and firm size data on many firms.

The PRATS sample includes 120 firms that would have incurred incremental costs as a result of the proposed rule had it been in place from 1996-2002. Of these, 97 ultimate parent entities were identified. Twenty-three firms had insufficient D&B financial data to be classified by SBA size definitions. (One small and one large firm had employee data but not revenue data in D&B.) Table 6.1 shows the size distribution of the 97 parent entities in the PRATS sample. Of these 97 parent companies, 51% are small and 49% are large.

Table 6.1: Companies in the PRATS Sample by SBA Size.

Size[2]	Number of Parent Companies	Percentage of Parent Companies
Small	49	50.52%
Large	48	49.48%
Total	**97**	**100.00%**

Source: PRATS 2003, Dun & Bradstreet 2003.
[1] Twenty-three companies did not have sufficient Dun & Bradstreet (D&B) financial data to be classified by SBA size definitions.
[2] Size definitions vary according to the SBA small business definition associated with each NAICS code.

The PPIS database was queried in fall 2002 for all companies having one or more Section 3 or Section 24(c) (state) pesticide registrations. Companies with unique EPA company numbers in the PPIS database were consolidated based on the following criteria: (1) matching EPA company numbers with Dun & Bradstreet DUNS and ultimate parent DUNS numbers; (2) results of recent mergers and acquisitions; (3) matching company names associated with unique EPA company numbers; and (4) recommendations by EPA to be consolidated based on nearly identical name matching and/or prior knowledge. As a result, 1,804 unique companies represent the total universe of conventional pesticide registrants.

An attempt was made to match all 1,804 unique pesticide registrants with company information (total revenue and number of employees) from the Dun & Bradstreet (D&B) database. We assume D&B company information is available for all relatively large companies. However, D&B company information is not easily collected or readily available for relatively small companies.

A D&B data analysis of the 1,804 pesticide registrants identified 146 SBA-defined large pesticide registrants. This was done in two ways. First, 116 companies were successfully identified as large through cross-referencing D&B company numbers and associated company information with EPA company numbers from the 1,804 companies identified in the PPIS database. Second, the remaining companies were manually reviewed and we determined 30 additional companies met the SBA definition as large. The average revenue and employee numbers were determined for the 146 large pesticide registrants based on the company information reported in the D&B database.

The remaining 1,658 pesticide registrants were considered small companies (1,804 - 146). The average revenue and employee number for small pesticide registrants was determined from a random sample because sufficient D&B company information was not available for many small registrants. A random sample of 1,000 companies was taken from the original PPIS registrant data set and matched with company information (total revenue and number of employees) queried from the D&B database. Sufficient D&B company information was available for 565 of the 1,000 sample companies for classifying companies as small or large according to SBA standards. Of the 565 sample companies classified, 449 met the SBA definition for small. The average revenue and employee number for these 449 companies is assumed to be representative for all small pesticide registrants.

6.2.2 Sales and Employees

Tables 6.2 and 6.3 show the average sales and average number of employees for the parent entities in the PRATS and PPIS data set. The average sales for small parent entities in the PRATS data set is $24.3 million and the average sales for large parent entities is $9 billion. The average number of employees for small parent entities is 87, and the average number of employees for large parent entities is 33,274. The average sales for small parent entities in the PPIS data set is $8.8 million ,and the average sales for large parent entities is $5 billion. In PPIS data, the average number of employees for small parent entities is 39, and the average number of employees for large parent entities is 18,681.

Table 6.2: **Average Sales and Employees – PRATS Data Set**

Size	Sales		Employees	
	Number of Parent Companies with Data[1]	Average Sales	Number of Parent Companies with Data	Average Number of Employees
Small	48	$24,293,120	49	87
Large	47	$9,074,010,059	48	33,274

Source: PRATS 2003, Dun & Bradstreet 2003.
[1] One small and one large company reported employee data but no revenue data to D&B.

Table 6.3: Average Sales and Employees – PPIS Data Set

Size	Number of Parent Companies	Average Sales	Average Number of Employees
Small	1658	$8,840,000	39
Large	146	$5,041,690,000	18,681

Source: PPIS, Dun & Bradstreet 2002

Table 6.4 and 6.5 show the distribution of annual revenues and employees, by SBA threshold level, for PRATS and PPIS respectively.

Table 6.4: Number of Entities in Sample per SBA Category from PRATS Sample

SBA Threshold Criteria for Defining Small Businesses	Number of Sample Firms	Percentage of Sample Firms
100 or fewer employees	35	36%
500 or fewer employees	54	56%
750 or fewer employees	57	59%
1000 or fewer employees	59	61%
1,500 or fewer employees	60	62%
$4.0 million or less in revenue	20	21%
$5.0 million or less in revenue	21	22%
$6.0 million or less in revenue	21	22%
$7.0 million or less in revenue	22	23%
$12.0 million or less in revenue	28	29%
$18.5 million or less in revenue	32	34%
$20.0 million or less in revenue	33	35%

Table 6.5: Number of Entities in Sample per SBA Category and PPIS Sample

SBA Threshold Criteria for Defining Small Businesses	Number of Sample Firms	Percentage of Sample Firms
100 or fewer employees	409	72%
500 or fewer employees	477	84%
750 or fewer employees	486	86%
1000 or fewer employees	492	87%
1,500 or fewer employees	501	89%
$4.0 million or less in revenue	299	53%
$5.0 million or less in revenue	314	56%
$6.0 million or less in revenue	329	58%
$7.0 million or less in revenue	349	62%
$12.0 million or less in revenue	380	67%
$18.5 million or less in revenue	399	71%
$20.0 million or less in revenue	404	72%

6.3 Small Business Impact

As discussed above, the historical data suggest that the 120 entities in the PRATS sample are the most likely to incur costs under the rule over a given 7-year period. However, the number of small entities that are potentially subject to the regulation is actually much larger. In fact, any firm that might register or hold a registration for a conventional pesticide would be subject to the proposed rule once it is final. Therefore, the number of small entities subject to the proposed rule is equal to the number of small entities in our PPIS sample. In order to determine the number of small entities that will have compliance costs over a given cost-revenue threshold, it is necessary to consider all small entities subject to the regulation, even those that are expected

to incur no additional cost. The overall PPIS data set includes 1804 entities. For those entities that the Agency was able to determine a size, 79 percent were small. Assuming that 79 percent of all the PPIS entities are small, EPA estimated the number of regulated small entities to be 1434.

The Agency then looked at the number of entities that would have incurred costs under the rule had it been in place from 1996-2002. The PRATS data set includes 120 entities. For those entities for which a size could be determined, 50.5 percent were small. Assuming that 50.5 percent of all the PRATS entities are small, EPA estimated the number of regulated small entities that would have incurred additional costs to be 61. From the 49 small parent entities in our cost analysis (where we had both firm size and revenue information) the Agency projected the distribution of impacts to the 61 small firms. Most of small entities (1373) are not expected to incur additional costs as a result of the rule (1434 PPIS small entities - 61 PRATS small entities). The results of the analysis by percent impact are provided in Table 6.6.

Table 6.6: Estimated Small Business Impacts

Measure	Number of Small Companies			Percentage of Small Companies		
	Mean Lab Cost	Low Lab Cost	High Lab Cost	Mean Lab Cost	Low Lab Cost	High Lab Cost
Compliance Costs = 0 % of Revenue	1,373	1,373	1,373	95.7%	95.7%	95.7%
Compliance Costs >0% of Revenue	61	61	61	4.3%	4.3%	4.3%
Compliance Costs >1% of Revenue	35	32	34	2.4%	2.2%	2.4%
Compliance Costs >3% of Revenue	23	20	24	1.6%	1.4%	1.7%

In summary, the above table shows that for the mean lab cost:

61 small entities (4.3%) are likely to experience an impact greater than zero.

35 small entities (2.4%) of the 1373 small conventional entities that are subject to the proposed rule are likely to experience an economic impact of 1% or more of gross sales and,

23 small entities (1.6%) are likely to experience an economic impact of 3% or more of gross sales.

7 LIMITATIONS OF ANALYSIS

The important costs of this rule are associated with the increased cost of generating data in support of pesticide registration. Estimating this cost is uncertain and complicated due to a number of variables.

Unit Test Costs

Costs for guideline studies were gathered from a necessarily limited survey of commercial labs (see Appendix A, **Test Cost Data Used to Calculate Guideline Costs for Part 158 Rule**). For a number of studies there is a wide range of cost estimates. Although the Agency is not in a position to know the particular underlying reasons for this, presumably it is grounded in typical economic considerations tempered by the particular experience that labs may have had with the study protocols. Not surveyed were in-house labs that many companies use. Their costs might be expected to be lower than an independent lab.

Frequency of Various Tests Being Required

There is flexibility built into complying with Part 158 requirements. Agency experience has shown that pesticides and their uses vary widely. Individual chemical, toxicological, and exposure profiles may suggest quite different risk potential. To the extent practicable, the Agency has tried to guide users of tables with the proposed data requirements to the applicable requirements by including use categories and footnotes; however the utility of this application is limited. Ultimately, in certain cases, there is no substitute for Agency consultation with registrants so that appropriate "alternate" approaches or data can be considered for situations that do not exactly fit the tables.

It is very difficult to predict the extent to which a registrant may be able to satisfy a data requirement through a waiver request, bridging of existing data, or development of new data that adequately responds to the data requirement without performing a "guideline study". In estimating costs of newly codified data requirements, the Agency has relied upon scientific judgment of experienced staff to produce reasonable estimates of how often we expect to receive newly generated guideline studies to satisfy the proposed data requirements.

Number of Future Requested Registration Actions

Future requested registration actions may not closely reflect the past seven years of actions that the Agency used as a baseline for its estimate to predict future actions. This could be due to a number of factors including unforeseen changes in markets or scientific knowledge.

Other limitations include:

- Industry Structure. The analysis was based on 2002 financial data, but currently there is a trend where large companies are taking over small ones. For example, several large companies have purchased others and become vertically integrated, leaving a few large companies.

- Sales Data. About 449 of the 1,000 random sample of the conventional pesticide industry could be classified as large or small entities with sales data. Therefore, the analysis was based on this sample and projected to the industry. However, EPA cannot determine whether or to what extent this sample represents the total population of conventional pesticide entities.

- Cost Incidence. Because data limitations made it difficult to determine precisely when and

who bears the costs, several assumptions were made as listed below. Two of these assumptions, which average costs, tend to spread the costs to a greater number of entities at a lower cost per firm. Not allowing for data cost sharing has the opposite effect. EPA was not able to determine whether the net effect of these assumptions results in cost estimates that are overly concentrated or too spread out.

a. Data Cost Sharing. The analysis assumed that the registrants initiating registration actions would pay the full costs of the data required by these actions. Since many other registrants may pay to be able to cite data, the costs of data may be distributed more widely, resulting in a larger number of entities incurring smaller costs than estimated above.

b. Annual Average Costs. EPA averaged the costs over a 7 year period (1996-2002). Therefore, in any given year there are likely to be fewer entities bearing higher costs than what was estimated because it is unlikely that a specific entity will be introducing a new chemical every year.

c. Average Test Costs. Many of the tests are not required for all registration actions. EPA estimated average test costs per registration action by multiplying the test costs times the percent of time the tests are likely to be required. In reality, specific registration actions which require most of the tests may be more expensive, while others requiring few tests may be less expensive than the averages estimated.

In spite of these limitations, EPA concludes that there would not be a substantial number of small entities that would be significantly impacted as a result of the rule. The analysis shows a very low impact. Since the likely impact on small businesses is small, the Agency believes that a deleterious effect on the availability of pesticides to users is unlikely. On balance, the Agency believes that the costs of the rule are justified by the benefits from enhanced protection of human health and the environment.

8 ESTIMATION OF THE BURDEN OF THE DATA COLLECTION

The reporting and record keeping burden associated with the proposed rule is approximately 35,123 hours, and the burden cost is estimated to be $3,041,816 per year. These burdens are covered in the existing Section 3(Registration) ICR (Information Collection Request). The cost is shared by all respondents. This cost is an upper bound estimate. The Agency has already captured the burden for most of the data requirements it currently imposes (except for about 5 studies) through ICRs for the DCIs (Data Call-In). The calculation of the burden hours is shown in Table 8.1 below. Under Section 3 registration, registrants or applicants submit information in three categories:

- "Type A" activities involve a registrant or applicant assembling and submitting an application for registration of a new active ingredient (a.i.) or a major new use for a currently registered active ingredient. Typically for new a.i.'s, an application must be submitted for at least two new products – the manufacturing use product (either imported or

made in the U.S.) that may be formulated into an end use product and at least one end-use product (that bears the directions for the intended end use).

- "Type B" activities involve a registrant or applicant assembling and submitting an application for registration of a new or amended product that contains an active ingredient currently registered for the same use pattern. Often, the formulation of this product is identical or substantially similar to that of a currently registered end-use product. This is called "me-too" registration. In this case, the applicant only needs to cite data from the registered product. There are actually many cases where an applicant can cite data from one or more studies for another product (selective method) or site all data supporting a particular active ingredient (called the "cite-all" method) to support a new product.

- "Type C" activities involve registration of new conventional active ingredients or uses that may qualify as a "reduced risk" chemicals and/or organophosphate replacements, which are given expedited processing. An applicant must prepare an application that includes specific information, as described in PR notice 97-3 and/or 98-7, to explain why the new active ingredient or use may have a lower toxicity, exposure, or profile than currently registered products for the same commodity.

In this proposed rule only "Type A" and "Type C" activities are affected. Since "Type B" activities are "me too's", the applicant only needs to cite data from another source to support the new registration.

Table 8.1: Estimate for Type A Activities Annual Registrant Burden/Cost Estimates for Type A Activities for the Registration Division (RD): New Active Ingredients and New Uses

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. $121/hr.	Tech. $81/hr	Cler. $37/hr	Hours	Costs $
Read Instructions	19.44	0	0	19.44	$2,352
Plan activities	4.32	0	0	4.32	$ 523
Gather/create information	0	129.60	0	129.6	$10,498
Compile and review	4	8.64	0	12.96	$1,223
Complete paperwork	0	0	32.40	32.40	$1,199
Store/maintain data	0	0	10.80	10.08	$ 400
TOTAL	**28.08**	**138.24**	**43.20**	**209.52**	**$16,194**

ANNUAL BURDEN:

209.52 hours x 141 new active and new uses = 29,542 Hours

ANNUAL COSTS:

(a) Management: 28 hours x $121 x 141 new active and new uses = $ 477,708
(b) Technical: 138 hours x $81 x 141 new active and new uses = $1,576,098
(c) Clerical: 43 hours x $37 x 141 new active and new uses = $ 224,331
Total = $ 2,590,963

Table 8.2: Estimate for Type C Activities Annual Registrant Burden/Cost Estimates for Type C Activities for the Registration Division (RD): Reduced Risk

Collection Activity	Burden Hours (per year)			Total	
	Mgmt. $121	Tech. $81	Cler. $37	Hours	Cost
Read instructions	23.76	0	0	23.76	$2,875
Gather Information	0	397.44	0	397.44	$32,193
Process, Compile and Review Information	86.4	86.4	0	172.8	$17,453
Record and Report Information	0	0	77.76	77.76	$2,877
Store, File and Maintain Information	0	0	25.92	25.92	$959
TOTAL	**110.16**	**483.84**	**103.68**	**697.68**	**$56,357**

ANNUAL BURDEN:

697.68 hours x 8 new reduced risk = 5,581 Hours

ANNUAL COSTS:

(a) Management: 110.16 hours x $121 x 8 new reduced risk = $ 106,634.88
(b) Technical: 483.84 hours x $81 x 8 new reduced risk = $ 313,528.32
(c) Clerical: 103.68 hours x $37 x 8 new reduced risk = $ 30,689.28
Total = $ 450,852.48

Total burden hours is: 29,542 + 5,581 = 35,123.
Total burden cost is: $2,590,963 + 450,852.48 = $3,041,815.

9 ESTIMATION OF AGENCY BURDEN

EPA would incur costs primarily in reviewing the additional data required in the proposed Part 158 rule. EPA estimates the total annual cost to the Agency of reviewing the additional data to be approximately $1.5 million. The analysis is based on:

The average time reviewing the data (based on EPA experience).
The average hourly labor cost (based upon typical contractor costs and wage rate plus overhead for an employee at GS -13, Step 5).

This cost is multiplied by the average annual number of additional times each test is likely to be required to estimate the total incremental annual EPA cost of reviewing data from each requirement. The number of times a test is likely to be required annually was estimated in Section 3, where the average annual number of registration actions was multiplied by the percentage of time each test is likely to be required. See Appendix C.

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APPENDIX A: TEST COST DATA USED TO CALCULATE GUIDELINE COSTS[1]
for Part 158 Rule

Guideline Number[2]	Number of Labs[3]	Data Requirement	Average Cost	Average Low Cost	Average High Cost
73-3	1	Whole sediment - acute toxicity to pore water, fish and invertebrates	$37,500	$25,000	$50,000
74-1	2	Whole sediment - chronic toxicity, freshwater and marine invertebrates	$51,350	$34,700	$68,000
830.6313	8	Stability	$6,400	$5,557	$7,244
830.7050	8	UV/Visible Absorption	$2,022	$1,972	$2,072
830.7520	3	Particle Size	$1,333	$1,333	$1,333
830.7550,60,70	8	Partition Coefficient (N-Octanol/water)	$5,792	$5,372	$6,212
835.2120	5	Hydrolysis	$25,230	$20,560	$29,900
835.2370	1	Photodegradation in air	$110,000	$100,000	$120,000
835.2410	6	Photodegradation on soil	$42,350	$39,517	$45,183
835.4100	4	Aerobic soil metabolism studies	$94,375	$90,125	$98,625
835.4300	4	Aerobic aquatic metabolism studies	$44,475	$41,600	$47,350
835.4400	4	Anaerobic aquatic metabolism studies	$80,900	$75,275	$86,525
835.6100	3	Terrestrial field dissipation studies	$317,767	$269,467	$366,067
835.6200	2	Field dissipation studies for aquatic uses and aquatic impact uses	$267,250	$180,500	$354,000
835.6300	2	Forestry field dissipation studies	$275,500	$188,500	$362,500
835.7100	2	Groundwater monitoring	$1,225,000	$450,000	$2,000,000
850.1025 850.1035 850.1045 850.1055 850.1075	4	Acute LC50/EC50 estuarine and marine organisms	$16,969	$7,538	$26,400

APPENDIX A: TEST COST DATA USED TO CALCULATE GUIDELINE COSTS[1] for Part 158 Rule

Guideline Number[2]	Number of Labs[3]	Data Requirement	Average Cost	Average Low Cost	Average High Cost
850.1300	4	Fish early stage life and aquatic invertebrates	$118,063	$73,325	$162,800
850.1350	3	Mysid chronic toxicity	$36,333	$31,667	$41,000
850.1400	5	Fish early-life stage (freshwater)	$37,279	$33,179	$41,379
850.1950	2	Field testing in aquatic non-target organisms	$512,500	$375,000	$650,000
850.2100	1	Avian single-does oral LD50	$10,100	$6,400	$13,800
850.2200	3	Avian dietary	$6,480	$6,313	$6,647
850.2300	1	Avian reproduction test	$168,250	$121,000	$215,500
850.2500	1	Simulated or actual field testing	$650,000	$600,000	$700,000
850.3020	4	Honeybee acute contact LD50	$3,175	$3,175	$3,175
850.3040	2	Field testing for pollinators	$30,000	$21,250	$38,750
850.4100	4	Seedling Emergence Tier I	$14,625	$13,625	$15,625
850.4150	4	Vegetative Vigor Tier I	$15,875	$14,875	$16,875
850.4225	4	Seedling Emergence Tier II	$20,375	$18,750	$22,000
850.4250	4	Vegetative Vigor Tier II	$24,500	$22,500	$26,500
850.4400a	4	Aquatic Plant Toxicology Tier I	$35,155	$30,784	$39,525
850.4400b	4	Aquatic Plant Toxicology Tier II	$35,155	$30,784	$39,525
860.1300	3	Nature of the residue in animals	$105,833	$93,333	$118,333
860.1340	5	Residue analytical method	$62,850	$51,700	$74,000
860.1460	2	Magnitude of Residue - food handling	$205,000	$180,000	$230,000
870.1735	4	Whole sediment - acute invertebrates, fresh water	$20,250	$18,200	$22,300

APPENDIX A: TEST COST DATA USED TO CALCULATE GUIDELINE COSTS[1]
for Part 158 Rule

Guideline Number[2]	Number of Labs[3]	Data Requirement	Average Cost	Average Low Cost	Average High Cost
870.1740	4	Whole sediment - acute invertebrates, marine	$20,625	$18,575	$22,675
870.3200	8	21/28-day dermal	$83,240	$81,798	$84,681
870.3250	8	90-Day dermal	$137,094	$136,074	$138,114
870.3700	6	Developmental toxicity - rats	$76,844	$76,651	$77,037
870.3800	6	Multigenerational Reproduction	$378,479	$375,725	$381,233
870.6100	4	28 - day neurotoxicity	$79,375	$78,125	$80,625
870.6200a	6	Acute neurotoxicity - rat	$89,596	$87,513	$91,680
870.6200b	6	Chronic 90-day neurotoxicity - rat	$184,039	$181,668	$186,410
870.6300	5	Development neurotoxicity	$406,904	$396,672	$417,135
870.6500	2	Schedule controlled operant behavior	$164,000	$164,000	$164,000
870.6850	1	Peripheral nerve function	$110,000	$110,000	$110,000
870.6855	1	Neurophysiology: sensory evoked potentials	$110,000	$110,000	$110,000
870.7800	2	Immunotoxicity	$56,648	$55,564	$57,731
875.1100	7	Dermal outdoor exposure	$167,857	$143,571	$192,143
875.1200	7	Dermal indoor exposure	$126,429	$102,143	$150,714
875.1300	7	Inhalation outdoor exposure	$164,286	$143,571	$185,000
875.1400	7	Inhalation indoor exposure	$126,429	$102,143	$150,714
875.1500	7	Biological monitoring	$188,393	$157,500	$219,286
875.1600	0	Application Exposure data reporting and calculations	$7,500	$5,000	$10,000
875.1700	0	Product use information	$3,000	$2,000	$4,000

APPENDIX A: TEST COST DATA USED TO CALCULATE GUIDELINE COSTS[1] for Part 158 Rule

Guideline Number[2]	Number of Labs[3]	Data Requirement	Average Cost	Average Low Cost	Average High Cost
875.2100	5	Dislodgeable foliar residue and turf transferable	$55,100	$54,100	$56,100
875.2200	4	Soil Residue Dissipation	$83,125	$81,250	$85,000
875.2300	4	Indoor surface residue dissipation	$35,000	$32,000	$38,000
875.2400	5	Dermal Exposure	$125,500	$118,000	$133,000
875.2500	5	Inhalation Exposure	$73,000	$65,000	$81,000
875.2600	6	Biological monitoring	$166,875	$142,083	$191,667
875.2700	0	Product use information	$3,000	$2,000	$4,000
875.2800	0	Description of human activity	$3,000	$2,000	$4,000
875.2900	0	Post application exposure data reporting and calculations	$3,000	$2,000	$4,000
875.3000	3	Nondietary ingestion exposure	$75,000	$66,667	$83,333

[1] Only guidelines with non-zero action code probabilities are included (i.e., only those that affect the cost of the new Part 158 data requirements).

[2] A letter attached the end of a guideline number denotes a guideline which may have several different implementations, each with its own set of probabilities and costs (e.g. neurotoxicity testing could be performed on both rats and rabbits under the same OPPTS guideline). Therefore, in some instances each specific application of an OPPTS guideline is given a unique identifier for the analysis.

[3] Represents the number of unique laboratories that reported cost information for the OPPTS guideline of interest. For instances where two or more laboratory cost estimates were collected from a particular lab based on variability in study design, costs were not "double-counted" and one average test cost per lab per OPPTS guideline was used. In instances where the number of labs reporting costs is zero, this is due to certain OPPTS guidelines where field or laboratory data are not required and documentation preparation usually is required. For these OPPTS guidelines, the costs were estimated using best professional judgement by SciReg, a multidisciplinary scientific, regulatory, and quality assurance consulting firm.

APPENDIX B: COST SPREADSHEETS

DESCRIPTION

Using a Lotus 120 spreadsheet, Part 158 unit and aggregate costs were estimated for the proposed rule and a regulatory option for new conventional pesticide registrations. An explanation of columns and rows follows. Header row shows data category, action code affected by the proposed data requirement, number of actions per year and the annual incremental increase.

Column

Guideline	EPA guideline number that describes the test protocol.
Data Requirement	The name of the test.
Action code	Each registration action is assigned an action code that defines the specific type of registration action. The PRATS database provides a list of pesticide registration actions submitted by each applicant or registrant, including the dates applications were received by EPA and when the Agency responded to each application. For this analysis, the Agency utilized a subset of the PRATS dataset with registration action codes relevant to Part 158 submitted from 1996 through 2002 for conventional chemicals. See Appendix E for more detailed explanation of the different action codes.
New Active Ingredient Food Use	Requirement is triggered by applicant request to register an active ingredient with no current registered user for a food use.
New Active Ingredient Non-Food Use	Requirement is triggered by applicant request to register an active ingredient with no current registered food uses solely for a non-food use.
Major New Use	Requirement is triggered by applicant request to add a major new use for an active ingredient with existing registered uses. The incremental percent increase represents an estimate of how often the active ingredient (a.i.), will need and not already have an adequate study.
Individual Test Cost	The average of the maximum and minimum cost for performing the test to obtain the data.

Increased % of Actions Tests are Likely to be Required	The increase in percentages of new registrations and new uses that are likely to require each test. This is estimated by EPA specialists in each subject area. (The percentages are incremental differences between the proposed rule and the baseline, current part 158). EPA is continuing its current system of identifying the applicability of data requirements in the data tables. Because of the variety of chemicals and use patterns, and because EPA must retain flexibility to tailor data requirements to its needs, it uses only qualitative descriptors in the tables. These are used for convenience to make the table format feasible, but serve only as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

The table descriptors (NR (not required), R (required), and CR (conditionally required) can be viewed as markers along a spectrum of the likelihood that the data requirement applies. The use of R does not necessarily indicate that a study is always required, but that it is more likely to be required than not. The use of CR means a study is less likely to be required. If percentages were to be assigned, R typically represents the range of 50-100% and CR represents up to 50%. EPA welcomes comment on ways to characterize the data requirements that would better serve applicant needs

Number of Tests	Incremental increase in the total number of times the test is likely to be required each year. = ∑(Number of registrations per year x Increased % of Actions Tests are Likely to be Required)
New Tests	Annual incremental increase in the cost of newly codified tests = Individual test cost x Number of Tests
Increased Requirement	Annual incremental increase in the cost of newly codified expanded requirements for existing tests = Individual test cost x Number of Tests
Newly Imposed	Annual incremental increase in the cost of newly imposed tests = Individual test cost x Number of Tests

Types of Data Requirements

All tests are newly codified

New Test:	All newly codified tests: Test requirements that are not currently included in 40 CFR Part 158 are not in the baseline, even though they may be currently required in practice. Therefore, the incremental costs include the cost of all tests in the proposed rule that are not now codified in the CFR.
Newly imposed:	This subset of new tests shows the costs of tests that are not currently being imposed.

Exhibit B.1: Newly Codified Data Requirements and Costs **Toxicology**						**Annual Incremental Increase**			
		Action Code:	100	115	various				
		# Action/Year:	12	5	123		**Newly Codified**		**Newly Imposed (subset of newly codified)**
Guideline	**Data Requirement**	**Individual Test Cost**	**New AI**		**Major New Use**	**Num-ber of Tests**	**New Test**	**Increased Requirement**	
			Food Use	**Non Food**					
Acute Testing									
870.6200	Acute neurotoxicity - rat	$89,596	100%	100%	5%	23.6	$2,114,473	$0	$0
Subchronic Testing									$0
870.3100	90-day feeding - rodent[1]	$0	0%	0%	0%	0.0	$0	$0	$0
870.3200	21-day dermal[2]	$83,240	30%	-40%	0%	1.7	$0	$143,886	$0
870.3250	90-day dermal[2]	$137,094	-40%	30%	5%	2.7	$0	$370,153	$0
870.6100	28-day neurotoxicity - hen	$79,375	10%	10%	5%	7.9	$628,196	$0	$0
870.6200	90-day neurotoxicity -rat	$184,039	100%	100%	10%	29.8	$5,479,104	$0	$0
Developmental Toxicity and Reproduction									
870.3700	Prenatal developmental toxicity - rat and rabbit, preferred[3]	$76,844	0%	100%	1%	6.2	$0	$479,065	$479,065
870.3800	Reproduction[4]	$378,478	0%	45%	0%	2.2	$0	$851,576	$0
870.6300	Developmental neurotoxicity[5]	$406,904	60%	20%	10%	20.8	$8,463,595	$0	$0
Mutagenicity Testing									
870.5100 870.5300 870.5375 870.5385 870.5395	Current mutagenicity battery[6]	$0	0%	0%	0%	0	$0	$0	$0
Special Testing									
870.6500	Schedule controlled operant behavior	$164,000	1%	1%	1%	0.8	$129,794	$0	$0
870.6850	Peripheral nerve function	$110,000	1%	1%	1%	0.8	$87,057	$0	$0
870.6855	Neurophysiology: sensory evoked potentials	$110,000	1%	1%	1%	0.8	$87,057	$0	$0
870.7800	Immunotoxicity	$56,648	100%	100%	1%	13.9	$1,057,206	$0	$1,057,206
Total Toxicology*		**$1,876,218**					**$18,046,482**	**$1,844,680**	**$1,536,271**

*Sums are not exact due to rounding off.

Exhibit B.2: Newly Codified Data Requirements and Costs **Applicator and Post-Application Exposure**						**Annual Incremental Increase**			
		Action Code:	100	115	various				
		# Action/Year:	12	5	123	**Number of Tests**	**Newly Codified**		**Newly Imposed (subset of newly codified)**
Guideline	**Data Requirement**	**Individual Test Cost**	**New AI**		**Major New Use**		**New Test**	**Increased Requirement**	
			Food Use	**Non Food**					
Applicator Exposure[1]									
875.1100	Dermal outdoor exposure	$167,857	20%	20%	5%	9.7	$1,621,020	$0	
875.1200	Dermal indoor exposure	$126,429	20%	20%	5%	9.7	$1,220,939	$0	
875.1300	Inhalation outdoor exposure	$164,286	20%	20%	5%	9.7	$1,586,531	$0	
875.1400	Inhalation indoor exposure	$126,429	20%	20%	5%	9.7	$1,220,939	$0	
875.1500	Biological monitoring[2]	$188,393	1%	1%	1%	1.4	$265,365	$0	
875.1600	Data reporting and calculations	$7,500	100%	100%	80%	116.2	$871,286	$0	
875.1700	Product use information[3]	$3,000	100%	100%	80%	116.2	$348,514	$0	
Total Application Exposure*		**$783,894**					**$7,134,594**		
Post-Application Exposure[1]									
875.2100	Dislodeagable foliar residue and turf transferable residues[2]	$55,100	25%	25%	5%	10.5	$0	$580,124	
875.2200	Soil residue dissipation	$83,125	25%	5%	5%	9.5	$0	$792,063	
875.2300	Indoor surface residue dissipation	$35,000	25%	25%	10%	16.7	$584,500	$0	
875.2400	Dermal exposure	$125,500	25%	25%	5%	10.5	$0	$1,321,336	
875.2500	Inhalation exposure	$73,000	5%	5%	5%	7.0	$0	$514,129	
875.2600	Biological monitoring[3]	$166,875	1%	1%	1%	1.4	$235,055	$0	
875.2700	Product use information[4]	$3,000	100%	100%	80%	116.2	$348,514	$0	
875.2800	Description of human activity	$3,000	100%	100%	80%	116.2	$348,514	$0	
875.2900	Data reporting	$3,000	100%	100%	80%	116.2	$348,514	$0	
875.3000	Nondietary ingestion Exposure	$75,000	10%	10%	1%	3.0	$223,286	$0	
Total Post Application Exposure*		**$622,600**					**$2,088,383**	**$3,207,652**	

*Sums are not exact due to rounding off.

Exhibit B.3: Newly Codified Data Requirements and Costs **Terrestrial and Aquatic Non-target Organisms**						**Annual Incremental Increase**			
		Action Code:	100	115	various				
		# Action/Year:	12	5	123		**Newly Codified**		**Newly Imposed (subset of newly codified)**
Guideline	**Data Requirement**	Individual Test Cost	**New AI**		**Major New Use**	**Number of Tests**	**New Test**	**Increased Requirement**	
			Food Use	**Non Food**					
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	$10,100	100%	100%	1%	18.7	$188,495	$0	$188,495
850.2200	Avian dietary toxicity	$6,480	0%	-10%	0%	-0.5	$0	($3,240)	$0
850.2300	Avian reproduction	$168,250	50%	42%	0%	8.3	$0	$1,396,074	$0
850.2500	Simulated or actual field testing[1]	$650,000	5%	4%	0%	0.8	$0	$539,345	$0
Aquatic Organism Testing[2,3,4,5]									
850.1025, 1035, 1045, 1055,1075	Acute toxicity estuarine and marine organisms	$16,969	75%	63%	3%	16.1	$0	$274,033	$0
850.1300	Aquatic invertebrate life-cycle (freshwater)	$118,063	20%	17%	3%	7.0	$0	$829,024	$0
850.1350	Aquatic invertebrate life-cycle (saltwater)	$36,333	5%	4%	0%	0.8	$0	$30,148	$0
850.1400	Fish early life-stage (freshwater)	$37,279	25%	21%	3%	7.9	$0	$292,705	$0
Sediment Testing									
Whole Sediment - Acute Invertebrates[6]									
870.1735	--freshwater	$20,250	20%	17%	5%	9.5	$0	$192,182	$0
870.1740	--marine	$20,625	15%	13%	5%	8.7	$178,627	$0	$0
- Whole sediment									
none	-Chronic invertebrates (freshwater and marine)[7]	$51,350	15%	13%	4%	7.4	$0	$381,347	$0
Acute pore water									
None	–fish and invertebrates	$37,500	5%	4%	5%	7.0	$262,545		
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	$3,175	50%	42%	5%	14.5	$0	$45,939	$0
850.3040	Field testing for pollinators	$30,000	5%	4%	0%	0.8	$0	$24,893	$0
	Total Terrestrial and Aquatic*	**$1,168,874**					**$629,667**	**$4,002,450**	**$188,495**

*Sums are not exact due to rounding off.

Exhibit B.4: Newly Codified Data Requirements and Costs **Environmental Fate**						**Annual Incremental Increase**			
		Action Code:	100	115	various				
		# Action/Year:	12	5	123		**Newly Codified**		**Newly Imposed (subset of newly codified)**
		Individual Test Cost	**New AI**		**Major New Use**	**Number of Tests**	**New Test**	**Increased Requirement**	
Guideline	**Data Requirement**		**Food Use**	**Non Food**					
Degradation Studies-Laboratory									
835.2120	Hydrolysis	$25,230	0%	12%	1%	1.2		$30,288	$0
835.2410	Photodegradation on soil	$42,350	30%	30%	10%	7.0		$298,265	$0
835.2370	Photodegradation in air	$110,000	1%	1%	1%	0.8		$86,140	$0
Metabolism Studies-laboratory									
835.4100	Aerobic soil metabolism	$94,375	1%	1%	0%	0.3		$27,310	$27,310
835.4400	Anaerobic aquatic metabolism	$80,900	45%	38%	5%	13.6		$1,103,418	$0
835.4300	Aerobic aquatic metabolism	$44,475	45%	38%	5%	13.6		$606,607	$
Dissipation Studies - Field									
835.6100	Terrestrial field dissipation	$317,767	1%	1%	1%	1.4		$444,949	$0
835.6200	Aquatic field dissipation	$267,250	1%	1%	1%	1.4		$374,214	$374,214
835.6300	Forestry dissipation	$275,500	0%	-10%	-1%	-1.7		($477,796)	$0
Accumulation Studies									
850.1950	In aquatic non-target organisms	$512,500	1%	0%	0%	0.1		$67,967	$0
Ground Water Monitoring									
835.7100	Ground water monitoring	$1,225,000	1%	1%	1%	0.8	$969,500		$0
Total Environmental Fate*		**$2,995,347**					**$969,500**	**$2,561,362**	**$401,524**

*Sums are not exact due to rounding off.

Exhibit B.5: Newly Codified Data Requirements and Costs **Non-Target Plant Protection**						**Annual Incremental Increase**			
		Action Code:	100	115	various				
		# Action/Year:	12	5	123	**Num-ber of Tests**	**Newly Codified**		**Newly Imposed (subset of newly codified)**
		Individual Test Cost	**New AI**		**Major New Use**		**New Test**	**Increased Requirement**	
Guideline	**Data Requirement**		**Food Use**	**Non Food**					
Non-target Area Phytotoxicity Tier I									
850.4100	Seedling emergence	$14,625	10%	10%	0%	1.7		$25,489	
850.4150	Vegetative vigor	$15,875	10%	10%	0%	1.7		$27,668	
850.4400	Aquatic plant growth	$35,155	10%	10%	0%	1.7		$61,269	
Non-target Area Phytotoxicity Tier II									
850.4225	Seedling emergence	$20,375	3%	3%	0%	0.5		$10,653	
850.4250	Vegetative vigor	$24,500	3%	3%	0%	0.5		$12,810	
850.4440	Aquatic plant growth	$35,155	11%	11%	0%	1.9		$67,396	
Total Non-Target Plant Protection*		**$145,685**					**$0**	**$205,285**	**$0**

*Sums are not exact due to rounding off.

Exhibit B.6: Newly Codified Data Requirements and Costs **Residue and Product Chemistry**						**Annual Incremental Increase**			
		Action Code:	100	115	various				
		# Action/Year:	12	5	123	**Num-ber of Tests**	**Newly Codified**		**Newly Imposed (subset of newly codified)**
		Individual Test Cost	**New AI**		**Major New Use**		**New Test**	**Increased Requirement**	
Guideline	**Data Requirement**		**Food Use**	**Non Food**					
Residue Chemistry									
860.1300	Nature of the residue in livestock	$105,833	20%	20%	15%	22.0	$0	$2,328,326	
860.1340	Residue analytical methods	$62,850	95%	0%	10%	26.3	$0	$1,517,828	
860.1460	Food handling	$205,000	25%	25%	20%	29.0	$0	$5,953,786	
	Total Residue Chemistry	**$373,683**					**$0**	**$9,799,940**	**$0**
Product Chemistry									
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/ water)[1]	$5,792	45%	45%	5%	14.0	$0	$81,171	
830.6313	Stability to temperatures, metals, and metal ions[2]	$6,400	-50%	-50%	-5%	-14.9	$0	($95,269)	
830.7050	UV/visible light absorption	$2,022	100%	100%	10%	29.8	$60,198	$0	
830.7520	Particle size, fiber length, and diameter distribution	$1,333	5%	5%	5%	7.0	$9,388	$0	
	Total Product Chemistry*	**$15,547**					**$69,586**	**($14,098)**	**$0**

*Sums are not exact due to rounding off.

Exhibit B.7: Newly Codified Data Requirements and Costs		Annual Incremental Increase			
Summary of Part 158 Incremental Data Costs		Newly Codified			Newly Imposed (subset of Newly Codified)
Test Category Totals	Individual Test Cost	New Test	Increased Requirement	Total	
Total Toxicology	$1,876,218	$18,046,482	$1,844,680	$19,891,162	$1,267,195
Total Application Exposure	$783,894	$7,134,594	$0	$7,134,594	$0
Total Post Application Exposure	$622,600	$2,088,383	$3,207,652	$5,296,035	$0
Total Terrestrial and Aquatic	$1,168,874	$629,667	$4,002,450	$4,632,117	$188,495
Total Environmental Fate	$2,995,347	$969,500	$2,561,362	$3,530,862	$401,524
Total Non-Target Plant Protection	$145,685	$0	$205,285	$205,285	$0
Total Residue Chemistry	$373,683	$0	$9,799,940	$9,799,940	$0
Total Product Chemistry	$15,547	$69,586	($14,098)	$55,488	$0
Grand Total	**$7,981,848**	**$28,938,212**	**$21,607,271**	**$50,545,483**	**$1,857,214**

*Sums are not exact due to rounding off.

ENDNOTES:

TOXICOLOGY DATA REQUIREMENTS

Subchronic Testing

[1] Guideline 870.3100 - 90 Day Feeding - Rodent
The 90-day subchronic feeding study in the mouse is not required in current Part 158. However, it was generally conducted as a dose selection study for the mouse cancer study. This study along with the 90-day rat feeding study would form the basis for the doses used for the rat and mouse cancer studies which are required for all food use pesticides. For all practical purposes, registrants have been doing this study as the initial part of the mouse cancer study.

[2] Guideline 870.3200 - 21-Day Dermal and Guideline 870.3250 - 90-Day Dermal
For both food and non-food uses, dermal testing may be needed on the end-use product. The 21-day subchronic test may be required for food use pesticides for worker risk assessments. However, the Agency recognizes that not all food use applications pose worker risk and will consider waiver requests if warranted. The 90-day study (in lieu of the shorter subchronic study) would be required for non-food uses if the dermal route is the major route of exposure. For the Economic Analysis, the costs shown cover both the end-use product and the technical grade active ingredient.

Developmental Toxicity and Reproduction

[3] Guideline 870.3700 - Prenatal Developmental Toxicity
To the extent that a study is needed to approve a new use of a registered active ingredient, the cost for testing a second species is included.

[4] Guideline 870.3800 - Reproduction
This study is now required for non-food uses. This data requirement is still exposure-based and as such may not be necessary. To support a waiver of the requirement, the registrant must demonstrate that the anticipated use human exposure of a chemical is insignificant.

[5] Guideline 870.6300 - Developmental Neurotoxicity
The developmental neurotoxicity study is being required for all food use and non-food use pesticides. However, the Agency recognizes that there are a number of situations where this study may not be needed and will consider waiver requests if warranted.

Comparative sensitivity testing, in relation to the developmental neurotoxicity study, has only been required for those organophosphorus pesticides with tolerances that were included in the DCI. In the future, as DCIs are developed for additional chemical classes, it is probable that comparative cholinesterase studies will be required for carbamate pesticides (with tolerances) that have been shown to inhibit cholinesterase, but not for other carbamates. It is unlikely that any other chemical class will be affected. The costs of comparative cholinesterase testing is not included in the EA because: 1) Comparative sensitivity testing for cholinesterase inhibition is not a broad testing requirement, rather, it is specific to only one or two chemical classes, 2) there is no standardized guideline for comparative sensitivity testing, and 3) it is not expected that the testing will be required broadly in the future.

Mutagenicity Testing

[6] Guideline 870.5100, 870.5300, 870.5375, 870.5385, and 870.5395 - Mutagenicity Battery
There is no significant change in cost, because Agency is replacing the current studies with other comparably priced mutagenicity studies.

APPLICATOR EXPOSURE DATA REQUIREMENTS

[1] Whenever possible, existing surrogate data will be used to assess the occupational and residential exposure to pesticides. Because the Agency does not commonly require these studies and because surrogate data is often available, the Agency does not expect that "full" studies will often be needed.

[2] Guideline 875.1500 - Biological Monitoring
EPA rarely requires biomonitoring data. Usually biomonitoring is voluntarily selected by the registrant as an alternative to other studies since it eliminates factors such as dermal and inhalation absorption from an exposure assessment. However in certain situations, such as swimmer assessments, passive dosimetry techniques are not feasible and EPA needs the flexibility to require biomonitoring data, if other methods of estimating exposure are not sufficient.

[3]Guideline 875.1700 - Product Use Information
The product use information data requirement is necessary to identify the use-patterns for a given product so that EPA can identify with reasonable accuracy the appropriate handler and post-application exposure scenarios associated with that product. In general, the needed information should be readily available to the registrant from their files.

POST-APPLICATION EXPOSURE DATA REQUIREMENTS

[1] Post-application exposure monitoring data are proposed to be pesticide- or formulation-specific, however, surrogate exposure data may be submitted, if appropriate. In general, the studies required are dependent upon the pesticide site and use patterns, potentially exposed populations, significant exposure routes, and the time duration over which the exposure occurs. The employment of exposure mitigating measures, such as packaging or use restrictions, *e.g.,* tamper-resistant bait stations, may alleviate the need for some or all of the data requirements in this subpart. The Agency does not believe that "full" studies will be commonly required.

[2] Guideline 875.2100 - Dislodgeable Foliar Residue and Turf Transferable Residue
Generally, EPA asks for these studies on representative crops. For large agricultural chemicals, we may request studies on 1-3 crops. For ornamental plants, one study should generally be sufficient. Although it is likely to be an overestimation to include more than one crop, EPA will assume that an average of 2 crops (i.e., 2 studies) would be required for active ingredients that have use patterns where these residues may occur.

[3] Guideline 875.2600 - Biological Monitoring
EPA rarely requires biomonitoring data. Usually biomonitoring is voluntarily selected by the registrant as an alternative to other studies since it eliminates factors such as dermal and inhalation absorption from an exposure assessment. However in certain situations, such as swimmer assessments, passive dosimetry techniques are not feasible and EPA needs the flexibility to require biomonitoring data, if other methods of estimating exposure are not sufficient.

[4] Guideline 875.2700 - Product Use Information
The product use information data requirement is necessary to identify the use-patterns for a given product so that EPA can identify with reasonable accuracy the appropriate handler and post-application exposure scenarios associated with that product. In general, the needed information should be readily available to the registrant from their files.

TERRESTRIAL AND AQUATIC ORGANISMS DATA REQUIREMENTS

Avian and Mammalian Testing

[1] Guideline 870.2500 Simulated or Actual Field Testing
Although the Agency proposes to expand this conditional requirement to include terrestrial feed crop and aquatic non-food outdoor uses, this requirement would be based on the results of lower tiered studies such as acute and subacute bird and mammal testing, intended use pattern, and environmental fate characteristics that indicate potential exposure. Testing would be required only for those products that appear to pose significant risks to non-target wildlife.

Aquatic Organism Testing

[2] Guidelines 850.1025, 850.1035, 850.1045, 850.1055, and 850.1075 - Acute toxicity: Estuarine and Marine Organisms
Since only 3 out of the 5 studies would be needed to satisfy the data requirement, the Economic Analysis only includes the cost for 3.

[3] For the acute toxicity study (Guideline 850.1025), the test costs included the TGAI. The TEP would only be required if the conditions specified in the test note are met.

[4] For the freshwater fish toxicity study (Guideline 850.1075), the test costs associated with testing the TEP were not included, since only one test substance (preferably TGAI) will be used.

[5] For the aquatic invertebrate life-cycle (freshwater) (Guideline 850.1350) and fish early-life stage (freshwater) (Guideline 850.1400), the Agency is proposing to require terrestrial, aquatic (food and non-food outdoor), and forestry uses which are currently conditionally required.

Sediment Testing

[6] Guidelines 850.1735 and 850.1740 - Whole Sediment: Acute Toxicity to Invertebrates, Freshwater and Marine
The Economic Analysis included the estimated cost of $18,000 to $22,000 for testing one set of sediment. For freshwater or marine exposure, initially, only one set of sediment with a 3% organic content is tested. Depending on the results from this study, additional sets of sediment may be tested.

[7] For the Whole Sediment: Chronic Toxicity to Invertebrates study, the cost of testing one species including the analytical work is $32,000.

PRODUCT CHEMISTRY

[1] Guidelines 830.7550, 830.7560, and 830.7570 - Partition Coefficient (n-octanol/water)
The Agency proposes to change the requirement from "conditionally required" to "required," because the majority of currently registered pesticides are organic non-ionic chemicals that are not expected to significantly hydrolyze or solubilize in water. In the event a chemical fully hydrolyzes or is completely soluble in water, this data requirement would be waived.

[2] Guideline 830.6313 - Stability to Temperatures, Metals, and Metal Ions
The Agency proposes to change the requirement for stability data from "required" to "conditionally required." Data on the stability to metals and metal ions is required only if the active ingredient is expected to come into contact with either metal during storage.

Appendix C
Agency Impacts

Exhibit C.1. Estimate of Annual EPA Cost of Reviewing Data

Guideline	Data Requirement	Review hours/test		Cost per Test	Average number of additional tests/year	Annual Cost
		EPA	Contractor			
Toxicology						
Acute Testing						
870.6200	Acute neurotoxicity - rat	30	30	$3,763	23.6	$88,813
Subchronic Testing						
870.3200	21-day dermal	20	20	$2,509	1.7	$4,337
870.3250	90-day dermal	45	45	$5,645	2.7	$15,241
870.6100	28-day neurotoxicity -hen	20	20	$2,509	7.9	$19,856
870.6200	90-day neurotoxicity - rat	55	55	$6,899	29.8	$205,403
Developmental Toxicity and Reproduction						
870.3700	Prenatal developmental toxicity - rat and rabbit, preferred	30	30	$3,763	6.2	$23,461
870.3800	Reproduction	20	20	$2,509	2.2	$5,645
870.6300	Developmental neurotoxicity	60	60	$7,527	20.8	$156,552
Special Testing		0	0	$0	0.0	$0
870.6500	Schedule controlled operant behavior	45	45	$5,645	0.8	$4,468
870.6850	Peripheral nerve function	45	45	$5,645	0.8	$4,468
870.6855	Neurophysiology: sensory evoked potentials	45	45	$5,645	0.8	$4,468
870.7800	Immunotoxicity	45	45	$5,645	13.9	$78,537
	Total Tox					**$611,247**
Applicator Exposure						
875.1100	Dermal outdoor exposure	40	40	$5,018	9.7	$48,457
875.1200	Dermal indoor exposure	40	40	$5,018	9.7	$48,457
875.1300	Inhalation outdoor exposure	40	40	$5,018	9.7	$48,457
875.1400	Inhalation indoor exposure	40	40	$5,018	9.7	$48,457
875.1500	Biological monitoring	40	40	$5,018	1.4	$7,068
875.1600	Data reporting and calculations	2	0	$131	116.2	$15,205
875.1700	Product use information	2 0	$131 116.2	$15,205		
Total Applicator Exposure						**$231,304**
Post-Application Exposure						
875.2100	Dislodeagable foliar residue and turf transferable residues	40	40	$5,018	10.5	$52,829
875.2200	Soil residue dissipation	40	40	$5,018	9.5	$47,811
875.2300	Indoor surface residue dissipation***	40	40	$5,018	16.7	$83,795
875.2400	Dermal exposure	40	40	$5,018	10.5	$52,829
875.2500	Inhalation exposure	40	40	$5,018	7.0	$35,339
875.2600	Biological monitoring***	40	40	$5,018	1.4	$7,068
875.2700	Product use information***	2	0	$131	116.2	$15,205
875.2800	Description of human activity***	2	0	$131	116.2	$15,205

Guideline	Data Requirement	Review hours/test		Cost per Test	Average number of additional tests/year	Annual Cost
		EPA	Contractor			
875.2900	Data reporting***	2	0	$131	116.2	$15,205
875.3000	Nondietary ingestion Exposure***	40	40	$5,018	3.0	$14,938
	Total Post-Application Exposure					**$340,225**
Terrestrial and Aquatic Non-target Organisms						
Avian and Mammalian Testing						
850.2100	Avian oral LD_{50}	2	6	$491	18.7	$9,161
850.2200	Avian dietary	2	6	$491	-0.5	($245)
850.2300	Avian reproduction	8	30	$2,324	8.3	$19,280
Aquatic Organism Testing						
850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	2	6	$491	16.1	$7,927
Sediment Testing						
Whole Sediment -Acute Invertebrates						
870.1735	--freshwater	2	6	$491	9.5	$4,659
870.1740	--marine	2	6	$491	8.7	$4,251
	Whole sediment					
none	-Chronic invertebrates	8	30	$2,324	7.4	$17,256
Insect Pollinator Testing						
850.3020	Honeybee acute contact toxicity	2	6	$491	14.5	$7,103
850.3040	Field Testing for Pollinators	10	50	$3,654	0.8	$3,032
	Total Eco					**$82,688**
Environmental Fate						
	Degradation Studies-Laboratory					
835.2120	Hydrolysis	14	45	$3,616	1.2	$4,341
835.2370	Photodegration in air	14	45	$3,616	0.8	$2,832
	Metabolism Studies-laboratory					
835.4100	Aerobic soil	18	60	$4,778	0.3	$1,383
835.4400	Anaerobic aquatic	21	70	$5,574	13.6	$76,029
835.4300	Aerobic aquatic	21	70	$5,574	13.6	$76,029
	Dissipation Studies - Field					
835.6100	Terrestrial	26	85	$6,801	1.4	$9,524
835.6200	Aquatic (sediment)	21	70	$5,574	1.4	$7,805
835.6300	Forestry	21	70	$5,574	(1.7)	($9,667)
	Accumulation Studies					
850.1950	In aquatic non-target organisms	21	70	$5,574	0.1	$739
Ground Water Monitoring						
835.7100	Ground water monitoring	21	70	$5,574	0.8	$4,412
	Total Fate					**$173,427**
Non-target Plant Protection						

Guideline	Data Requirement	Review hours/test		Cost per Test	Average number of additional tests/year	Annual Cost
		EPA	Contractor			
Nontarget Area Phytoxicity Tier I						
850.4100	Seedling emergence	10	20	$1,854	1.7	$3,232
850.4150	Vegetative vigor	10	20	$1,854	1.7	$3,232
850.4400a	Aquatic plant growth	10	20	$1,854	1.7	$3,232
Nontarget Area Phytoxicity Tier II						
850.4225	Seedling emergence	10	20	$1,854	0.5	$970
850.4250	Vegetative vigor	10	20	$1,854	0.5	$970
850.4400b	Aquatic plant growth	10	20	$1,854	1.9	$3,555
Total Plant Protection						**$15,190**
Residue Chemistry						
860.1300	Nature of the residue in livestock	8	60	$4,124	22.0	$90,718
860.1340	Residue analytical methods	8	60	$4,124	26.3	$108,390
860.1460	Food handling	8	60	$4,124	29.0	$119,759
	Total Residue Chemistry					**$318,867**
Product Chemistry						
830.7550 830.7560 830.7570	Partition Coefficient (n-octanol/water)	10	60	$4,254	14.0	$59,623
830.6313	Stability	10	60	$4,254	-14.9	($63,330)
830.7050	UV/visible light absorption	10	60	$4,254	29.8	$126,660
830.7520	Particle size	10	60	$4,254	7.0	$29,963
	Total Product Chemistry					**$152,916**
	Total All Tests					**$1,939,115**

*Sums are not exact due to rounding off.

Appendix D
Industry Profile

This profile relies on a number of sources of information on the pesticide industry. The major sources include the following:

- EPA Office of Pesticide Programs (OPP) publications and estimates
- Pesticide industry profiles prepared for previous regulatory analyses for EPA's Offices of Pesticide Programs, Water, and Air
- Industry profiles prepared by private research firms
- Dunn & Bradstreet industry data
- Research on specific companies using publicly available business databases accessed through the Internet
- Searches of academic and industry literature
- Economic Census data from the U.S. Census Bureau
- Other U.S. Department of Commerce sources

Use of Census Data

Whenever a data source contained complete information to illustrate a certain aspect of the pesticide industry, we chose to present that information. In other cases, the only source of national level information was the U.S. Census Bureau's Economic Census of Manufacturers. There are inherent difficulties associated with using data from the Economic Census preformed by the U.S. Census Bureau to characterize certain industrial sectors contained in this profile.

The Census Bureau has recently revised its industry classification system and now uses "North American Industrial Classification System" (NAICS) codes to describe industrial sectors. Information in the 1997 Census is organized according to the NAICS. The NAICS replaces the Standard Industrial Classification (SIC) system that had been used in all earlier Census publications. NAICS assignment for an establishment is made according to one of 20 major industrial sectors. These sectors are further divided into 96 subsectors, 313 industry groups, and 1,170 industries.

In some cases, the relevant Census data required for this economic profile was available at a sufficiently disaggregated level that it corresponds reasonably accurately to the establishments in the industrial sectors of interest here. In other cases, the Census categorization reflects a very large and diverse industry, of which the relevant sector may be a small part. Finally, many pesticide industry participants are classified into entirely different Census industry categories because their primary product is not related to pesticides. In the latter cases, the Census data do not provide a precise representation of the characteristics of establishments of interest.

Exhibit D.1 provides descriptions of the NAICS categories used to present Census data for each sector examined in this profile. It also indicates whether NAICS-based data correspond to SIC-based data over time. The Census categories used for each of the major pesticide industry sectors included in this profile and their relative precision as a measure of the pesticide and related industries are discussed in more detail below.

Exhibit D.1: Census Industry Classifications Used in Profile			
Profile Sector	**NAICS/ SIC**	**Description**	**SIC - NAICS Correspondence**
Conventional Active Ingredient Producers and Formulators, Packagers, and Repackagers	325199/ 2869	All Other Basic Organic Chemical Manufacturing	no
	325320/ 2879	Pesticide and Other Agricultural Chemical Manufacturing	yes
Source: U.S. Department of Commerce, 1992 and 1997.			

EPA has incorporated data from several public sources in addition to using the Economic Census. For the most part, these sources continue to use the SIC system to organize and present information. These data are noted as SIC-based data in the text. EPA uses time series data from these sources because of the consistent categorization of industry groups across time.

General Pesticide Industry Description

Pesticides are important products that play a significant role in many aspects of the economy. They are used by diverse economic sectors such as agriculture, industry, and residential. Pesticides reduce or eliminate undesirable weeds, insects, animals, fungi, and bacteria and are used to preserve wood and regulate plant growth. All of these pesticide uses produce desirable outcomes such as increased agricultural productivity and improved human health. However, due to their nature, their use also implies some environmental and health risks (U.S. EPA, 1999c).

Pesticide products themselves fall into several categories: conventional pesticides, specialty and niche pesticides, and antimicrobial pesticides. Conventional pesticides are those products that are commonly available to users including herbicides (weed killers), insecticides ("bug" killers), and fungicides (fungus killers), as well as some special classifications such as fumigants used to sterilize soil to remove pathogens. The vast majority of pesticides used in the U.S. fall into this category.

Pesticide production involves combining a more than one substance into a formulation. The main ingredient of a pesticide product is the active ingredient: the chemical that is toxic to the targeted pest. Some pesticide formulations contain more than one active ingredient, depending on their target or targets. These pesticide active ingredients, or active ingredients, cannot be applied in their basic form for reasons of safety and effectiveness. EPA regulates both active ingredients and formulations through a registration process. There are roughly 890 active ingredients registered with EPA, and nearly 18,000 registered formulations. Depending on the context or the data source, this profile will make a distinction between discussions of active ingredient and discussions of formulations.

Exhibit D.2 presents a summary of the number of regulated conventional pesticide products and tolerances.

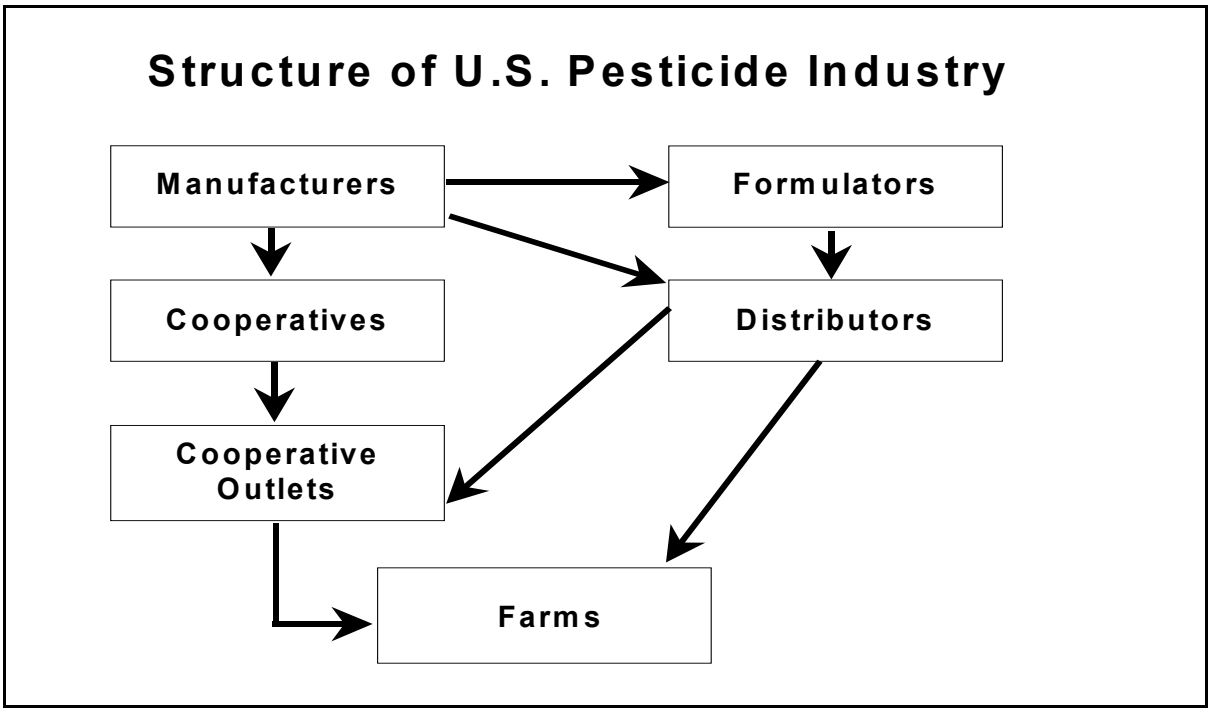
Exhibit D.2: Regulated Pesticide Products	
Product Segment	**Number of Products**
Active Ingredients with Active Registrations (Federal and State)	891
Active Ingredients with Food/Feed Tolerances (September 1998)	523
Formulated Products with Federal Registrations (June 1998)	17,713
Tolerances in Place (September 1998)	9,783
Source: U.S. EPA, 1999c	

The pesticide industry participants addressed in this profile include the entities that manufacture active ingredients, formulate, package, and repackage pesticides. These companies are presented in Exhibit D.3 below.

Exhibit D.3: Pesticide Industry Participants	
Production Segment	**Number of Establishments**
Major Basic Active Ingredient Producers	18
Other Active Ingredient Producers	100
Formulators - Major	150-200
Formulators - Other	approx. 2000
Sources: EPA, 1999c	

While all the economic sectors mentioned previously consume pesticide products, the agricultural sector is by far the largest conventional pesticide user. Figure D.4 provides a schematic of how pesticide products flow from manufacturer to agricultural end users. The entities that manufacture active ingredients ship their products either in raw form or as formulated product. The majority of pesticides are shipped to distributors and dealers as formulations. A small portion of pesticides are shipped to independent formulators for further preparation. Distributors and dealers may receive the product in a packaged form ready for sale to agricultural end users or may repackage the product for final sale. Some pesticide products reach agricultural end users through production cooperatives.

Figure D.4: Structure of the U.S. Pesticide Industry (Agricultural Uses)



Source: SRI International, 1999.

Conventional Pesticide Market

The conventional pesticide market comprises the majority of the pesticide industry. There are four major types of conventional pesticide products:

- Herbicides
- Insecticides
- Fungicides
- Other, including plant growth regulators (PGRs), etc.

Herbicides, insecticides, and fungicides make up the largest portion of the conventional pesticide market. All pesticide products have certain characteristics that affect demand. These characteristics include the following:

- Spectrum of control – the range of pests controlled
- Efficacy – the ability to control pests, and the application rates needed for control
- Ease of use – the ability to mix with other products, low equipment requirements, etc.
- Toxicity (human and wildlife) – the degree to which toxicity determines limitations on usage

- Price – the cost of the pesticide input relative to its return in improved conditions such as crop yield

Over time, some of these basic product characteristics have changed. For example, more reduced risk (low toxicity) pesticides are now available (U.S. EPA, 1999c). In addition, low-use pesticide are available that require lower application rates to maintain efficacy.

Exhibit D.5 presents the U.S. pesticide sales at user level for 1997, as well as volume of active ingredients at user levels.

Exhibit D.5: U.S. Pesticide Sales at User Level 1997 Estimates

Pesticide Class	User expenditures		Volume of Active Ingredient	
	Millions ($)	Percent	Millions (lbs.)	Percent
Herbicides	6,846	58	568	46
Insecticides	3,553	30	129	10
Fungicides	802	7	81	7
Other*	696	6	453	37
Total	11,897	100	1,231	100

* Includes sulfur and petroleum/other chemicals but does not cover industrial wood preservatives, speciality biocides and chlorine/ hypochlorites.
Source: U.S. EPA, 1999c.

Herbicides, insecticides, and fungicides represent approximately 95 percent of U.S. pesticide sales, and 63 percent of the active ingredients used by the pesticide industry.

Pesticide products within each major category (i.e., herbicides, insecticides, fungicides) often tend to be developed to meet specific crop requirements. Each of these pesticide type/crop combinations, termed "use clusters," can be thought of as a distinct market. U.S. EPA's Office of Pesticide Programs has defined 57 use clusters, which were used as the basis for the market analysis for two economic analyses of proposed effluent guidelines affecting the pesticide industry (U.S. EPA, 1993 and 1994).

Herbicides

Herbicides are largely used on crops for the purpose of controlling weeds. Weeds compete with crops for nutrients, space, water, and sunlight. Controlling weeds decreases the need for farm labor and improves crop quality. Demand for herbicides is greatly affected by the weather.

A warm and wet spell can cause high growth of weeds, resulting in a greater demand for herbicides, whereas a dry and cold spell can lower demand considerably. The two major types of herbicides are as follows:

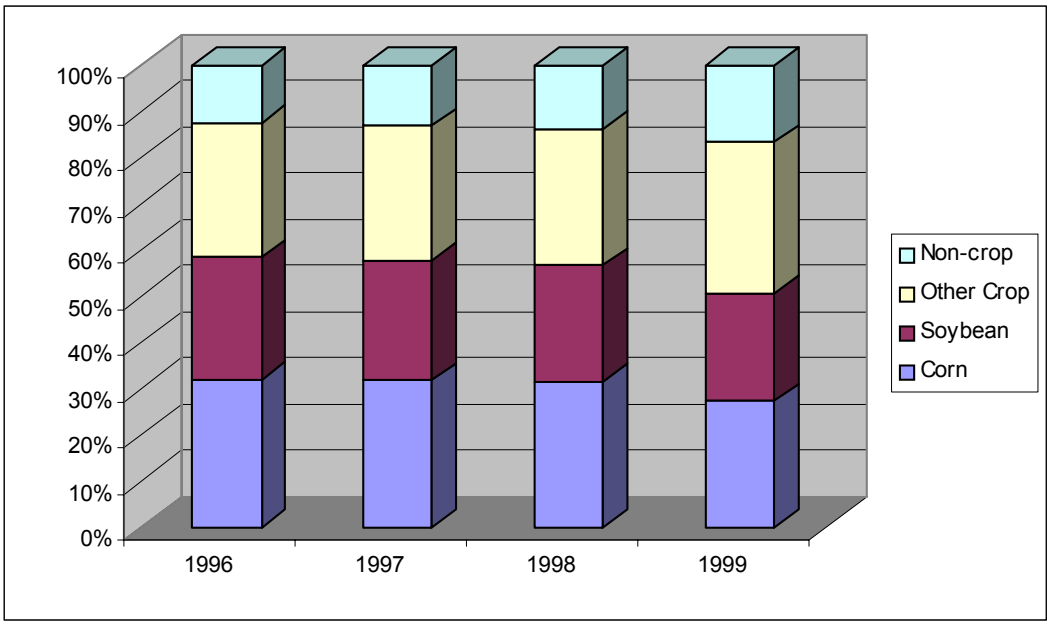
- Pre-emergent herbicides – applied soil before the seed is planted, to resist the growth of weeds
- Post emergent herbicides – applied to weeds after germination

Herbicides are used on a variety of crops:

- Corn
- Soybeans
- Other crops (cotton, rice, pastures, small grains, and fruit and vegetables)

Herbicides have end uses in industries other than agriculture as well: the forestry, industrial, turf, nursery and ornamental, and home and garden industries use herbicides. Exhibit D.6 and Exhibit D.7 show the percentage of revenues by application for herbicide market. Corn and soybean crops represent the greatest users of herbicides. From 1996 to 1999 the mainstream crop users (corn and soybean) decreased expenditures on herbicides relative to other users by 6.5 percent of total annual herbicide use, with corn crop applications falling the most. Soybean planted acreage increased over this period by nearly 15 percent (USDA, 1999b). Corn planted acreage was relatively constant between 1996 and 1998, and fell by 3.4 percent in 1999 (USDA, 2000a). In contrast to the relative drop in herbicide expenditures on major crops, other crop and non-crop expenditures on herbicides increased, with the largest increase occurring between 1998 and 1999 (Frost & Sullivan, 2000).

Exhibit D.6: Percent of U.S. Herbicide Sales by Year, 1996 - 1999



Source: Frost & Sullivan, 2000.

Exhibit D.7: Percent of U.S. Herbicide Sales by Year, 1996 - 1999

Year	Corn	Soybean	Other Crop	Non-crop	Total
1996	31.9%	26.4%	29.1%	12.5%	100%
1997	31.8%	26.0%	29.1%	13.2%	100%
1998	31.7%	25.0%	29.6%	13.8%	100%
1999	27.7%	23.3%	33.0%	16.0%	100%
% Change 1996-1997	-4%	-3%	4%	4%	

Note: Values may not add to 100 due to rounding.
Source: Frost & Sullivan, 2000.

Insecticides

Insecticides are used to control insects that damage crops by killing the plant or spoiling the fruit. Chlorinated hydrocarbons, organophosphates, and carbamates are used the most, with organophosphates the most commonly used of the three groups (Frost & Sullivan, 2000).

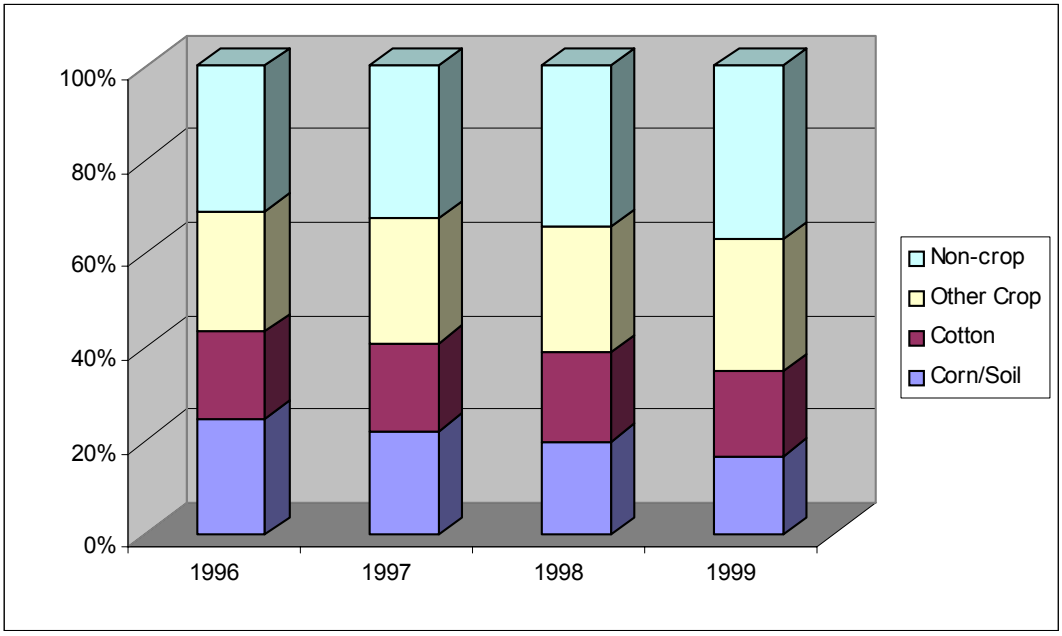
Insecticide use is greatly influenced by weather and outbreaks of insects. A warm and wet spell can be conducive to insect growth, which causes an increase in the demand for insecticides. Another factor currently affecting the demand for insecticides is the introduction of genetically modified (GM) crops. Genetic modification may alter crops to make them more insect resistant, often by modifying the plant to produce toxins that repel or kill insect pests. This is a new technology and to date has been confined to a few row crops like corn, cotton, and soybeans. It is extremely difficult to make plants resistant to all types of insects. Thus, even some GM crops are still being treated with insecticides (Frost & Sullivan, 2000). There are also concerns about the likelihood of insects adapting to the genetically modified crops and overcoming the plants' defenses.

The following are the main crop uses of insecticides:

- Corn
- Cotton
- Other crops (including potatoes, vegetables, fruits, sugar beets, peanuts, and tobacco)
- Non-crop uses (including turf, home and garden, professional care, public health, nursery, and ornamental) (Frost & Sullivan, 2000)

Exhibits D.8 and D.9 present the market use data for insecticide applications from 1996 to 1999 by percent of total annual use. Use of insecticides by the corn/corn soil category fell by three percent from 1998 to 1999 relative to other insecticide uses, fairly consistent with recent changes in cultivated acreage. While use of insecticides on cotton relative to other crops fell over all between 1996 and 1999, there was an upward trend from 1996 to 1998. Planted cotton acreage stayed nearly constant. Other crop and non-crop uses together accounted for over 65 percent of total insecticide use as of 1999. From 1996 to 1999, both sectors increased their use of insecticides relative to the other sectors, with the greatest increase occurring between 1998 to 1999.

Exhibit D.8: Percent of U.S. Insecticide Sales by Year, 1996 - 1999



Source: Frost & Sullivan, 2000.

Exhibit D.9: Percent of U.S. Insecticide Sales by Year, 1996 - 1999

Year	Corn/Soil	Cotton	Other Crop	Non-crop	Total
1996	24.8%	18.5%	25.7%	31.0%	100%
1997	22.0%	18.9%	26.5%	32.6%	100%
1998	19.8%	19.0%	26.9%	34.3%	100%
1999	16.8%	17.9%	28.2%	37.1%	100%
% Change 1996 - 1997	-8%	-1%	2%	6%	

Note: Values may not add to 100 due to rounding.
Source: Frost & Sullivan, 2000.

Fungicides

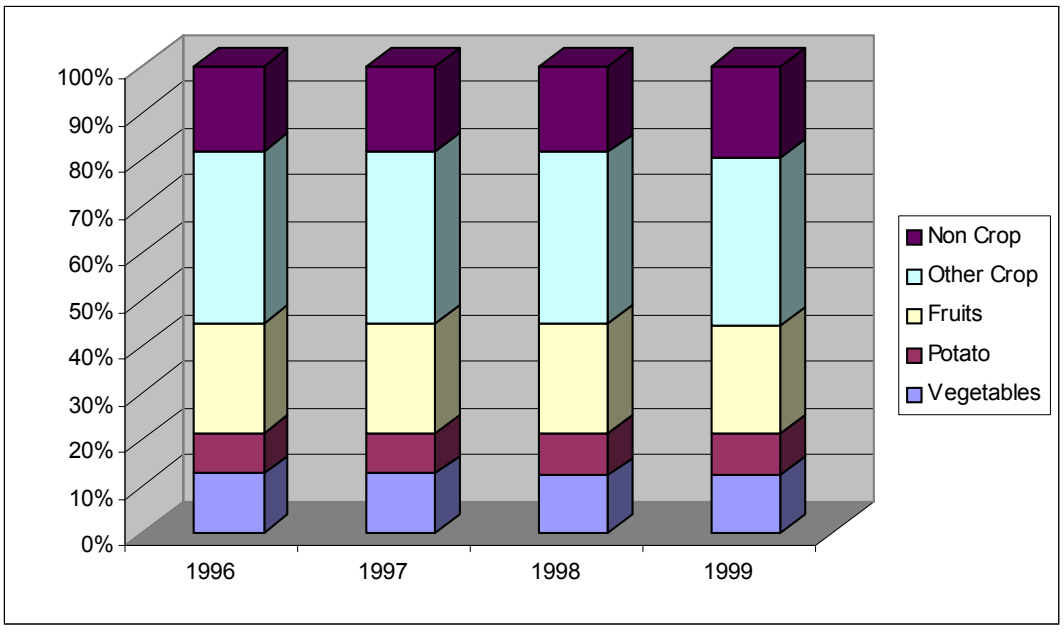
Fungicides control plant molds and diseases. The applications of fungicides are very diverse because any material is susceptible to a fungal attack. In agriculture, they are primarily used on specialty crops such as fruits and vegetables. Fungicides are used to retard or eliminate fungal infections that can produce toxicants.

Weather plays an important role in the fungicide market, as it does in both the herbicide and insecticide markets. Wet weather can cause an increase in fungal attacks on crops, boosting agricultural demand for fungicides. Some of the major uses of fungicides are as follows:

- Vegetables
- Potatoes
- Fruits (including grapes and citrus)
- Other crops (including corn, cotton, small grains, peanuts, rice, and tobacco)
- Non-crop uses (including turf, nursery, and ornamental)

Exhibit D.10 and Exhibit D.11 present the market use data for fungicide applications from 1996 to 1999 by percent of total annual use.

Exhibit D.10: Percent of U.S. Fungicide Sales by Year, 1996 - 1999



Source: Frost & Sullivan, 2000.

Exhibit D.11: Percent of U.S. Fungicide Sales by Year, 1996 - 1999						
Year	**Vegetables**	**Potatoes**	**Fruits**	**Other Crops**	**Non Crop Uses**	**Total**
1996	12.8%	8.6%	23.5%	36.7%	18.4%	100%
1997	12.8%	8.6%	23.4%	36.8%	18.4%	100%
1998	12.4%	9.0%	23.4%	36.6%	18.6%	100%
1999	12.6%	8.7%	23.2%	35.8%	19.7%	100%
% Change 1996 - 1997	-0.2%	0.1%	-0.3%	-0.9%	1.3%	

Note: Values may not add to 100 due to rounding.
Source: Frost & Sullivan, 2000.

Plant Growth Regulators

Plant growth regulators (PGRs) are used to increase yields and facilitate harvesting. PGRs have varied functions, depending on the crop. PGRs are used on fruits to inhibit rotting and maintain color and other aesthetic attributes during storage or transfer from field to market. Cotton is the largest source of demand for PGRs, representing approximately 40 percent of total PGR demand (Frost & Sullivan, 2000). Rice, tree fruits, peanuts, and potatoes are other major crop application sources of PGR demand. The major non-crop applications of PGRs are for turf and nursery and ornamental applications. Like all other pesticides, PGR demand is dependent upon weather conditions, with wet conditions promoting fungal growth (Frost & Sullivan, 2000).

Industry Structure

There are many different indicators of how an industry is structured. One approach is to evaluate Census data on the concentration of the industry to evaluate whether there is a tendency toward concentrated market power. Another approach is to obtain information on market share for specific market participants. Finally, recent trends in market structure can be suggested by reviewing the ownership and market share patterns of major producers in an industry. This section presents the first and third of these approaches.

Concentration

The U.S. Census provides two measures to indicate the degree of concentration in an industry: the "m-firm concentration ratio" and the "Herfindahl-Hirschman (HH) Index." The m-firm concentration ratio is simply the sum of the value of shipments of the largest "m" firms. A market is generally considered highly concentrated if the 4-firm concentration ratio is greater than 50 percent.

The HH index is an alternative measure of concentration equal to the sum of the squares of the market shares for the 50 largest firms in the industry. The higher the index, the more concentrated the industry is at the top. The U.S. Justice Department uses 1,000 as a benchmark for the presence of market concentration, where any industry with a Herfindahl-Hirschman index less than 1,000 is considered to be unconcentrated.

Exhibit D.12 shows concentration ratios by SIC code for the three census years, 1982, 1987, and 1992 for conventional pesticides industries, and for the industries that include antimicrobial producers and inert manufacturers.

Exhibit D.12: Concentration Ratios by SIC* Code, 1982-1992

Year	Percent of value of industry shipments shipped by the largest (in terms of shipment value)				Herfindahl-Hirschman Index
	4 Companies	8 Companies	20 Companies	50 Companies	
Conventional Active Ingredient Producers and FPRs					
Industrial Organic Chemicals (SIC 2869)					
1982	36	52	73	90	475
1987	31	48	68	86	376
1992	29	43	67	86	336
Pesticides and Other Agricultural Chemicals (SIC 2879)					
1982	44	66	85	94	703
1987	49	69	88	94	789
1992	53	69	87	95	834

Source: U.S. Department of Commerce 1992 Economic Census.

*NAICS codes were not available then.

The concentration ratios presented in Exhibit D.12 show only moderate evidence of market concentration in the relevant industries in 1992. Four-firm concentration ratios for all identified SIC codes are below 53. The HH indices for all SIC codes are well below the benchmark of 1,000. However, two important SIC codes have become noticeably more concentrated: 2879 (Pesticides and Other Agricultural Chemicals) and 2842 (Polishes and Sanitation Goods). The remainder have increased only slightly, remained constant, or decreased in concentration. In the case of the SIC codes associated with active ingredient, antimicrobial, inert, and adjuvant products, it is important to note that the data represent the entire chemical industry, not just firms supplying to the pesticide industry.

Increasing concentration in the agricultural chemicals industry is not entirely confirmed by comparison with earlier m-firm concentration ratios (U.S. EPA, 1993). The 1987 4-firm concentration ratio for Pesticide and Other Agricultural Chemicals overall was 49 percent, increasing from 34 percent in 1972, which is consistent with Exhibit D.12. On the other hand, the 1982 Census of Manufactures permitted identification of concentration ratios at a more

disaggregated level (5-digit SIC) (which are not directly comparable) and indicates concentration ratios decreasing since 1972/1977 for many subsectors of the pesticide formulating industry. The 4-firm concentration ratios for synthetic organic pesticides (SIC 28694), herbicide preparations (SIC 28796), fungicide preparations (SIC 28797), and household pesticidal preparations (SIC 28799) were all over 50 percent in 1982 and had been decreasing from 1972 through 1982.

Since 1992 the pesticide industry has undergone a period of consolidation. Many firms have merged or been purchased, decreasing the number of firms producing active ingredients. This has affected the concentration of active ingredient producers in that each sector is shifting to a few large competitors in each sector. For example, the herbicides market had a concentration of 45 percent (market share held by top three competitors) in 1999, and it is estimated that the concentration will continue to increase. (Frost & Sullivan, 2000).

Consolidation Through Mergers and Acquisitions

Conventional pesticide producers have experienced a period of consolidation in the past few years, as several major producers of active ingredients have either merged or been acquired. The following is a list of the mergers and acquisitions that recently occurred or are underway.

Mergers and Acquisitions

- Novartis with Astra Zeneca (expected 2000)
- AgrEvo and Rhone Poulenc to form Aventis (1999)
- Monsanto acquired DeKalb (1998)
- Dupont bought Pioneer Hi-Bred seed company(1999)
- Zeneca with Astra (1999)
- BASF acquired American Cyanamid (2000)

There are several reasons why there has been a recent trend towards mergers and acquisitions in the pesticide industry. The market is very saturated and therefore there is little room for growth, other than through gaining market share. Top companies have been purchasing smaller companies, as well as merging with each other in order to gain market share. Another way to gain market share is to expand operations into other sectors of the pesticide industry, including generic production. Since chemical manufacturing requires significant investment, it makes sense to align one company with another that already has the desired technology, instead of attempting to break into that sector of the market through new investment. Finally the threat of the introduction of genetically modified seeds is driving consolidation as well. There are two typical types of merger occurring: either a chemical company and a seed/life science company or a research company and a generic manufacturer. The first is in response to the growing acceptance of genetically modified seeds, while the second alliance is intended to combat increased competition from generic manufacturers.

Appendix E

Pesticide Registration Action Tracking System (PRATS) Action Codes

A. Registration (OPP Registration Division use only)

100 - Application for Registration - New Chemical - Food or Feed

115 - Application for Registration - New Chemical - Non-Food or Non-Feed Use

117 - Proposed Test Protocol - New Chemical

160 - Application for Registration - Routine "Me-Too" (Use 165 if science review required)

165 - Application for Registration - Old Chemical (Minor changes, i.e, substantial change in percentage of active ingredients, inerts, etc.) Requires Science review.

170 - Application for Registration - Old Chemical - "Me-Too" with an Additional Use (Use 175 if Science review required)

175 - Application for Registration - Old Chemical - New Use - Non-Food or Non-Feed - Requires Science review.

180 - Application for Registration - Old Chemical - First New Food or Feed Use

B. Amendments

305 - Amendment - Technical - Label Revision - Data Required (i.e., change in toxicity category, etc.) Use 320 if science review required.

310 - Amendment - Technical - Added "Me-Too" Use (Use 325 if science review required)

315 - Amendment - New Use - Non-Food or Non-Feed

320 - Amendment - Label revision - Data required - Requires science review.

325 - Amendment - Added "Me-too" use - Data required - requires science review.

330 - Amendment - Technical - New Use - Food or Feed (Use 370/371 if first food or feed use for chemical)

345 - Amendment - Technical - Formula Change - (Use 347 if review required.

347 - Amendment - Formula Change - Unregistered source of the active ingredient. (Requires Science review)

370 - Amendment - New Use - First Food or Feed Use for Chemical

385 - Amendment - Special Packaging (Sect. 162.16)

390 - Amendment - Inert Substitution

392 - Amendment - Minor Formulation Change for End Use Product - (Acceleratred Review)

395 - Amendment - Inert Label Warning Statement

Appendix F. OPTION & SENSITIVITY ANALYSIS			Percent of Actions Tests are Likely to be Required				Incremental Costs/Year--All actions		
High Sensitivity Estimate			New ai		Major	**Additional**	**Newly Codified**		**Newly**
Guideline	**Data Requirement**	**Individual Test Costs**	food use	non food use	new uses	**number of tests/ year**	**New Tests**	**Increased Requirement**	**Imposed**
		Action Code:	100.0	115.0	various				
		Avg actions/yr:	12.4	5.0	123.4	140.9			
Toxicology									
Acute Testing									
870.6200	Acute neurotoxicity - rat Ne	$91,680	100%	100%	5%	23.6	$2,163,648		
Subchronic Testing									
870.3100*	90-day Oral - 2 rodent speci								
870.3200	21/28-day Dermal	$84,681	50%	-40%		4.2		$356,870	
870.3250	90-day Dermal	$138,114	-40%	50%	5%	3.7		$511,022	
870.6100	28-day delayed neurotoxicity	$80,625	10%	10%	5%	7.9	$638,089		
870.3800	Reproduction(Revised)	$381,233		95%		4.8		$1,810,857	
Chronic Testing									
870-6200	90-Day Neurotoxicity -rabbit	$186,410	100%	100%	10%	29.8	$5,549,692		
870.3700	Developmental toxicity - 2nd	$77,037		100%	1%	6.2		$480,271	$480,271
870.6300	Developmental neurotoxicity	$417,135	100%	100%	10%	29.8	$12,418,705		
Special Testing									
870.6500	Schedule controlled operant	$164,000	1%	1%	1%	0.8	$129,794		
870.6850	Peripheral nerve function ne	$110,000	1%	1%	1%	0.8	$87,057		
870.6855	Neurophysiology: sensory e	$110,000	1%	1%	1%	0.8	$87,057		
870.7800	Immunotoxicity New Require	$57,731	100%	100%	1%	18.7	$1,077,425		$1,077,425
	Total Tox	**$1,898,646**					**$22,151,468**	**$3,159,019**	**$1,557,696**

Appendix F. OPTION & SENSITIVITY ANALYSIS			Percent of Actions Tests are Likely to be Required				Incremental Costs/Year--All actions		
High Sensitivity Estimate			New ai		Major	**Additional**	**Newly Codified**		**Newly**
Guideline	**Data Requirement**	**Individual Test Costs**	food use	non food use	new uses	**number of tests/ year**	**New Tests**	**Increased Requirement**	**Imposed**
		Action Code:	100.0	115.0	various				
		Avg actions/yr:	12.4	5.0	123.4	140.9			
Application Exposure									
875.1100	Dermal outdoor exposure (N	$192,143	100%	100%	5%	23.6	$4,534,575		
875.1200	Dermal indoor exposure (Ne	$150,714	100%	100%	5%	23.6	$3,556,850		
875.1300	Inhalation outdoor exposure	$185,000	100%	100%	5%	23.6	$4,366,000		
875.1400	Inhalation indoor exposure (	$150,714	100%	100%	5%	23.6	$3,556,850		
875.1500	Biological monitoring (Newly	$188,393	1%	1%	1%	1.4	$265,365		
875.1600	Data reporting and calculati	$10,000	100%	100%	80%	116.2	$1,161,714		
875.1700	Product use information (Ne	$4,000	100%	100%	80%	116.2	$464,686		
	Total Application Exposur	**$880,964**					**$17,906,041**		
Post Application Exposure									
875.2100	Dislodeagable foliar residue	$56,100	75%	75%	5%	19.2		$1,079,524	
875.2200	Soil residue dissipation	$85,000	75%	5%	5%	15.7		$1,338,143	
875.2300	Indoor surface residue dissi	$38,000	100%	100%	10%	29.8	$1,131,314		
875.2400	Dermal exposure	$133,000	75%	75%	5%	19.2		$2,559,300	
875.2500	Inhalation exposure	$73,000	75%	75%	5%	19.2		$1,404,729	
875.2600	Biological monitoring (Newly	$191,667	1%	1%	1%	1.4	$269,977		
875.2700	Product use information (Ne	$4,000	100%	100%	80%	116.2	$464,686		
875.2800	Description of human activit	$4,000	100%	100%	80%	116.2	$464,686		
875-2900	Data reporting (newly codifie	$4,000	100%	100%	80%	116.2	$464,686		
875-3000	Nondietary ingestion Exposu	$83,333		100%	1%	6.2	$519,522		
	Total Post-Application Exp	**$672,100**					**$3,314,870**	**$6,381,696**	

Appendix F. OPTION & SENSITIVITY ANALYSIS			Percent of Actions Tests are Likely to be Required				Incremental Costs/Year--All actions		
High Sensitivity Estimate			New ai		Major	**Additional**	**Newly Codified**		**Newly**
Guideline	**Data Requirement**	**Individual Test Costs**	food use	non food use	new uses	**number of tests/ year**	**New Tests**	**Increased Requirement**	**Imposed**
		Action Code:	100.0	115.0	various				
		Avg actions/yr:	12.4	5.0	123.4	140.9			
Terrestrial and Aquatic									
	Avian and Mammalian Tes								
850.2100	Avian oral LD50 (Red Wing)	$13,800	100%	100%	1%	18.7	$257,547		$257,547
850.2200	Avian dietary (expanded Us	$6,480		-10%		-0.5		-$3,240	
850.2400	Wild mammal toxicity								
850.2300	Avian reproduction(expand	$215,500	50%	42%		8.3		$1,788,137	
850.2500	Simulated or actual field tes	$650,000	5%	4%		0.8		$539,345	
	Aquatic Organism Testing								
50.1075	Acute LC50/EC50 estuarine	$26,400	75%	63%	3%	16.1		$426,341	
850.1300	Aquatic invertibrate life-cycle	$162,800	60%	50%	3%	13.7		$2,223,848	
850.1350	Aquatic invertibrate life-cycle	$36,333	5%	4%		0.8		$30,148	
850-1400	Fish early life-stage (freshwa	$41,379	60%	50%	3%	13.7		$565,237	
850.1950	Simulated or actual field tes	512500							
	Sediment Testing								
	-Acute invertebrates								
870.1735	--freshwater(newly codifie	$20,250	20%	17%	5%	9.5		$192,182	
870.1740	--marine (newly codified)	$20,625	15%	13%	5%	8.7	$178,627		
	-Acute pore water								
none	--fish and invertebrates	$37,500	5%	4%	5%	7.0	$262,545		
	Whole sediment								
none	-Chronic invertebrates	$51,350	15%	13%	4%	7.4		$381,347	
850.1900	Microcosm dropped in rule								
	Insect Pollinator Testing								
850.3020	Honeybee acute contact LD	$3,175	50%	42%	5%	14.5		$45,939	
850-3040	Field Testing for Pollinators	$38,750	5%	4%		0.8		$32,153	
	Total Eco	**$1,324,342**					**$698,719**	**$6,221,438**	**$257,547**

Appendix F. OPTION & SENSITIVITY ANALYSIS			Percent of Actions Tests are Likely to be Required				Incremental Costs/Year--All actions		
High Sensitivity Estimate			New ai		Major	**Additional**	**Newly Codified**		**Newly**
Guideline	**Data Requirement**	**Individual Test Costs**	food use	non food use	new uses	**number of tests/ year**	**New Tests**	**Increased Requirement**	**Imposed**
		Action Code:	100.0	115.0	various				
		Avg actions/yr:	12.4	5.0	123.4	140.9			
Environmental Fate									
	Degradation Studies-Laboratory								
835-2120	Hydrolysis	$29,900		12%	1%	1.2		$35,894	
835-2240	Photodegration in water								
835-2410	Photogradation on soil	$45,183	100%	30%	10%	15.7		$711,310	
835-2370	Photodegration in air	$110,000	1%	1%	1%	0.8		$86,140	
	Metabolism Studies-laboratory								
835-4100	Aerobic soil	$94,375	1%	1%	0%	0.3		$27,310	$27,310
835-4200	Anaerobic soil no change								
835-4400	Anaerobic aquatic	$86,525	50%	42%	5%	14.5		$1,251,934	
835-4300	Aerobic aquatic	$47,350	50%	42%	5%	14.5		$685,109	
	Dissipation Studies - Field								
835.6100	Terrestrial	$317,767			1%	1.2		$392,215	
835.6200	Aquatic (sediment)	$267,250	6%	5%	1%	2.2		$595,968	$595,968
835.6300	Forestry	$275,500		-10%	-1%	-1.7		-$477,796	
835-6400	Combination and tank mixes								
	Accumulation Studies								
850.1950	In aquatic nontarget organis	$512,500	1%	0%		0.1		$67,967	
	Ground Water Monitoring								
835.7100	Ground water monitoring	$1,225,000	1%	1%	1%	0.8	$969,500		
	Total Fate	**$3,011,350**					**$969,500**	**$3,376,052**	**$623,278**

Appendix F. OPTION & SENSITIVITY ANALYSIS			Percent of Actions Tests are Likely to be Required				Incremental Costs/Year--All actions		
High Sensitivity Estimate			New ai		Major	**Additional**	**Newly Codified**		**Newly**
Guideline	**Data Requirement**	**Individual Test Costs**	food use	non food use	new uses	**number of tests/ year**	**New Tests**	**Increased Requirement**	**Imposed**
		Action Code:	100.0	115.0	various				
		Avg actions/yr:	12.4	5.0	123.4	140.9			
Non-target Plant Protection									
Nontarget Area Phytoxicity Tier I									
850-4100	Seedling emergence	$14,625	10%	10%		1.7		$25,489	
850-4150	Vegetative Vigor	$15,875	10%	10%		1.7		$27,668	
850-4400a	Aquatic Plant Growth	$35,155	10%	10%		1.7		$61,269	
Nontarget Area Phytoxicity Tier II									
850-4225	Seedling emergence	$20,375	3%	3%		0.5		$10,653	
850-4250	Vegetative Vigor	$24,500	3%	3%		0.5		$12,810	
850-4400b	Aquatic Plant Growth	$35,155	11%	11%		1.9		$67,396	
	Total Plant Protection	**$662,535**				**8.2**		**$205,286**	
Residue Chemistry									
860.1300	Nature of the residue in lives	$105,833	20%	20%	15%	22.0		$2,328,326	
860.1340	Residue analytical methods	$74,000	100%		10%	24.8		$1,833,086	
860.1460	Food handling	$205,000	25%	25%	20%	29.0		$5,953,786	
	Total Residue Chemistry	**$384,833**				**75.8**		**$10,115,197**	
Product Chemistry									
830-7550 830-7560 830-7570	Partition Coefficient (N-Octanol/Water)	$6,212	50%	50%	5%	14.9		$92,470	
830-6313	Stability	$6,400	-50%	-50%	-5%	-14.9		-$95,269	
830-7050	U/Visible Light (new)	$2,072	100%	100%	10%	29.8	$61,686		
830-7520	Particle Size	$1,333	100%	100%	5%	23.6	$31,459		
	Total Product Chemistry	**$16,017**				**53.4**	**$93,145**	**-$2,799**	
	Total All Tests						**$45,133,743**	**$29,455,890**	**$2,438,521**
	Total Incremental Costs							**$74,589,633**	