FINAL

REGULATORY IMPACT ANALYSIS: PROPOSED REGULATIONS FOR PLANT-PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

DPRA

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REGULATORY IMPACT ANALYSIS: PROPOSED REGULATIONS FOR PLANT-PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

I. INTRODUCTION

This introductory chapter discusses the purpose of the analysis, the requirements for analysis, and the scope of the analysis.

A. Purpose of Analysis

The Environmental Protection Agency (EPA) regulates pesticides in the United States. The principal legal authority is established by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA §3, a pesticide may not be sold or distributed in the United States unless it is registered or exempt from regulation. Before a product may be registered as a pesticide under FIFRA, it must be shown that when used in accordance with widespread and commonly recognized practices, it will not generally cause "unreasonable adverse effects on the environment." FIFRA defines the term "unreasonable adverse effects on the environment" as any unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. FIFRA authorizes EPA to require data to be submitted to evaluate whether a registration will be granted and under what conditions. Under FIFRA §25(b), EPA may exempt, by regulation, any pesticide determined to be (1) adequately regulated by another Federal agency or (2) of a character which is unnecessary to be subject to the Act in order to carry out the purposes of the Act.

Most pesticides currently regulated by EPA can be generally categorized as "chemical" pesticides (synthetic chemicals) or as "biological" pesticides (biochemical or microbial pesticides). Biological pesticides also include a category termed plant-pesticides. This category is defined as pesticidal substances that are produced in plants and the genetic material necessary for the production of the pesticidal substance. The types and amounts of

pesticidal substances that can now be produced by plants have been expanded beyond the technological capabilities of traditional plant breeding. Therefore, a wide range of transgenic plant-pesticides are expected in the future, including the introduction of pesticidal characteristics new to plants. The modification and enhancement of existing pesticidal characteristics also will likely be seen in the future. EPA considers substances produced in plants for the purpose of enabling plants to resist pest attack and disease to be plant-pesticides under FIFRA §2. EPA promulgated a final regulation under §25(b) in 1982 that exempted all macroorganisms used as biological control agents from the requirements of FIFRA (40 CFR 152.20). Although plants were implicitly exempted under 152.20, the status of pesticidal substances produced in plants (plant-pesticides) requires clarification.

Additionally, under §408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA has the authority to regulate pesticide residues in raw foods and animal feeds. Under FFDCA §408, any poisonous or deleterious pesticide chemical added to a raw agricultural commodity that is not "generally recognized as safe" (GRAS) is deemed to be unsafe unless a tolerance, or an exemption from the requirement for a tolerance under FFDCA §408(c), for such pesticide is established and the pesticide is within the tolerance limits. A tolerance is the amount of pesticide residue allowed in the commodity as it goes to market. Section 408 of the FFDCA applies to all "pesticide chemicals" which are defined in §201(q) of the FFDCA as:

> any substance which, alone, in chemical combination, or in formulation with one or more other substance, is "a pesticide" within the meaning of [FIFRA]...and which is used in the production, storage, or transportation of raw agricultural commodities.

Pesticides, therefore, subject to regulation under FFDCA are defined by reference to the definition of a pesticide under FIFRA. A tolerance, or an exemption from a tolerance, must be established for plant-pesticides under FFDCA.

This report presents the results of a regulatory impact analysis (RIA) evaluating the costs and benefits of amending the Federal code to allow for the regulation or exemption of specific types of plant-pesticides under FIFRA (40 CFR Part 152.20 and 152.27) and tolerance exemptions or reviews under FIFRA (40 CFR Part 174).

B. Requirements for Analysis

This report is intended to meet the requirements for a RIA as established by Executive Order No. 12866, the Regulatory Flexibility Act, and §25 of FIFRA. This document also serves as input in preparing any analysis required under the Paperwork Reduction Act of 1980.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, it has been determined that this rule is a "significant regulatory action" because it raises novel policy issues arising out of FIFRA legal mandates. As such, this action will be submitted to OMB for review, and any comments or changes made in response to OMB suggestions or recommendations, will be documented in the public record.

The Regulatory Flexibility Act (RFA) requires that Agencies take special note of the impact of proposed regulations on small entities. Analysis requirements under the RFA can and should be combined with the analysis required under Executive Order 12866.

FIFRA, at §25(a)(2)(b), requires that the Administrator of EPA consider such factors as "...the effect of regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy..." when issuing regulations under §25.

C. Scope of Analysis

Analyses of alternative approaches to achieving a regulatory objective is specified as mandatory in both Executive Order 12866 and OMB guidance implementing that Order. This analysis addresses the consequences of no regulation and addresses the effects of four regulatory alternatives: (1) an alternative option that is more narrow in regulatory scope than the proposed scope, (2) an alternative option representing the Agency's proposed regulatory scope, (3) a broader alternative option than the Agency's proposed scope, and (4) an alternative option that encompasses nearly all plant-pesticides. The focus of this report is on estimating the costs of compliance and the economic impacts associated with the four regulatory alternatives, all of which have been developed within the scope of FIFRA and FFDCA.

Primarily affected by this proposed regulation will be those companies involved with agricultural biotechnology that have been identified as presently developing and testing plant-pesticides. While agricultural biotechnology is currently in its infancy with 1993 sales estimated at less than two percent of total biotechnology sales, future sales are forecasted to grow at an average annual rate of 33 percent to the year 2003. The impacts of EPA regulation of plant-pesticides to this growing market sector will not be all negative. Companies involved with agricultural biotechnology have asked for plant-pesticide regulations and they stand to benefit tremendously from these proposed regulations.

II. SUMMARY OF FINDINGS

The Environmental Protection Agency (EPA) under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has the responsibility for regulating the sale and use of pesticides. However, the Agency has not clearly stated its policies under FIFRA for the regulation of pesticidal substances produced in plants (plant-pesticides). EPA is proposing to amend Parts 152.20 and 180, and create Part 174 of CFR 40 to establish the scope of its regulation of plant-pesticides based on benefit/risk considerations.

The proposed Rule would:

- Clarify which types of plant-pesticides would warrant regulation under FIFRA and/or the Federal Food, Drug, and Cosmetic Act (FFDCA).

The statement of policy would:

- Describe the scientific considerations that will be used to evaluate those plant-pesticides that the Agency has determined would be subject to EPA regulation; and
- Outline how the Agency will assess plant-pesticides at different stages of field testing and at sale or distribution.

Some substances produced within plants for pesticidal purposes (plant-pesticides), may pose many of the same, or other types, of environmental and human health risks as do the chemical, biochemical, and microbial pesticides that are currently regulated by EPA. As such, their development and commercialization must be accompanied by appropriate regulation.

The environmental concerns associated with plant-pesticides are similar in many respects, to the environmental concerns identified with traditional pesticides. These concerns revolve around the potential for exposure to the pesticide and the chemical, and the toxicological properties of the pesticide. Another environmental risk consideration for plant-pesticides is whether the potential exists for new or significantly different exposures of nontarget organisms to the pesticide. Some plants may be modified to produce pesticidal substances that may be new to the plant and thus, present new exposures to organisms that associate with

the plant. As a whole, environmental concerns increase as plant-pesticides are planted on increasingly larger, uncontained acreages.

Human health concerns focus on circumstances where a plant-pesticide produced in a food crop would result in qualitative or quantitatively new dietary exposures to pesticide substances with some toxicity. The greatest dietary risks associated with plant-pesticides are those for which there is no record of prior significant human exposure and thus, no documentation of an absence of adverse effects to humans.

Industry concerns are directed at the uncertainty of the regulatory environment, the costs associated with eventual EPA regulation of plant-pesticides, the human health and environmental risks to be addressed under FIFRA, and the dietary risks to be addressed under FFDCA. In the face of regulatory uncertainty, companies developing plant-pesticides are unable to devise long-term plans for their products, are concerned that regulatory delays may give competing firms marketing advantages, and are concerned about delays in large-scale seed production.

While the public has expressed a fairly positive attitude toward biotechnology in general, it is particularly concerned about possible dietary and outcrossing risks. The public sector needs assurance that the food derived from transgenic plants is safe for consumption. Another public concern is the possible negative environmental effects of biotechnology--its impact on ecosystems, environmental quality, and nontarget organisms. Finally, the public fears that the potential profits associated with agricultural biotechnology may be given greater consideration by firms than the potential effects of environmental releases of genetically engineered organisms.

This Regulatory Impact Analysis (RIA) summarizes the costs and benefits of the proposed Rule and policy, and presents the alternative regulatory options that were considered by the Agency. Four approaches to the regulation of plant-pesticides under FIFRA were evaluated in this analysis that allowed for varying degrees of regulatory coverage. Option 1 is the most limited alternative in regulatory scope. Option 2 represents EPA's proposed regulatory scope

and is broader in coverage than Option 1. In addition to those plant-pesticides regulated under Option 2, Option 3's scope would include viral coat proteins used as pesticides. Finally, under Option 4, all plant-pesticides are subject to the requirements of FIFRA.

Approximately 1,300 firms are involved with some type of biotechnology application in the U.S. Currently, about 19 firms are developing transgenic plants that express plant-pesticides. Some of these firms will eventually develop their plant-pesticides to the commercialization stage and will be required to fulfill some of the registration requirements specified in this proposed Rule. Firms developing biotechnology products are quite diverse and include large, multinational corporations, biotechnology companies (both large and very small), chemical companies, and seed companies. While sales from the agricultural biotechnology sector ($95 million) are currently less than two percent of total biotechnology sales ($6 billion), they are forecasted to grow at an average annual rate of 33 percent to the year 2003.

Generally, costs will depend on whether the Agency exempts a plant-pesticide or whether it requires a registration. The costs of regulating plant-pesticides are dependent upon the data needed for the registration of the particular types of plant-pesticides. Data needs are irrelevant for exempted plant-pesticides. For regulated plant-pesticides, data needs will vary according to the gene product of the plant-pesticide and the recipient crop. Other factors influencing data needs include: whether the crop is intended for human consumption, whether the crop is grown in or near water, whether the crop has wild relatives in the U.S., and whether there is information available on the characteristics and function of the gene product. For example, the data needs and associated costs for the EPA registration of a plant-pesticide where the pesticidal substance is derived from the monera kingdom, differ significantly depending upon whether the recipient crop has wild relatives in the U.S. (estimated registration cost = $732,700) or does not have wild relatives in the U.S. (estimated average registration cost = $63,700).

After estimating the costs associated with the anticipated data needs by plant-pesticide type and predicting the number of plant-pesticide submissions by plant-pesticide type, it was possible to estimate the aggregate total compliance costs to industry, that are associated with

this proposed Rule. The costs associated with existing Federal regulations were then subtracted from the aggregate total compliance costs to yield aggregate incremental compliance costs, or the true costs of this proposed Rule. Aggregate incremental compliance costs under regulatory Option 1 are estimated to range from $53,700 in the first year of implementation, to $2.6 million in the tenth year of implementation. Under EPA's proposed scope (Option 2), aggregate incremental compliance costs are predicted at $53,700 in year 1, increasing to $3.1 million in year 10. Aggregate incremental compliance costs for Option 3's regulatory scope are estimated at nearly $741,100 in the first year of implementation and $5.1 million in the tenth year. Finally, under Option 4's broad regulatory scope, aggregate incremental compliance costs are projected to range from $76.6 million in year 1 to $81 million in year 10.

Aggregate incremental compliance costs to industry were discounted to allow for the time value of money and to determine an equivalent, constant level cost per year (also known as an annual revenue requirement (ARR)). Under Option 1, ARRs are estimated at $1.2 million for the regulated community, or approximately $413,000 per plant-pesticide submission. ARRs under EPA's proposed scope, Option 2, are forecasted at about $1.6 million for the regulated community with an ARR per submission of $311,000. Under Option 3, ARRs are predicted at $2.9 million for those firms affected, or approximately $324,000 per submission. Lastly, the total ARR is estimated at nearly $79 million for the regulated community with a per submission ARR of approximately $279,000, under Option 4.

Costs were also estimated for the labor burden that would result from EPA staff preforming various activities associated with the registration of plant-pesticides. Some of these activities may include the establishment of the docket, internal reviews, requests for additional information, and consultations with applicants. The cost for the Agency to preform these activities under Option 1 is estimated to range from nearly $40,000 in year 1 to approximately $259,000 in year 10. Under EPA's preferred regulatory scope, Option 2, annual labor burden costs range from approximately $40,000 in the first year of Rule implementation, to $391,000 ten years after the Rule is promulgated. Labor burden costs are estimated to range between $123,000 in year 1 to $640,000 in year 10. Under the broad

regulatory scope of Option 4, EPA's labor costs are predicted to range between $14.7 million in year 1, to $15.2 million in year 10. Labor burden cost estimates vary by year, due to the number and type of plant-pesticide submissions the Agency is predicted to receive.

The aggregate cost to society of the proposed plant-pesticide regulation is the sum of the total costs to industry, plus the total costs to the Agency to implement the proposed Rule. After calculating aggregate societal costs, they were discounted to allow for the time value of money and to determine a constant level annual cost. The annual societal revenue requirement over the 1-10 year period of analysis was estimated at nearly $1.4 million under Option 1, $1.8 million under Option 2, $3.3 million under Option 3, and $93.7 million under Option 4.

The annual societal revenue requirement was also calculated on a per plant-pesticide submission basis using the estimated annual average number of submissions by option. On a per plant-pesticide submission basis, the proposed regulation is estimated to cost society $456,000 annually for 10 years under Option 1, $356,000 under Option 2, $368,000 under Option 3, and $332,000 under Option 4.

The proposed Rule will generate a wide range of benefits for the public, the firms involved with agricultural biotechnology, the environment, nontarget organisms, and states. Benefits to the public include a Federally implemented plant-pesticide registration process that should help alleviate concerns regarding the consumption of transgenic plant products and it should assure the public of a food supply free from harmful pesticide residues. Registrants of plant-pesticides should benefit from the resolution of uncertainty regarding regulatory issues. With the promulgation of the proposed regulations, firms developing and testing plant-pesticides can plan ahead for timely product development and commercialization which should, in turn, attract investors to the agricultural biotechnology sector. The environment will benefit from safety measures that will protect against unintended environmental effects of accidental and deliberate releases of genetically engineered organisms. Nontarget organisms, including endangered species, will benefit from a registration process that will carefully consider the potential effects that certain plant-pesticides may have upon them. Finally, states will benefit

by having a set of standardized Federal regulations that will be more easily conveyed, interpreted, and enforced. Many states may also benefit by not having to establish their own set of agricultural biotechnology regulations.

Adverse economic impacts from the implementation of the proposed plant-pesticide regulations are not expected under EPA's proposed scope (regulatory Option 2). Due to the lack of detailed financial information on those firms that are currently developing and testing plant-pesticides, the conclusion of "no adverse economic impacts" was based on public and proprietary information provided to EPA by industry financial advisory groups, biotechnology associations, university biotechnology specialists, and small biotechnology firms.

The regulatory flexibility of these proposed regulations for plant-pesticides is demonstrated within the structuring of the four regulatory options proposed. These options were considered after extensive evaluations of the benefit/risk tradeoffs between option cost and risk reduction provided. The Agency has structured the resulting options from a narrow regulatory scope (Option 1) to a broad regulatory scope (Option 4) and as such, has conducted an "inherent" sensitivity analysis for small firms likely to be affected by this regulation. The Agency has determined that the tradeoffs between the benefits and risks of the proposed regulations are optimized under Option 2, EPA's proposed scope.

III. NEED FOR REGULATION

Some pesticides produced within plants (plant-pesticides) may pose many of the same or other types of environmental and human health risks as do the chemical, biochemical, and microbial pesticides that are currently regulated by EPA. This chapter presents a discussion of the risks and concerns associated with plant-pesticides. Some of these concerns are similar to pesticides applied externally to plants, since some of the plant-pesticides expressed by transgenic plants are the same as those applied externally. These concerns are grouped into four areas: human health, environment, industry, and the public.

A. Human Health Concerns

Many substances having pesticidal activity occur naturally at low concentrations in edible plants and have long been accepted as part of the human diet. The safety of these foods is accepted based on extensive use and experience, and they usually do not warrant regulation. For example, plant breeders depend primarily on their familiarity with food crops (e.g., knowledge of which crop plants have the ability to produce which toxicants) to ensure the safety of food from the various crop plant varieties. If the plant species is known to possess the ability to produce a toxicant, such as potato plants that express solanine, new varieties of the plant are tested for toxicant content (e.g., potato varieties are tested for alkaloid content).

Under FIFRA and FFDCA, the safety of food containing pesticides is addressed. Under the FFDCA, EPA has the responsibility for establishing tolerances for new pesticidal residues in food. A tolerance is the amount of pesticide that may legally remain on a crop after harvesting. For traditional pesticides, EPA determines tolerance levels based upon both toxicological and chemical residue data requirements codified in Part 158 of 40 CFR.

Also under FFDCA, EPA can establish an exemption from the requirement of a tolerance for a pesticide if the Agency determines that a tolerance is not necessary to protect the public health. On this basis, the Agency is proposing to exempt certain categories of plant-pesticides

that the Agency believes would not result in significantly different dietary exposures and therefore do not require an establishment of a tolerance to protect the public health.

There are, however, circumstances where a plant-pesticide produced in food would result in qualitative or quantitatively new dietary exposures to pesticidal substances with some toxicity. For example, a qualitatively different exposure could occur if a food plant was modified to produce a pesticidal substance derived from a non-food source such as certain microorganisms and animals. A qualitatively different dietary exposure could also result if an engineered plant-pesticide has a significantly different structure, function, or composition than a constituent known to exist in food.

The dietary risks of most concern to the Agency, are those associated with plant-pesticides for which there is no record of prior significant human exposure. As a result, documentation is unavailable to demonstrate that certain plant-pesticides will not have adverse or toxic effects on humans.

B. Environmental Concerns

In many respects, the underlying risk assessment paradigm for plant-pesticides is similar to that used for more traditional pesticides. These risk assessment considerations revolve around the potential for exposure to the pesticide and the chemical, and the toxicological properties of the pesticide. The properties of the plant-pesticide will determine the potential for hazards to nontarget organisms.

An important component in the evaluation of the chemical and toxicological properties of the pesticide with regard to the potential for adverse affects of pesticides on nontarget organisms, is the way in which the pesticidal substance acts on the target pest. The way in which a pesticidal substance affects the target pest could likely be the way it also affects nontarget organisms.

A pesticidal substance that acts directly on the target pest through a general toxic mechanism of action may, for example, also be toxic to nontarget organisms. For example, a substance that acts by inhibiting DNA synthesis of the pest could have the same effect on other organisms. Toxic mechanisms of action include, but are not limited to, those that affect: (1) membrane permeability, (2) cell division, (3) gene expression, (4) DNA replication, or (5) other metabolic functions.

Exposure to the plant-pesticide will be determined by the type of plants that produce the substance: whether the production of the substance is limited to particular plant parts; the amount of plant-pesticide expressed and where it is expressed; the acreage planted; where the plants grow; and the potential for spread of the plant's genetic material. Because plants can reproduce sexually and/or asexually, the plant-pesticide could potentially spread through vegetative growth of the plant or through successful hybridization of the plant with its wild, or other relatives, as well as through intentional human cultivation.

A risk consideration for plant-pesticides is whether the potential exists for new or significantly different exposures of nontarget organisms to the pesticide. Some plants may be modified to produce pesticidal substances that may be new to the plant and thus present new exposures to organisms that associate with the plant.

If a plant-pesticide has not been a component of a plant or its sexually compatible relatives, the organisms that associate with the plant may never have been exposed to the substance. For instance, spider mites produce an insecticidal toxin. Plants are not known to produce this toxin in nature nor is it likely to be produced by plants developed through traditional breeding techniques. If this toxin were introduced into the gene pool of specific plants, organisms that had never previously been exposed to the toxin might now be exposed.

Prior to the introduction of the toxin into these plants, only those organisms that interact with the spider mite could potentially be exposed to the toxin in nature. If plants could now express the toxin, a different or larger group of organisms--those that associate with the plant

--could be exposed to it, possibly resulting in adverse effects to these organisms. For instance, insects that feed on the plant could be exposed to the toxin. If the toxin is found in pollen, pollinators could also be exposed.

Another risk consideration associated with plant-pesticides is the possible transfer through outcrossing of a transgenic plant-pesticide gene to a cultivated or wild relative of that transgenic plant. Outcrossing and potential gene flow between a transgenic plant and its cultivated, wild, or weedy relatives would most likely be achieved through the movement of pollen with resulting changes in plant behavior that may subsequently affect plant and/or other populations. For instance, if weeds acquire increased resistance to insect or other pests from transgenic plants through hybridization, they may become more competitive than other plant species and because of their increased competitiveness, may alter both natural and agricultural ecosystems1/.

C. Industry Concerns

This section will focus on the primary concerns of the biotechnology industry: the uncertain regulatory environment, the costs for registering plant-pesticides under FIFRA, and obtaining a tolerance or exemption from a tolerance under FFDCA.

1. Uncertainty of regulatory environment

To this point in time, most plant-pesticide testing has been conducted in laboratories, greenhouses, or in small field tests, with such tests being contained (i.e. the potential spread of the plant's genetic material is controlled) and overseen by USDA. Some companies involved with agricultural biotechnology have plant-pesticide products that have been developed and tested to the point where product commercialization--including marketing,

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1/A natural ecosystem is an area inhabited exclusively, or nearly so, by wild, native species including several hundred plant species, thousands of insect species, and numerous other invertebrates, birds, and mammals. An agroecosystem is a simpler area, usually containing one plant of interest (e.g., corn or alfalfa), a few weeds, plant pests and their natural enemies, and a few transient species.

sales, and distribution--is near. Due to the lack of regulations for plant-pesticides, many companies are unsure of what they will need to do to secure EPA approval to market their plant-pesticides commercially. Some of the consequences of this regulatory uncertainty include the inability of companies to devise long-term plans, concern that regulatory delays may give competing firms marketing advantages, delays in large-scale seed production, and stifled university research (Crawford, 1990).

Recently, some companies have progressed to the point where large-scale field testing and registration are necessary. Given the uncertainty of the final regulatory framework at the Federal and State levels, and desiring compliance with future regulatory requirements and a method of reassuring the public concerning their products, these companies have voluntarily applied for experimental use permits from EPA. One company has submitted information for a plant-pesticide registration. Having developed the technology for transgenic pesticidal plants, industry wants to know the regulatory framework and wants it in place to allow for timely product development (Crawford, 1990; U.S. Congress, 1992).

2. Costs for registration under FIFRA

Prior to marketing any pesticide, no person in any state may "distribute, sell, offer for sale, hold for sale, deliver for shipment, or receive, (having so received) deliver, or offer to deliver, to any person any pesticide which is not registered with the Administrator." Registration under FIFRA can be a costly, time-consuming factor in the development and marketing of traditional pesticides, with less time and money required for biological pesticides, including perhaps, plant-pesticides.

Potential registrants of plant-pesticides have expended considerable amounts of resources on the research and development of products that may not even be accepted by the public. Several of the smaller companies involved with the development of plant-pesticides have reported negative net incomes due to heavy research and development expenses and little sales, and don't expect positive incomes until sufficient market sales are generated. These companies have substantial research and development costs, and possibly lower potential

profits than the traditional chemical pesticide manufacturers, and thus they may possibly assume a greater market risk. Therefore, potential plant-pesticide registrants are concerned about the costs associated with the data needs that EPA may require for the registration of their products.

3. FFDCA tolerances or exemptions from tolerances

Under FFDCA, EPA has the authority to set tolerances for pesticide residues in or on raw agricultural commodities and to establish food additive regulations for pesticide residues in or on processed foods. A tolerance or an exemption from the requirement of a tolerance is likely to be indicated for some plant-pesticides that are used in food/feed. The regulatory decisions EPA makes under FFDCA involve a risk analysis.

D. Public Concerns

The growing use of biotechnology in many fields, including agriculture and its potential use in others, has raised several public concerns. The results of a 1992 national survey provide some of the most current research on consumers' attitudes, awareness, and acceptance of biotechnology (Hoban and Kendall, 1992). Overall, the survey found that although the awareness level and understanding of biotechnology was low, most respondents expressed at least "fairly" positive attitudes towards biotechnology in general. Most significantly, at least two-thirds of the survey's respondents indicated that (1) they could personally benefit from applications of biotechnology, (2) biotechnology would have a positive effect on food quality and nutrition, and (3) they supported biotechnology in agriculture and food production.

The 1992 survey found that respondents acceptance of biotechnology products was lower when animals (versus plants) were involved and when gene transfers from different organisms (e.g., human to farm animal) was specified. These findings support earlier research on consumer attitudes towards biotechnology (Hoban, 1990; Hoban and Burkhart, 1991).

One of the more relevant findings of the survey, was that the public is concerned over the possible negative environmental effects of biotechnology. Over a third of the respondents cited concerns about biotechnology negatively impacting environmental quality, fish, and wildlife.

In addition to the above concerns found in the Hoban and Kendall survey, the following concerns are addressed in this section: inadequate consideration by firms of the public consequences of biotechnology research and development, and the safety of the food supply.

1. Inadequate consideration of public consequences

One public fear is that firms may not adequately consider the public consequences of biotechnology research and development. In the absence of regulations, the potential profits associated with certain plant-pesticides developed by some companies and the survivability of some firms, may be given greater consideration by those companies than the potential effects of an environmental release. Also, without a regulatory framework there is little incentive for companies to build potentially costly risk mitigation measures into plans for research and development (Larson and Knudson, 1991). Thus, regulatory oversight by Federal and State agencies is necessary to ensure that the environment will not suffer undue consequences as a result of biotechnology products, including transgenic plants with pesticidal qualities.

2. Safety of the food supply

There is concern from the public sector that pesticide residues in food from some traditional pesticide use may be harmful, even carcinogenic. The wide publicity given alar residues in apples for example, deserved or not, fed such fears. Concern extends to the safety of food from transgenic crops.

Michael Phillips, senior associate of the Congressional Office of Technology Assessment, is quoted as saying, "Genetic tinkering can change the toxicity and nutrient value of foods," while Monsanto's plant protection and improvement manager, Ganesh Kishore, is quoted as

saying, "The probability is very low...that a toxin would be produced that we don't know to look for" (Nazario, 1991). Rebecca Goldberg, at the Environmental Defense Fund, worries that foreign genes could interfere with a food's natural nutritional value, or release new, potentially dangerous toxins (Keehn, 1992). Because of differing public perceptions regarding the safety of food produced from transgenic plants, oversight and testing of food products at the Federal level, including tolerance reviews under FFDCA, will likely be essential for the public's acceptance of such food products.

IV. ALTERNATIVE APPROACHES

This chapter begins with a discussion of the nonregulatory approaches to the control of potential risks from plant-pesticides. Next, four options are presented in this chapter to analyze the costs of controlling various risk potentials in the regulation of plant-pesticides. Under FIFRA, options range from the narrowest in regulatory scope (Option 1), to EPA's proposed regulatory scope (Option 2), to a broader regulatory scope that includes coat proteins from plant viruses (Option 3), to the broadest in regulatory scope that includes all plant-pesticides (Option 4). Under FFDCA, the regulatory scope will be similar to that for FIFRA.

A. Nonregulatory Approaches

Nonregulatory approaches might include having no regulatory oversight over plant-pesticides or in relying upon the market system to address and resolve any issues relevant to plant-pesticides. Even maintaining the status quo, however, would not result in "no regulatory oversight." Under U.S. Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS), environmental release permits (ERPs) or notifications are required for field tests of introductions of transgenic plants, including those engineered to produce plant-pesticides. One key focus of USDA/APHIS ERPs is to prevent the release of "plant-pests" into the environment, thus, containment of the plant pest is an important issue for APHIS. EPA's primary concerns are human health, non-target organism exposure, and environmental impacts. Companies ready to conduct field tests (greater than an accumulative total of 10 acres) of plant-pesticides have voluntarily applied for experimental use permits (EUPs) from EPA, just as such companies are required to do for conventional pesticides. Therefore, based on voluntary compliance with EPA regulations relevant to conventional pesticides, having no regulatory oversight is not a likely, nor feasible option.

Another concern associated with nonregulatory approaches at the Federal level, is the possible development of a profusion of inconsistent, individual state regulations for plant-pesticides.

State regulations pertaining to pesticide producing transgenic plants were summarized in Appendix A for five selected states. In Appendix A, summary tables compare several components of each state's regulations. From these tables it becomes obvious that state regulations governing plant-pesticides vary, sometimes greatly, by state. In 1990, at least 22 separate states were considering various methods of regulating plant-pesticides (Crawford, 1990). Without Federal regulations, it is possible that the United States could have a multitude of different state regulations relevant to plant-pesticides.

Relying on the market to provide regulatory oversight of plant-pesticides is also likely to be insufficient. There are differences of opinion regarding the safety of various types of transgenic plants, including those containing plant-pesticides, even among the scientific community. If there should be negative consequences of environmental releases, industry does not have the legal authority to control the use of its products once they are sold. Public concerns regarding the safety of the food supply, potential unknown consequences of a release to the environment, and reliance on the market system might result in the public not accepting the products of biotechnology, involved companies not recouping their costs of research and development, and an erosion in public trust. The market system may also not work because once a high risk organism is released, it may reproduce and spread in the environment. Thus, risks must be evaluated at an early stage to avoid potentially serious consequences and as such, a reliance on the market system is not likely to be a viable option.

B. Regulatory Approaches

Having demonstrated the need for regulation, and given that EPA is the Federal agency primarily responsible for the regulation of pesticides, environmental and human health concerns associated with plant-pesticides can best be addressed through regulatory approaches as developed by the EPA. USDA/APHIS currently has the authority to issue ERPs for the testing of transgenic plants, if the genetically engineered plants or products meet the definition of "plant pests." The testing of plant-pesticides on small contained plots combined with the ERP requirements assures the public of the low risk of such pesticides. However, USDA's focus is on plant pest risks and as such, its permitting requirements do not

specifically address the potential human health and environmental risks associated with plant-pesticides. Given EPA's authority in regulating pesticides (chemical and biological pesticides), combined with the knowledge gained from prior and continuing EPA participation in USDA reviews for field testing, it is appropriate that EPA provide regulatory oversight for plant-pesticides. EPA's focus would be the larger environmental and dietary exposures associated with large-scale testing and commercial uses. This is especially relevant now that some companies have developed their biotechnology to the point where larger field testing and commercial production is near.

The following sections present a discussion of potential alternatives to regulating plant-pesticides under both FIFRA and FFDCA, with such alternatives analyzed within this report. Under all regulatory options, the term "plant-pesticide" can be defined as: a pesticidal substance that is produced in the plant and the genetic material necessary for the production of the substance.

The alternatives differ in the scope of plant-pesticide to be regulated and range from a very limited scope that captures only a narrow universe of plant-pesticides, to a broader alternative which captures virtually all plant-pesticides including plant varieties developed through natural breeding procedures. EPA's proposed regulations eliminate certain plant-pesticides that pose little risk from registration and capture those plant-pesticides with novel exposures that may present a risk to human health or the environment.

For this RIA, the costs of FFDCA regulation are included with the FIFRA case study estimates, since the primary FFDCA costs are those associated with data requirements. Data to be gathered on Human Health Effects are the major FFDCA costs of the proposed Rule.

1. Regulatory Scope Under FIFRA

The four regulatory options and their associated scopes for the regulation of plant-pesticides will be discussed in this section under FIFRA.

a. Regulatory Option 1

Of the four regulatory options proposed by EPA, Option 1 is the most limited in regulatory scope. Under Option 1, all plant-pesticides will be regulated by the Agency unless they meet at least one of the following criteria which makes them exempt from the requirements of FIFRA:

(1) The genetic material leading to the expression of the pesticidal substance is derived from the plant Kingdom and has never been derived from a source(s) outside the plant Kingdom; or

(2) The plant-pesticide acts primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant or invading the plant's tissue in at least one of the following ways:

(i) Acts as a structural barrier to attachment of the pest to host, structural barrier to penetration of the pest or structural barrier to spread of pest in host, for example through the production of wax, lignin, or length of trichomes (plant hairs); or

(ii) Acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest; or

(iii) Acts by creating a deficiency of plant nutrient(s) or chemical component(s) essential for pest growth on/in host; or

(3) Is a coat protein from a plant virus.

b. Regulatory Option 2

Option 2 represents EPA's proposed scope and is broader in regulatory scope than Option 1. Plant-pesticides will be regulated by EPA under this proposed option unless they meet at least one of the following criteria which then exempts them from the requirements of FIFRA:

(1) The genetic material leading to the expression of the pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source(s) outside sexually compatible plants; or

(2) The plant-pesticide acts primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of the following ways:

(i) Acts as a structural barrier to attachment of the pest to host, structural barrier to penetration of the pest or structural barrier to spread of pest in host, for example through the production of wax, lignin, or length of trichomes (plant hairs); or

(ii) Acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest; or

(iii) Acts by creating a deficiency of plant nutrient(s) or chemical component(s) essential for pest growth on/in host, or

(3) Is a coat protein from a plant virus.

c. Regulatory Option 3

Option 3 is broader in regulatory scope than Option 2, but more narrow than Option 4. Option 3 includes within its scope those plant-pesticides regulated under EPA's proposed scope (Option 2) and coat proteins from plant viruses. Under this Option, all plant-pesticides will be regulated under FIFRA and FFDCA unless they meet at least one of the following exemptions:

(1) The genetic material leading to the expression of the pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source(s) outside sexually compatible plants; or

(2) The plant-pesticide acts primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of the following ways:

(i) Acts as a structural barrier to attachment of the pest to host, structural barrier to penetration of the pest or structural barrier to spread of pest in host, for example through the production of wax, lignin, or length of trichomes (plant hairs); or

(ii) Acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest; or

(iii) Acts by creating a deficiency of plant nutrient(s) or chemical component(s) essential for pest growth on/in host.

d. Regulatory Option 4

Option 4 is the broadest option in regulatory scope. Under Option 4, all plant-pesticides, including those that result from traditional plant breeding, are subject to the requirements of FIFRA and FFDCA.

V. BASELINE REGULATORY OVERVIEW AND COMPLIANCE HISTORY

At the Federal level, the U.S. Department of Agriculture's (USDA), Animal and Plant Health Inspection Service (APHIS) has regulated the field testing of genetically engineered plants since 1987. Some of the plants under APHIS regulation produce plant-pesticides that would be subject to EPA regulation under FIFRA and FFDCA. Much of the information that APHIS will need to evaluate early field testing is similar to the information that the Agency may need to evaluate later stages of development. APHIS regulations will serve as the baseline of requirements for companies producing plant-pesticides. In addition to APHIS regulations, several states have biotechnology regulations that cover certain aspects of the research and development of plant-pesticides. This chapter will examine these existing regulations.

A. Federal Regulations

On June 16, 1987, USDA/APHIS published regulations which established a permit requirement for the introduction of genetically engineered organisms which are plant pests or for which there is reason to believe are plant pests (Plant Pests; Introduction of Genetically Engineered Organisms or Products; Final Rule; 52 FR 22891). Such regulations were issued under the authority of the Federal Plant Pest Act (FPPA) (7 U.S.C. 150aa *et seq.*) and the Plant Quarantine Act (PQA) (7 U.S.C. 151 *et seq.*) and are found at 7 CFR 330 and 340.

The above referenced regulations provide that a permit is necessary to import, move interstate, or release into the environment a genetically engineered organism or product if the organism has been altered or produced through genetic engineering from an organism (donor, vector, or recipient) that is included in the list at 7 CFR 340 and meets the definition of a plant pest (or is an unclassified organism or any other product produced by genetic engineering which APHIS determined to be a plant pest). APHIS regulations cover a broader scope of genetically engineered organisms than the regulations proposed by EPA for plant-pesticides under FIFRA and FFDCA. Since 1988, APHIS regulations have resulted in

numerous individuals or firms submitting applications for environmental release permits (ERPs) and receiving such permits before conducting field tests of transgenic plants. The application for an ERP addresses 14 points, as outlined at 7 CFR 340 and shown in Table V-1.

Requirements include detailed descriptions of how the organisms will be prevented from dissemination into the environment, both during transport and during the field test, and monitoring procedures. Under a letter of agreement with USDA, EPA has cooperatively reviewed field tests of plant-pesticides that are under the permitting jurisdiction of the Plant Pest Act.

On March 31, 1993 USDA/APHIS amended their regulations to provide for a notification process for the introduction of certain plants with which APHIS has had experience regulating. The introduction of certain regulated articles under notification may be allowed provided that the introduction is in accordance with the provisions of the amendments. The amendment also provides for a petition process which grants a determination that certain plants are no longer regulated articles. This petition process provides a waiver from regulation for plants which do not present a plant pest risk (Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status; Final Rule; 58 FR 17044).

As of February 1994, three APHIS-permitted plant-pesticide products (Bt in cotton, Bt in potato, and Bt in corn) had reached the stage in development where large-scale field testing was necessary. The companies developing these products voluntarily applied to EPA for experimental use permits (EUPs) to conduct large-scale field testing. Since the issuance of the three EUPs, another company has voluntarily applied to EPA for a registration and several more have contacted the Agency about EUPs and registrations.

Table V-1. Information to be included in an application to USDA/APHIS for a permit for release into the environment

Information requirement
1. Name, title, address, telephone number, signature of the responsible person and type of permit requested (for importation, interstate movement, or release into the environment).
2. All scientific, common, and trade names, and all designations necessary to identify the: Donor organism(s), recipient organism(s); vector or vector agent(s); constituent of each regulated article which is a product; and regulated article;
3. Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article;
4. A description of the means of movement (e.g., mail, common carrier, baggage, or handcarried (and by whom));
5. A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics);
6. A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article;
7. Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced;
8. A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design;
9. The quantity of the regulated article to be introduced and proposed schedule and number of introductions;
10. A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article;
11. A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location);
12. A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;
13. A detailed description of any biological material (e.g., culture medium or host material) accompanying the regulated article during movement; and
14. A detailed description of the proposed method of final disposition of the regulated article.

Source: Plant Pests; Introduction of Genetically Engineered Organisms or Products; Final Rule; 52 FR 22891; June 16, 1987.

B. State Regulations

A number of states have regulations pertaining to genetically engineered organisms, including transgenic plants which express pesticidal substances (plant-pesticides). An article published in Science reports that in 1990, about 22 states were considering various methods of regulating plant-pesticides (Crawford, 1990). For this analysis, the regulations of five States--Illinois, Minnesota, North Carolina, Oklahoma, and Wisconsin--were reviewed, as follows:

- Illinois — Public Act 86-306, An Act in relation to notification and review of the release of genetically engineered organisms into the environment (effective July 1, 1990);
- Minnesota — Chapter 18B: Pesticide Control

  Chapter 18C: Fertilizers, Soil Amendments, Agricultural Liming Materials, and Plant Amendments

  Chapter 18D: Chemical Liability

  Chapter 18F: Genetically Engineered Plants

  Rules for the Release of Genetically Engineered Organisms Into the Environment (Adopted May 21, 1992; Effective August 3, 1992), including Amendments to Chapter 4410 and New Chapter 4420;
- North Carolina — Regulations for Genetically Engineered Organisms (Title 2, Chapter 48, Subchapter 48E of the North Carolina Administrative Code), 1991/92;

  Genetically Engineered Organisms Act (Chapter 106, Article 64 of the General Statutes of North Carolina), 1991/92;
- Oklahoma — Oklahoma Agriculture Biotechnology Act (2 O.S. 1990 Supplement Sections 2100 Thru 2019; Effective May 17, 1990); and
- Wisconsin — 1989 Wisconsin Act 15 (Effective June 13, 1989).

Illinois and Wisconsin are "notification and review" states in that applicants for a USDA/APHIS environmental release permit must notify the Department of Agriculture in

each state at approximately the same time that an application is sent to the Federal agency. Notification includes a copy of all information being submitted to USDA/APHIS, including a summary of confidential business information (CBI) in lieu of CBI material. Following review, the states may submit comments to the Federal agency.

North Carolina requires a permit to be obtained through the state's Genetic Engineering Review Board before a genetically engineered organism may be released into the environment, sold, offered for sale, or distributed for release into the environment. This Review Board may grant, deny, suspend, modify, or revoke such permits. They also may submit written comments to any Federal agency reviewing a proposed or completed release.

Oklahoma, through its Department of Agriculture, requires a permit for the release into the environment of any regulated articles. Exempt, however, are persons who have applied for regulatory approval from the appropriate Federal agency.

In Minnesota, permit applications are requirements of the Department of Agriculture (MDA) and the Environmental Quality Board (EQB). If the release being requested is associated with an experimental use, a permit from the EQB must be obtained, whereas if its a commercial use, then a permit from the MDA is required (Mason, 1993). While a State permit is required, the application made to USDA/APHIS usually contains sufficient information for the MDA (Mason, 1993). An Environmental Assessment Worksheet (EAW) has to be prepared by the MDA for all permits, with help from industry; if findings from the EAW warrant, an Environmental Impact Statement (EIS) must also be prepared (Mason, 1993). To date, however, no EIS has been required.

Appendix A, Tables A-1 and A-2 present summaries of state regulations pertaining to genetically engineered organisms in Illinois, Minnesota, North Carolina, Oklahoma, and Wisconsin.

In some states, existing laws and procedures are considered adequate for biotechnology. Therefore, no specific regulations pertaining to genetically engineered organisms have been

developed. Written into USDA's regulations are provisions for notification by APHIS of state officials. States are kept informed about pending biotechnology permit applications which may involve the field testing and/or introduction of genetically engineered plants within state boundaries (McCammon and Medley, 1990(a)).

VI. ECONOMIC PROFILE OF FIRMS CURRENTLY RESEARCHING AND TESTING PLANT-PESTICIDES

To the extent that available data allow, this chapter identifies and profiles the financial conditions of those entities that are currently involved with the research and testing of plants that express pesticides. It begins with a discussion of the approximate number and type of firms presently testing and researching plant-pesticides, and concludes with an examination of the size and organizational structure of these firms.

A. Number and Type of Firms

According to the U.S. Department of Commerce, there are approximately 1,300 firms involved with the application of biotechnology in the U.S. These 1,300 firms include 675 new, small companies that have been formed to market the technology developed in universities, 440 supply companies, and 200 established companies that are predominantly involved in pharmaceutical, medical supply, and chemical biotechnology (U.S. Department of Commerce, 1993).

Of those 1,300 firms involved with biotechnology, only those companies that develop plants that produce pesticidal substances would be required to fulfill EPA's proposed requirements under its approach to registering plant-pesticides. Reilly (1989) estimates that 116 firms are involved in biotechnology activities in crop production. Because crop production biotechnology is a subset of biotechnology, it is possible that many of these 116 biotechnology-crop production firms reported by Reilly are a subset of the 200 established biotechnology firms reported by the Department of Commerce. These 116 companies are likely to comprise the **universe** of firms potentially affected by the proposed registration requirements and Table VI-1 shows the activities that occur in these firms. Of all the types of activities that occur in crop production biotechnology firms, only some of the activities associated with biopesticides (12.5 percent), pesticide/disease resistance (11.7 percent), and other (1.2 percent) would potentially require EPA registration.

Table VI-1. Activities of the 116 firms involved in crop production biotechnology

Activity	Percent of total activities
	(%)
Improved crops	19.2
Propagation techniques	17.1
Genetic engineering	13.3
Biopesticides	12.5
Pesticide/disease resistance 1/	11.7
Miscellaneous crops	8.3
Nitrogen fixation	7.1
Stress resistance	4.6
Diagnostics	2.9
Growth promoters	2.1
Other 2/	1.2
	100.0

Source: Reilly, John M. 1989(Dec). Consumer Effects of Biotechnology. U.S. Department of Agricultural, Economic Research Service.

1/ Activities that may be affected by registration requirements for plant pesticides.

2/ Medicinal plants and ornamental plants.

Within Reilly's universe of 116 potentially affected firms lies a subset of companies that are currently, actively involved with the research and testing of plants with pesticidal properties. For purposes of developing economic profile information, this analysis will focus on those companies that have received Environment Release Permits (ERPs) from the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) to field test plots of plants that produce pesticidal substances. These companies are diverse and include chemical, seed, biotechnology, and agricultural firms, as well as universities, and one governmental agency.

Once the companies that had received USDA/APHIS permits for the field testing of plants that produce pesticidal substances were identified, economic profile information was sought from the limited number of private organizations and industry associations that record relatively detailed financial information on private companies. Unfortunately, the financial information that is needed and available, is based on the aggregated performance of the entire company and not on specific sectors, such as biotechnology. The lack of specific data is due to the integration of biotechnology processes with research and production in most companies. Thus, specific standardized information on production, employment, trade, and research and development are not available for the companies involved. Therefore, any data used to profile the economic status of these companies is based on the companies aggregated profits, sales, number of employees, etc.

Since 1987, approximately 56 various public and private companies, universities, and one governmental agency have received ERPs from USDA/APHIS for the field testing of transgenic plants. The gene types of transgenic plants that have received ERPs from APHIS are broader than EPA's proposed scope of plant-pesticides to be regulated under FIFRA and FFDCA.

Thus, all companies that have received APHIS permits for the field testing of plants that have <u>not</u> been modified to express pesticidal substances, would not be regulated by EPA and are not considered further. A portion of the remaining companies, universities, and governmental

agencies will eventually commercialize some of their plant-pesticides and may be affected by the plant-pesticide registration requirements.

Presently, approximately 19 diverse companies are known to be developing and testing plant-pesticides that may need to fulfill the registration requirements proposed under this proposed Rule (See Table VI-2). Some examples of this diversity include large, multinational companies such as Pepsico, Inc. and Dow Chemical, biotechnology companies such as Biosource Genetics Corporation and Calgene, Inc., chemical companies like Monsanto and Sandoz, and seed companies such as Harris Moran Seed, Rogers NK Seed, and Rohm & Haas Seeds, Inc. In addition to the firms found in Table VI-2, 11 universities have developed transgenic plants with pesticidal properties and have received APHIS permits. These universities along with the crop(s) and plant-pesticide(s) developed are listed in the following table. The USDA's Agricultural Research Service (ARS) is another type of APHIS permit recipient that has developed plant-pesticides.

Universities that have developed potentially EPA regulated plant-pesticides

University	Crop(s)	Gene Type(s)
Iowa State	Tobacco	Insect resistant
Louisiana State	Rice	Insect resistant
Michigan State	Melon	Virus resistant
Montana State	Potato	Insect/disease resistant
North Carolina State	Tobacco	Insect resistant
University of Arizona	Tobacco	Virus resistant
University of California	Apple, Walnut	Insect resistant
University of Florida	Tobacco	Virus resistant
University of Hawaii	Papaya	Virus resistant
University of Idaho	Potato	Virus resistant, insect resistant
University of Kentucky	Tobacco	Virus resistant

Source: U.S. Department of Agriculture, Animal, Plant, and Health Inspection Service. 1992.

Table VI-2. Selected financial information on firms currently researching and testing plant-pesticides

Parent *Subsidiary involved with biotechnology*	Fiscal year	Parent sales rank	Sales (million $)	Profit before tax (PBT) (million $)	Number of employees	Sales per employee ($)
LARGE FIRMS			**Average Sales = $19 billion; Average PBT = $1.8 billion**			
Amoco Corp.	91	1	25,325.0	2,035.0	54,190	467,300
Amoco Technology Co.	*NA*		*111.5*	*NA*	*1,350*	
Pepsico, Inc.	91	2	19,292.2	1,659.7	338,000	60,000
Frito-Lay, Inc.	*NA*		*3,000.0*	*NA*	*26,000*	
Dow Chemical Co.	91	3	18,807.0	1,688.0	62,200	302,400
Dow Gardens	*NA*		*NA*	*NA*	*NA*	
Sandoz Agricultural	NA	4	12,400.0	NA	50,000	248,000
Northrup King Co.	*90*		*200 0*	*NA*	*1,000*	
Rogers NK Seed Co.	*90*		*104.0*	*NA*	*375*	
Sandoz Crop Protection	*NA*		*250 0*	*NA*	*1,100*	
MEDIUM FIRMS			**Average Sales = $4 billion; Average PBT = $389 million**			
Monsanto Co.	91	5	7,936	354.0	39,300	225,500
Monsanto Agricultural Co.	*90*		*1,717.0*	*NA*	*4,000*	
Campbell Soup Co.	91	6	6,204.1	667.4	43,256	144,800
W.R. Grace & Co.	91	7	5,569.9	395.7	49,000	123,400
Agracetus	*NA*		*1.2*	*NA*	*75*	
CIBA-Geigy Corp.	NA	8	3,800.0	NA	16,000	237,500
Agricultural Biotechnology Research Unit	*NA*		*0*	*NA*	*125*	
Upjohn Co.	91	9	3,426.3	720.2	19,193	178,500
Asgrow Seed Co.	*NA*		*NA*	*NA*	*NA*	
Rohm & Haas Co.	91	10	2,763.0	240.0	12,872	214,700
Rohm & Haas Seeds, Inc.	*NA*		*1 2*	*NA*	*19*	
Lubrizol Corp.	91	11	1,467.9	178.1	5,299	278,600
Agrigenetics Advanced Science Co.	*NA*		*117.0*	*NA*	*700*	
Pioneer Hi-Bred International, Inc	91	12	1,124.9	169.6	4,768	235,900
SMALL FIRMS			**Average Sales = $53 million; Average PBT = $(1.2) million**			
DeKalb Genetics Corp.	91	13	275.8	24.0	2,350	127,700
Harris Moran Seed Co.	NA	14	40.0	NA	200	200,000

...Continued

Table VI-2. Selected financial information on the regulated community (Cont'd)

Parent *Subsidiary involved with biotechnology*	Fiscal year	Parent sales rank	Sales (million $)	Profit before tax (PBT) (million $)	Number of employees	Sales per employee ($)
Calgene, Inc.	91	15	26.1	(14.3)	282	77,700
Mycogen Corp.	91	16	18.3	(3.3)	279	84,600
DNA Plant Technology	91	17	8.9	(4.2)	144	75,700
Biosource Genetics Corp.	90	18	2.3	NA	25	92,000
Crop Genetics International Corp.	91	19	1.5	(8.4)	100	14,000

Source: 1992 Million Dollar Directory
1992 Directory of Corporate Affiliations
1991 Dun and Bradstreet files
Disclosure database (10K)

NA = Not Available

B. Size and Structure of Firms

Total sales from the biotechnology industry are predicted to reach nearly $6 billion by the end of 1993, a 35 percent increase from 1992 sales (Burrill and Lee, 1993). Sales from the agricultural biotechnology sector are estimated at $95 million in 1993, or less than two percent of total biotechnology sales. While agricultural biotechnology sales currently are a small percentage of total biotechnology sales, tremendous growth is predicted. To the year 2003, agricultural biotechnology sales are forecasted to grow at an average annual rate of 33 percent (Indiana Agrinews, 1993).

As discussed previously, the aggregation of financial statistics from publicly available sources prevents the categorization of the individual companies that are currently involved with plant-pesticide development and testing into size classifications based solely on **biotechnology** sales, income, or employment figures. Companies involved with plant-pesticide development include the larger, highly diversified public corporations such as Pepsico and Amoco, that are developing and marketing their agricultural biotechnology products through subsidiaries such as Frito-Lay and Amoco Technology, respectively. The larger firms may also market their agricultural biotechnology products through subsidiaries (i.e., Monsanto Agricultural Company of Monsanto Company), or those that do not have subsidiaries may market their agricultural biotechnology through the parent company (i.e., Pioneer Hi-Bred International). There are also several small companies currently researching and testing plant-pesticides. Some of these small firms specialize in agricultural biotechnology products, with two examples being Biosource Genetics and DNA Plant Technology. However, with the exception of these few specialized small firms, most parent companies as well as their subsidiaries are developing and marketing a wide spectrum of commodities--not just biotechnology products.

Thus, in this chapter, discussions of the size of individual firms will be based on the sales of the parent company. Within Table VI-2, natural breaks in the magnitudes of sales of the parent companies become apparent. To facilitate discussions of the financial status of companies potentially affected by these proposed regulations, these natural breaks are used to divide the companies involved with plant-pesticide research and testing, into three sizes of

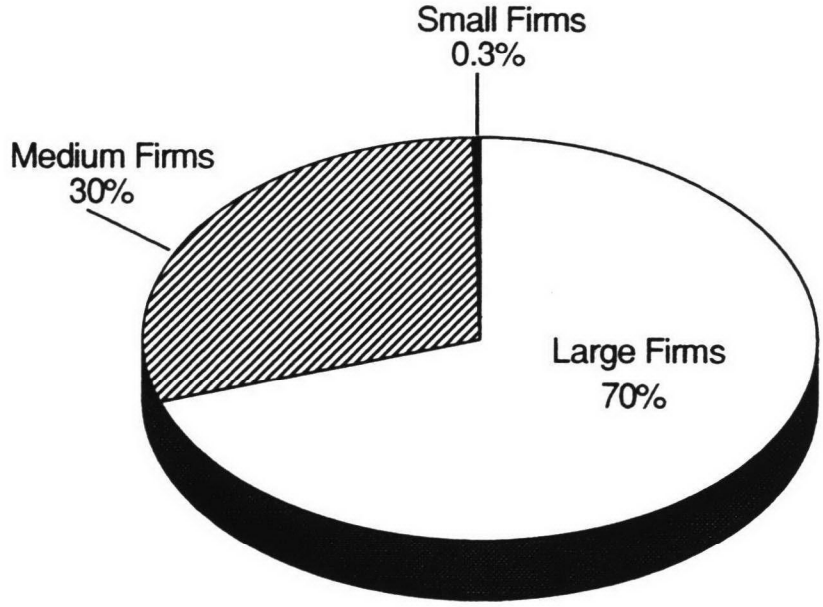
firms: small--firms that have sales of less than $300 million, medium--firms that have sales of greater than $300 million but less than $8 billion, and large--firms with sales of greater than $8 billion.

Although only 21 percent of the firms currently involved with plant-pesticide research and testing are considered "large", they account for nearly 70 percent of the total sales of the 19 firms presently involved with plant-pesticide research and testing as shown in Figure VI-1. The top ranking parent company is Amoco Corporation with $25.3 billion in sales and over 54,000 employees (Table VI-2). At $467,300, Amoco also has the highest average sales per employee. Along with Amoco Corporation, Pepsico, Inc. with $19.3 billion in sales, Dow Chemical with $18.8 billion, and Sandoz Agricultural with $12.4 billion account for the "large" firms presently testing and researching plant-pesticides.

Forty percent of the firms currently identified as involved with plant-pesticide research and testing are considered "medium" sized and together, account for approximately 30 percent of the total sales of all the firms presently testing and researching plant-pesticides (Figure VI-1). Sales in this size category range from $1.1 billion for Pioneer Hi-Bred International to nearly $8.0 billion for Monsanto. It is interesting to note that Upjohn Company, with a midpoint sales figure of $3.4 billion, has over twice the profits before tax of Monsanto (Table VI-2). Many of the plant-pesticide products that are nearest to commercialization, have been developed by firms in the "medium" sized category. Monsanto with its *Bacillus thuringiensis* (Bt) in cotton and potato, CIBA-Geigy with its *Bt* in corn, and Upjohn Company with its virus resistant squash and cantaloupe have or will soon reach the product development stage where large-scale field testing is necessary.

Many of the firms currently involved with the research and testing of plant-pesticides that are denoted as "small", are specialized agricultural biotechnology companies with sales ranging from $1.5 million to $276 million. Calgene, Mycogen, DNA Plant Technology, and Crop Genetics International all have negative profits before taxes reflecting heavy research and development expenses, and few sales. However, industry sources believe that "meaningful" sales should start at any time and this segment of the industry should grow rapidly as

Figure VI-1. Firms currently researching & testing plant-pesticides: percentage of sales by size of firm



Total sales = $109 billion

Source: Table VI-2.

investors are attracted (Burrill and Lee, 1993). Probably the most famous agricultural biotechnology product so far, the Flavr Savr tomato, was developed by one of these "small" specialized biotechnology firms (Calgene).

VII. COMPLIANCE COST ANALYSIS OF DATA NEEDS

This chapter presents a compliance cost analysis of the data needed for the registration of plant-pesticides by examining four regulatory options which vary in the scope of plant-pesticides to be regulated. Option 1 is the most limited in regulatory scope and is therefore the least costly regulatory option proposed. Option 2 represents EPA's proposed regulatory scope and is broader in regulatory scope than Option 1. Option 3 includes within its scope, those plant-pesticides regulated under Option 2 in addition to coat proteins from plant viruses (VCPs). Option 4 is the broadest option in regulatory scope and would regulate all plant-pesticides. Option 4 is likely to be very costly to industry and EPA to implement. In addition to the four regulatory options, Appendix B independently estimates the costs of EPA regulating (1) VCPs in plants with wild relatives in the U.S., and (2) all VCPs (with and without wild relatives in the U.S.).

To estimate compliance costs, it is necessary to 1) determine the types of tests needed for the different plant-pesticides, 2) obtain the costs for the data generation and submittal of testing information, and 3) project the number of potential plant-pesticide submissions by type of plant-pesticide the Agency may receive for registration.

USDA/APHIS requirements for environmental release permits (ERPs) serve as the existing baseline of Federal requirements for companies that are testing genetically engineered plant-pesticides in field trials. Once the costs for certain data currently required by USDA/APHIS are accounted for as the baseline costs, the additional costs associated with the data needs directly attributable to EPA registration needs for plant-pesticides, are calculated as the costs of this proposed Rule.

This chapter is organized as follows: first, the general methodology used to estimate compliance costs is outlined; second, direct **industry** compliance costs are estimated; third, the labor burden costs to **EPA** are estimated; fourth, the aggregate costs of regulating plant-pesticides to society are discussed and; fifth, the limits of the cost analysis are summarized.

For ease of reading, all tables in this chapter can be found at the end of the chapter, rather than being dispersed throughout.

A. General Methodology

The costs of regulating plants that express certain plant-pesticides are dependent upon the data needed for the registration of a particular type of plant-pesticide, and the unit costs of performing the tests to acquire the data. Obtaining accurate information about these two factors is difficult due to a number of variables affecting them, especially uncertainty. Since the technology for plant-pesticides is a new and evolving process, it is difficult to predict the specific data needs of these pesticides before they are developed. For example, data needs for a particular type of plant-pesticide will vary depending upon the recipient crop--whether it is intended for human consumption, whether it is grown in or near water, whether it has wild relatives in the U.S., etc. The general approach for developing and compiling such information is described below.

1. Unit or Individual Testing Costs

Cost estimates for performing individual tests were either obtained from secondary sources, EPA experts, or industry specialists. Time and resource constraints prevented a rigorous, systematic, statistically designed data collection process.

Many of the anticipated data needs for plant-pesticides have been required for the registration of conventional chemical, biochemical, and microbial pesticides and have established protocols with detailed guidelines approved by EPA. Tests such as the *acute oral toxicity* (CFR guideline number 152-10) and the *avian oral LD50* (CFR guideline number 71-1) are two examples of tests required for the registration of chemical pesticides as well as certain plant-pesticides. Costs for the conventional chemical, biochemical, and microbial tests were obtained from a 1990 EPA Regulatory Impact Analysis (RIA) of the reregistration requirements for traditional and microbial pesticides (U.S. EPA, 1990).

However, some of the anticipated data needs for the registration of plant-pesticides are new and have not had protocols established by EPA. Tests such as *in vitro digestibility assay, hybrid viability, pollen viability, selective advantage,* and *dispersion* are some examples. For these new data needs, costs were estimated after examining (1) existing traditional chemical, biochemical, and microbial test requirements for similarities and then using their estimated costs or portions of their estimated costs, (2) estimates provided by firms that have plant-pesticides close to commercialization, and (3) expert opinion within the Agency.

Both lower and upper bounds were created for each unit test cost. The lower bound test costs were either estimated in today's cost by the Agency or industry specialists, or were obtained from secondary (1989) sources and adjusted for the inflation that has occurred in test costs since 1989 1/ by a factor of 10 percent for each year up to 1993. These 1993 inflation-adjusted direct cost estimates provided the basis for the lower bound test costs. Upper bound test costs were estimated as the lower bound test costs plus 25 percent to account for some of the additional effort needed to revise protocols and endpoints, and to account for the administrative burden associated with consultations with EPA personnel regarding specific data needs. Midpoint test costs or the mean values 2/ were used in aggregating total compliance costs.

Finally, the costs associated with the production of the pesticidal substance and its purification for testing purposes were estimated. The Agency believes that most registrants will use a method other than extracting the active ingredient from the plant for the test material, because of the expense. It is likely that registrants will extract only a small amount of the pesticidal substance from the transgenic plant or will independently produce a similar

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1/ According to some industry representatives, recent EPA reregistration requirements for existing chemicals has put an increased demand on private laboratory testing services to complete the new testing requirements. This increased demand for testing services has caused increased costs for these services. The annual increase in test costs is believed to have increased faster than the overall inflation rate and thus, the use of an annual 10% inflation rate.

2/ Midpoint test costs were calculated by summing the lower and upper bound estimates, and then dividing by two.

pesticidal substance. This small amount of pesticidal substance will be needed only to verify the equivalence of the alternative source and the plant-produced test material.

2. Development of Case Studies

Case studies are used to estimate the potential costs of registering different types of plant-pesticides. Twelve case studies were developed to represent the variety of plant-pesticides that the Agency has had some experience with, or has reason to believe may be developed in the near future.

Some of the data needs for certain types of plant-pesticides will require minimal additional effort by the time the registrant seeks EPA registration. These data consist of basic information that is created as part of the research and development of these pesticides. Therefore, the costs associated with the product analysis data needs for Case Studies 1-5 and 7-8 are similar to USDA/APHIS permitting requirements and as such, are not a cost of this proposed Rule (these costs are later subtracted from total costs to obtain incremental costs). The costs attributable to pesticide exposure data are one example. Total costs are estimated as a range to account for the varying degrees of test protocol development needed and for the amount of administrative burden that may be incurred by individual registrants.

a. Case Study 1

Case Study 1 reflects the anticipated data needs for plant-pesticides in plants without wild relatives in the U.S., that have information available on the gene product. In this case study, the source of the pesticidal substance is the monera kingdom. The data needs and associated costs of registering a plant-pesticide in plants without wild relatives in the U.S., for which information on characteristics and function of the gene product is available, will cost a registrant between $54,900 and $72,500 depending upon the amount of protocol development needed and administrative burden incurred (see Appendix Table C-1).

b. Case Study 2

Case Study 2 depicts the anticipated data needs and associated costs for the registrant of a plant-pesticide in a plant with no wild relatives in the U.S., and with information available on the characteristics and function of the gene product. In this case study, the source of the pesticidal substance is derived from within the plant kingdom or same plant family. It is estimated to cost the registrant an average of nearly $102,400, with a potential range of $89,300 to $115,500, to fulfill the anticipated data needs for the registration of Case Study 2 type plant-pesticides (Appendix Table C-2). The estimated costs of registration are likely to be somewhat overstated as the Tier II terrestrial and aquatic nontarget organisms effects test for pollinators is only predicted to be needed 25 percent of the time.

c. Case Study 3

Case Study 3 reflects the potential data needs and associated costs for plant-pesticides in plants with wild relatives in the U.S., and for which information on the characteristics and function of the gene product is available. As with Case Study 1, the source of the pesticidal substance is from the monera kingdom (e.g., Bt) and this type of plant-pesticide would be regulated under all regulatory options. It is estimated to cost registrant's between $649,500 and $815,800 with a midpoint cost of $732,700 to register an individual plant-pesticide with Case 3's characteristics (Appendix Table C-3).

The majority of the tests needed for the registration of this type of plant-pesticide fall under the environmental fate heading (see Appendix Table C-3). Tier III biological fate tests may not be needed always, i.e., not all plant-pesticides of this type will need these three costly tests (marked "sometimes needed" in the "when required" column). In fact, the Agency predicts that most likely only 10 percent of all Case Study 3 type plant-pesticides submitted for EPA registration will need Tier III biological fate data. However, at this time, it is not possible for the Agency to predict exactly which submissions will need Tier III biological fate tests, and which will not. Thus, rather than to make an unsubstantiated assumption, EPA chose to err on the high side and assumed that all Case Study 3 type plant-pesticide

submissions would need Tier III biological fate testing. Therefore, for the average plant-pesticide submission of a Case Study 3 type plant-pesticide, the total costs for fulfilling the data needs are likely to be overestimated.

d. Case Study 4

Case Study 4 reflects the data needs and associated costs for a plant-pesticide in plants with no wild relatives in the U.S., and no information available on the characteristics and function of the gene product. In this case study, the source of the pesticidal substance is from within the plant kingdom or same plant family. The data needed for EPA to register this type of plant-pesticide are estimated to cost registrants approximately $386,800 per submission (Appendix Table C-4).

While most of the data needs associated with a Case Study 4 type plant-pesticide are from the terrestrial and aquatic nontarget organisms effects section, the need for Tier II and III tests will be determined on a case-by-case basis, depending upon the recipient crop and the geographic location of the planting. This is reflected in the table as "sometimes needed" and is labeled "SN". The Agency estimates that only one out of four (25 percent) submissions of Case Study 4 type plant-pesticides will require Tier II and III testing. Thus, it should be noted that for the average plant-pesticide submitted with Case Study 4's characteristics, total costs for EPA registration are likely to be overestimated.

e. Case Study 5

Case Study 5 depicts a plant-pesticide in plants with wild relatives in the U.S., and no information available on the characteristics and function of the gene product. The pesticidal substance is derived from the animal kingdom in a Case Study 5 type plant-pesticide.

As shown in Appendix Table C-5, the cost to register a Case Study 5 type plant-pesticide is about three times as much as a Case Study 4 type: $945,100 to $1.2 million depending upon the administrative burden and protocol development necessary to complete the data needs.

This increased cost is attributable to the additional Tier II and III environmental fate data needs to determine whether a particular plant expressing a plant-pesticide has the ability to breed with its wild relatives and to determine if the resulting progeny have inherited the ability to express the plant-pesticide.

f. Case Study 6

Case Study 6 depicts the anticipated data needs for plant-pesticides from sexually compatable plants that have been developed through traditional breeding methods emphasizing the development of new plant varieties which are insect-, virus-, or disease-resistant.

Appendix Table C-6 displays the data needs associated with the registration of Case Study 6 type plant varieties. Unlike Case Studies 1 through 5, the costs for product analysis data needs are not attributable to USDA/APHIS permitting requirements for Case Study 6. While USDA/APHIS issues permits for plant-pesticides of the type depicted in Case Studies 1-5, new plant varieties are not required to obtain permits. Therefore, the product analysis data needs will be included in the compliance cost analysis for Case Study 6 in this proposed Rule.

The only other data needs associated with the EPA regulation of plants in this category, would be the acute oral toxicity and *in vitro* digestibility assay under human health effects and mammalian toxicology (see Appendix Table C-6). The total cost estimate to register a Case Study 6 type plant variety is estimated to range between $14,700 and $18,400, with an average cost of $16,600 per submission.

g. Case Study 7

In Case Study 7, the anticipated data needs and their associated costs for the EPA regulation of viral coat proteins (VCPs) in plants are described (Appendix Table C-7). The example used in this case study is a recipient crop with no wild relatives in the U.S. (e.g., tomato)

with virus resistance from a VCP. Registration costs are estimated to be relatively modest at $15,400 to $23,100 with a midpoint cost of $19,200.

As with Case Studies 1-5, the product analysis data needs are attributable to USDA/APHIS permitting requirements. The only data needs costs are for Tier I biological fate analysis tests which may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (about $2,000).

h. Case Study 8

VCPs in plants with wild relatives in the U.S. are depicted in Case Study 8. Potential recipient crops with wild relatives in the U.S. are squash and melon. It is estimated to cost between $610,000 and $766,400 to fulfill the data needed for the EPA registration of VCPs in crops with wild relatives in the U.S. (Appendix Table C-8).

As compared to VCPs in plants without wild relatives in the U.S., VCPs in plants with wild relatives in the U.S. are relatively costly to register. The sources of the added costs are the Tier II and Tier III biological fate data needs which are necessary for all EPA-registered transgenic plants with wild relatives in the U.S. Although Tier III biological fate data needs were estimated to be required on only one out of 10 submissions for Case Studies 3 and 5, they are predicted to be needed more often (one out of five submissions) for Case Study 8 type plant-pesticides. In any case, the total costs shown in Appendix Table C-8 and used throughout this analysis, are the full costs of Tier II and Tier III tests with no adjustments to account for only one out of five submissions predicted to actually need these tests. Thus, as previously discussed under Case Studies 3 and 5, the total costs to register a plant-pesticide of Case Study type 8 are likely to be overestimated.

i. Case Studies 9 through 12

It is possible that new plant varieties developed through traditional breeding methods may express pesticidal substances. Case Studies 9 through 12 would further illuminate Case Study

6 since some traditional breeding plant varieties may have more data needs than those projected for Case Study 6. Thus, Case Studies 9 through 12 represent four possible plant varieties developed through traditional plant breeding that express pesticidal substances. The characteristics of plant-pesticides described under Case Studies 2 through 5 were used to model Case Studies 9 to 12. For example, Case Study 9 was modeled after Case Study 2 where information is available on the characteristics and function of the gene product and the recipient crop has no wild relatives in the U.S. (Appendix Table C-9). The data needs and their associated costs remain the same in the two case studies ($102,400).

Appendix Tables C-9 through C-12 present the data needs and costs of the EPA registration of new plant varieties expressing pesticidal substances.

3. Methodology for Determining Aggregate Costs

To estimate the aggregate costs associated with the regulation of plant-pesticides, the midpoint total cost of the anticipated data needs by case study were multiplied by the projected number of annual plant-pesticide submissions by case study. Since the Agency considered four regulatory options under FIFRA that varied in the scope of plant-pesticides to be regulated, aggregate costs needed to be estimated for all four regulatory options. This was accomplished by allocating the costs of registering the various plant-pesticides (as represented by case studies) into the four regulatory options as follows:

- **Option 1** - - Case Studies 1, 3, and 5
- **Option 2** - - Case Studies 1-5
- **Option 3** - - Case Studies 1-5, 7, and 8
- **Option 4** - - Case Studies 1-12

Not only were annual projections of plant-pesticide submissions by case study needed, they were needed for a 10-year period into the future (due to the great deal of uncertainty involved in projecting potential plant-pesticide registrations into the future, aggregate costs were

estimated for a 10-year period). Furthermore, plant-pesticide submissions were likely to vary by year and by case study.

Data limitations prevented the use of a statistical model to predict potential plant-pesticide submissions. The only data available on the types and numbers of plant-pesticides that could possibly seek EPA registration, are from USDA/APHIS's list of ERPs issued for field tests of introductions of transgenic plants. The Agency explored several methodologies that used the information available from the USDA/APHIS list to predict future plant-pesticide submissions. However, the various complexities involved with the development and testing of plant-pesticides, combined with limitations of the APHIS list ultimately prevented the Agency from predicting future plant-pesticide submissions based on the USDA/APHIS list. Several of the aforementioned problems are detailed in the following paragraphs.

Plant-pesticide product developmental "lags": Based on the very limited number of Environmental Use Permit (EUP) applications received by the Agency, it has historically taken a **minimum** of four years from the time a company first receives a USDA/APHIS ERP to field test a particular plant-pesticide, to the time the company applies to EPA for an EUP. Companies likely spend this four year period refining the plant-pesticide, testing its efficacy, determining average crop yields, etc. However, not all plant-pesticides that receive USDA's ERP will reach the next stage in product development--large-scale field testing and EPA's EUP in four years; some plant-pesticides could take much longer to develop. Thus, if projecting plant-pesticide submissions based on USDA ERPs, one would have to account for those plant-pesticide products that take longer than four years to develop, by "carrying them over" or accounting for them in the following year(s). Because a majority of the USDA ERPs have been issued since 1990, and the four year average product development period would only begin to be realized in 1993, most plant-pesticides that have been permitted by USDA are still in the development stage and are not yet ready for an EPA EUP.

Plant-pesticide product "drop-outs": Another problem with projecting plant-pesticide submissions based upon USDA ERPs, is that even though a particular plant-pesticide receives an ERP in any one year, it may not be supported by its manufacturer through the entire

development period for a variety of reasons. Plant-pesticides that are not efficacious, are associated with reduced yields and/or quality in the host plant, or are being developed by several companies so that competition is intense, could be removed from the development process. After reviewing USDA's list of transgenic plants that have received ERPs, it is evident that many products "drop out" of the development process before the company applies for an EPA-issued EUP. However, while it may appear easy to identify those products that have "dropped out" by the lack of permit renewals, it has been suggested to the Agency that something else may be occurring. Based on conversations with industry specialists, some companies have completed contained field tests of certain plant-pesticides and have purposely not renewed their ERPs. Even though some of their products may be ready for large-scale field testing under EPA's EUP, the companies are waiting for EPA to issue regulations on plant-pesticide registration requirements before applying for an EUP. Therefore, within USDA's list of ERPs, it is very difficult to distinguish between products that have dropped out of the development process, and those products that are ready for large-scale testing but are purposely being held back by the developing company.

Unknown gene types: USDA/APHIS ERPs are issued for field tests of introductions of transgenic plants which not only include transgenic plants with gene products that will likely be regulated by EPA, but those with gene products that will **not** be regulated by EPA. Glyphosate (herbicide) tolerant tomatoes, 2,4-D (herbicide) tolerant potatoes, oil modification genes in canola, storage protein genes in corn, and maker genes in tobacco are examples of transgenic plants that will not require EPA registration. By reviewing the descriptions of the gene products in USDA's list of ERPs, it is not inherently obvious whether some transgenic plants will be regulated by the Agency. This is because EPA proposes to regulate plant-pesticides based on the mode of action of the gene product and not on the gene product itself. Thus, without extensive review of the products, the Agency is unable to categorize many of the gene products permitted by USDA and as such, is unsure whether some of these products might be regulated under the proposed Rule.

Multiple ERP permits for identical plant-pesticides: Companies that wish to continue conducting field tests of transgenic plants past the ERP expiration date (one year from date of

issuance), must renew their permits annually with USDA/APHIS. Separate ERPs have sometimes been issued to companies for each state (or groups of states) in which the identical recipient crop/gene type combination was tested. For example, a recent USDA/APHIS ERP list shows that in 1991, Monsanto was issued four separate permits for insect resistant (Bt) cotton in: Alabama (permit #91-007-01); Hawaii (#91-144-01); Alabama, Arizona, Louisiana, Mississippi, and Texas (#90-347-01); and California and Mississippi (#91-018-04). Multiple ERPs are also issued to the same company, in the same year, for the same recipient crop, but with only slightly different gene types. For instance, in 1992, CIBA-Geigy received three separate ERPs for herbicide tolerant/insect resistant corn, with only slight differences in gene products. These annually renewed, multiple permits that are often issued for identical or only slightly different products3/, make it difficult for the Agency to determine the number of unique plant-pesticide products that have been permitted by USDA.

The methodology employed in this analysis is based upon the historical registration numbers of new chemical insecticides. This data is recorded by EPA and reported in its annual publication Pesticides Industry Sales and Usage. Basically, the number of new chemical insecticides registered during the first 10 years of EPA registration (1967-76) were used to forecast the number of plant-pesticide submissions in their first 10 years of EPA registration (referred to as "years 1-10"). Between 1967-76, EPA registered an average of 4.3 new chemical insecticides per year. Thus, over this 10-year period, a total of 43 new chemical insecticides were registered with the Agency.

Using chemical insecticide registrations as a proxy to predict plant-pesticide submissions, it was assumed that registrant's submitted between 40-50, or an average of 45, new plant-pesticides for registration between years 1-10. In Table VII-1, the row labeled "Total Submissions" shows the annual and total predicted number of plant-pesticide submissions the Agency will receive between years 1-10; these predictions are based upon the annual and total

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3/ The three similar ERP's for CIBA-Geigy's corn are:
- HT/IR - PAT & Bacillus thuringiensis sub. kurstaki (HD1 strain)
- HT/IR - PAT, GUS, Bacillus thuringiensis sub. kurstaki (Btk)
- HT/IR - PAT, GUS, Bacillus thuringiensis sub. kurstaki (HD1)

number of chemical insecticides registered between 1967-76. Total VCP submissions (23 + 22 = 45) are assumed to equal the total number of other plant-pesticide submissions (45) during the 10-year period. This assumption is based on the observation that the number of VCPs being developed and field tested has been about equal to the number of plant-pesticides being developed and field tested.

In order to estimate the aggregate costs of this proposed Rule, the total annual number of plant-pesticide submissions were needed by case study (plant-pesticide type). Thus, Table VII-1 also presents the estimated number of plant-pesticide submissions between years 1-10 for Case Studies 1 through 12. The estimated submissions for Case Studies 1 through 5 were derived after considering: the types and numbers of plant-pesticides that have received EPA-issued EUPs to date, the predicted number of EUPs to be issued in 1993, consultations with potential registrant's, and expert opinion within the Agency. The annual number of submissions predicted for Case Studies 6, and 9 through 12--new plant varieties developed by traditional breeding--were based on the average number of certificates of protection for new plant varieties issued by the Plant Variety Protection Office between 1990-92 (273 certificates issued). These 273 new plant varieties were allocated among Case Studies 6, and 9 through 12 based on assumptions made by the Agency (see footnote 2/ in Table VII-1 for further explanation). Annual VCP submissions were estimated based on the assumption that nearly equal numbers of VCPs without wild relatives in the U.S. (Case Study 7) and with wild relatives in the U.S. (Case Study 8) are being developed and thus, the nearly equal split in estimated submissions between the two in Table VII-1.

Due to the time commitment involved with research, development, and field testing necessary to bring plant-pesticides (including VCPs) to the registration stage, it was assumed that the annual number of plant-pesticide submissions would start out relatively small and would grow slowly during the following 10 years (Table VII-1). Submissions of plant-pesticides in new plant varieties were assumed to remain constant in the next 10 years--a reflection of the relatively stable number of certificates of protection issued by the Plant Variety Protection Office between 1990-92.

Once total plant-pesticide submissions were projected for the 12 case studies by year, it was necessary to determine which plant-pesticide submissions would be regulated under each regulatory option, as presented in Tables VII-2 to VII-5. For example, Option 1 exempts several types of plant-pesticides and thus, its regulatory scope is narrow in relation to Options 2, 3, and 4. Included in the scope of Option 1 are the types of plant-pesticides depicted in Case Studies 1, 3, and 5. Under Option 1, one plant-pesticide would need to fulfill data needs in support of EPA registration in year 1 (Table VII-2). In contrast, Option 4 is the broadest in scope, subjecting all plant-pesticides to the requirements of FIFRA. Under Option 4, 276 plant-pesticides (Table VII-5) would be regulated by EPA in year 1 and all would need to fulfill some data requirements. Table VII-3 presents the projected plant-pesticide submissions under regulatory Option 2, EPA's proposed scope, and Table VII-4 gives the estimated submissions under Option 3.

B. Estimated Direct Compliance Costs to Industry

This section presents the results of the cost analysis for the data needs associated with the registration of plant-pesticides. Table VII-6 summarizes the total estimated costs of the anticipated data needs for Case Studies 1 through 12. Tables VII-7 through VII-10 present the aggregate total compliance cost estimates for regulatory Options 1 through 4, respectively.

1. Option 1 Aggregate Total Compliance Costs

As previously noted, Option 1 is the most limited in regulatory scope. Please refer to Chapter IV, page IV-3 for a summary of those plant-pesticides that will be regulated under this option. Table VII-7 shows that under Option 1, midpoint aggregate total costs range from $63,700 in year 1, to approximately $2.7 million in year 10. Included in these aggregate total costs are the baseline costs (about $10,000) associated with USDA/APHIS permitting requirements. In year 1, it was predicted that the Agency would receive one plant-pesticide submission of Case Study 1 type (Table VII-2) to be regulated under Option 1. From Table VII-6 it was estimated that the midpoint cost of the data needs for a Case Study 1 type plant-pesticide would be $63,700. Thus, the aggregate total cost to regulate plant-pesticides under Option 1

in year 1 is $63,700 (1 X $63,700). In year 10, it was predicted that two plant-pesticide submissions of Case Study 1 type, two plant-pesticide submissions of Case Study 3 type, and one submission of Case Study 5 type would be received by the Agency (all regulated under Option 1). Again, the midpoint cost to register these types of plant-pesticides is shown in Table VII-6. Thus, the aggregate total cost to regulate plant-pesticides under Option 1 in year 10 is estimated at about $2.7 million [(2 X $63,700) + (2 X $732,700) + (1 X $1.1 million)]. This methodology can be used to determine all aggregate total costs by year and by regulatory option as calculated in Tables VII-7 through VII-10.

2. Option 2 Aggregate Total Compliance Costs

Option 2 represents EPA's proposed option and is somewhat broader in regulatory scope than Option 1. This option would regulate certain plant-pesticides that do not meet at least one of the criteria listed in Chapter IV, page IV-4 to IV-5. As presented in Table VII-8, aggregate total costs of regulating plant-pesticides under Option 2 are estimated to range from approximately $63,700 in year 1 when one plant-pesticide submission would be regulated, to nearly $3.2 million by year 10 when it is predicted that the Agency will receive seven new plant-pesticide submissions (see Table VII-3).

3. Option 3 Aggregate Total Compliance Costs

Option 3 is broader in regulatory scope than Option 2, but more narrow than Option 4. In addition to those plant-pesticides regulated under Option 2, Option 3 would regulate all coat proteins from plant viruses used as pesticides (See Chapter IV, page IV-5 for specific exemptions). The aggregate total compliance cost under Option 3 is estimated to range between nearly $771,100 in year 1 to $5.3 million in year 10 (Table VII-9). The difference between Option 3's aggregate costs and Option 2's aggregate costs are due to the cost of the data needs for coat proteins from plant viruses included in the scope of regulatory Option 3.

4. Option 4 Aggregate Total Compliance Costs

Option 4 is the broadest option in regulatory scope analyzed in this RIA. Under Option 4, all plant-pesticides are subject to the requirements of FIFRA. Aggregate total compliance costs under Option 4 are presented in Table VII-10 and are estimated to range between $76.6 million in year 1, to $81.1 million in year 10. The tremendous difference in cost between Option 4 and the other options, is due primarily to the large number of predicted annual submissions of plant varieties developed through traditional plant breeding methods (273 estimated submissions annually), which would be regulated only under Option 4.

5. Annualized Aggregate Incremental Compliance Costs

In order to estimate annualized aggregate incremental compliance costs of this proposed Rule, it was necessary to 1) subtract baseline costs from aggregate total costs, and 2) discount and annualize the resulting aggregate incremental costs.

a. Aggregate incremental compliance costs

As was previously noted, the costs associated with product analysis data needs are attributable to USDA/APHIS permitting requirements for Case Studies 1-5 and 7-8, and as such, are considered the baseline costs of regulating plant-pesticides. From the individual case studies (Appendix Tables C-1 through C-12), it can be seen that baseline costs (product analysis data needs) range from $8,858 to $11,072, with a midpoint value of nearly $10,000. Calculating the difference between the projected aggregate total compliance costs and the current baseline costs, yields the aggregate incremental compliance costs associated with the implementation of this proposed Rule (Table VII-11).

b. Discounting aggregate incremental compliance costs

The 10-year aggregate incremental compliance cost estimates by option as presented in Table VII-11 are nondiscounted costs stated in 1993 dollars. For plant-pesticides, these costs will

not be evenly allocated by the affected firms over the 10-year period. Instead, cash flows will be uneven, with relatively larger expenditures occurring in the last few years of the period when it is predicted that submissions may hit their peak, and plant-pesticides with more costly data needs may be developed. To appropriately account for these uneven cash flows, to allow for the time value of money, and to determine an equivalent, constant-level cost per year (also called an equivalent annual cash flow or annual revenue requirement), discounted cash flow procedures were used in this cost analysis.

Through discounting, cost streams were converted to their present values. The present value of a future cost stream shows what the value of that cost stream is today. Money has time value because of the opportunity to invest it at some rate of return. And to validly compare sums of money expended in different time periods, one must make adjustments for time. Present values are less than their future values because the present value could be invested at some rate of return and compounded to the larger future value.

Table VII-12 displays the annualized aggregate incremental compliance costs to the private sector by regulatory option. Under Option 1, annual revenue requirements for those firms currently involved with plant-pesticide research and testing are estimated at $1.2 million. Dividing the annual industry revenue requirement of $1.2 million by the average annual number of plant-pesticide submissions under Option 1 (3) yields an estimate of the annual revenue needed to register one plant-pesticide with EPA--$413,000. Annual industry revenue requirements under regulatory Option 2 are predicted at about $1.6 million for companies involved with plant-pesticide research and testing, with an annual revenue requirement of approximately $311,000 per plant-pesticide submission (based on an average of 5 submissions per year). Under Option 3 it is estimated that industry compliance would cost those firms identified as presently involved with plant-pesticide research and testing, approximately $2.9 million or almost $324,000 per plant-pesticide submission under the assumption that 9 new plant-pesticide submissions are received annually. Finally, under Option 4, annual industry revenue requirements for the affected firms are anticipated at $78.8 million, or approximately $279,000 annually, per plant-pesticide submission (annual average submissions = 282).

C. Estimated Labor Burden Costs to EPA

This section summarizes the estimated costs that EPA may incur while preforming the various activities necessary to register plant-pesticides. Some of these activities may include the establishment of the docket, internal reviews, requests for additional information, consultations with applicants, etc.

Table VII-13 summarizes the EPA hourly burden estimates by regulatory option, from years 1-10 after the implementation of the proposed plant-pesticide regulations. Three labor burden estimates have been provided under each option: a lower bound estimate representing the minimum amount of time that is likely to be needed to process plant-pesticide applications; an upper bound estimate representing the likely maximum time necessary; and an expected average estimate representing a point estimate of the amount of time needed to process "average" applications. See Appendix D for further documentation of EPA's labor burden estimates by option.

Under the Agency's preferred regulatory scope, Option 2, total expected average labor burden ranges from approximately 700 hours in the year the proposed Rule becomes effective, to nearly 6,900 hours 10 years after the proposed Rule becomes effective (Table VII-13). This variation in labor burden is due to the different types and varying numbers of plant-pesticide submissions predicted in years 1-10. For example, under Option 2 in the first year that the proposed Rule in enacted, it is projected that the Agency will receive one application for a plant-pesticide registration where the pesticidal substance will likely be derived from the monera kingdom. In year 5, the Agency predicts that it may receive up to six plant-pesticide applications, with the pesticidal substances derived from at least three sources (the monera kingdom, the plant family, and the animal kingdom).

Table VII-14 provides EPA's labor burden cost estimates by regulatory option, in years 1-10. The cost estimates in this table were calculated by multiplying the hourly estimates by year and labor classification, times the government wage rate by labor classification as documented in Appendix tables D-5 to D-8. Under Option 1, labor burden cost estimates vary from

$40,000 in year 1 to $259,000 in year 10. Option 2's (EPA's proposed scope) annual costs range from approximately $40,000 in year 1 to $391,000 in year 10. Labor burden estimates under Option 3 are predicted to range from $123,000 in year 1 to nearly $640,000 in year 10. Finally, under Option 4's broad regulatory scope, the Agency's labor costs to review plant-pesticide submissions are estimated to range from $14.7 million in year 1 to $15.2 million in year 10. As discussed in the previous paragraph, hourly labor burden, and thus costs, vary by year due to the number and type of plant-pesticide submissions the Agency is predicted to receive.

D. Aggregate Societal Costs of Regulating Plant-Pesticides

The aggregate cost to society of the promulgation of the proposed plant-pesticide regulations is the sum of the aggregate costs to industry plus the aggregate costs to the Agency for implementing the proposed Rule. Table VII-15 presents, by regulatory option: (1) estimated aggregate societal costs by year, (2) net present values of the aggregate societal costs by year, (3) annual societal revenue requirement, and (4) annual revenue requirement per plant-pesticide submission. Please refer to section B.5.b. of this chapter for a detailed discussion of net present values and annualized revenue requirements.

As shown in Table VII-15, the annual societal revenue requirements for this proposed Rule are estimated at approximately $1.4 million under Option 1, $1.8 million under Option 2, $3.3 million under Option 3, and $93.7 million under Option 4. Annual revenue requirements per plant-pesticide submission have been calculated at $455,800 under regulatory Option 1, $355,800 under EPA's proposed scope of Option 2, $367,600 under Option 3, and $332,400 under Option 4.

E. Limitations of the Cost Analysis

There is a great deal of uncertainty surrounding the projection of plant-pesticide registrations into the future. To date, no plant-pesticide products have reached the commercialization stage. However, at least two have sought registration from the Agency and several companies

have indicated to EPA their intentions of submitting plant-pesticides for registration in the near future. This analysis assumes that the first 10-years of plant-pesticide submissions can be modeled after the number of registrations of new chemical insecticides between 1967-76. In reality, we may find that the number of new plant-pesticides registered with the Agency to be only somewhat comparable with new chemical insecticide registrations. However, until registrants are ready to commercialize their plant-pesticides and until EPA begins registering these products, the methodology used to project plant-pesticide registrations in this analysis is intuitive, practical, and forthright.

It is possible that certain data needs will change as the Agency becomes more experienced with the registration needs for plant-pesticides. Currently, much is still unknown about the effects that the various plant-pesticide/recipient crop combinations will have on the environment, nontarget species, and humans. The Agency has made every effort to include those tests that are most likely to produce the information and data needed to make a determination that a particular plant-pesticide will not cause "unreasonable adverse effects on the environment". It is conceivable that some of the data needs listed in Case Studies 1 through 12 will not be required for certain plant-pesticide/crop combinations and/or that additional or entirely new data needs will be necessary. Thus, the aggregate compliance cost estimates for this proposed Rule will vary proportionately with the varying needs for information and data for particular plant-pesticides.

Table VII-1. Projected Plant-Pesticide Submissions by Case Study (type) and Year

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	1	1	1	1	2	1	1	1	1	2	12
Case Study 2 (no wild relatives in the U S & information available)	Pesticidal substance derived from the plant family			1	1	1	1	2	1	1	1	9
Case Study 3 (with wild relatives in the U S & information available)	Pesticidal substance derived from monera kingdom		1	1		1	1	1	1	2	2	10
Case Study 4 (no wild relatives in the U S & no info available)	Pesticidal substance derived from the plant family				1	1	1	1	1	2	1	8
Case Study 5 (with wild relatives in the U S & no info available)	Pesticidal substance derived from animal kingdom				1	1	1		1	1	1	6
	Total Submissions 1/	1	2	3	4	6	5	5	5	7	7	45
Case Study 6 (plant varieties developed by traditional breeding) 2/	Pesticidal substance derived from plant kingdom	137	137	137	137	137	137	137	137	137	137	1,370
Case Study 7 (VCPs without wild relatives in the U S) 3/	Pesticidal substance derived from the plant virus	1	1	2	2	2	3	3	3	3	3	23
Case Study 8 (VCPs with wild relatives in the U S) 3/	Pesticidal substance derived from the plant virus	1	1	1	2	2	3	3	3	3	3	22
Case Study 9 (no wild relatives in the U S & info available) 2/	Pesticidal substance derived from the same plant family or genus	41	41	41	41	41	41	41	41	41	41	410
Case Study 10 (with wild relatives in the U S & info available) 2/	Pesticidal substance derived from the same plant family or genus	41	41	41	41	41	41	41	41	41	41	410
Case Study 11 (no wild relatives in the U S & no info available) 2/	Pesticidal substance derived from the same plant family or genus	27	27	27	27	27	27	27	27	27	27	270
Case Study 12 (with wild relatives in the U S & no info available) 2/	Pesticidal substance derived from the same plant family or genus	27	27	27	27	27	27	27	27	27	27	270

1/ Estimated based on the following
- Total plant-pesticide submissions over the next 10 years are based upon total new chemical insecticide submissions during the first 10-years of EPA registration (1967-76)
- Between 1967-76, EPA registered an average of 4 3 new chemical insecticides per year
- Thus, over the 10 year period, a total of 43 new chemical insecticides were registered
- Based on the 43 new chemical insecticides, this analysis assumes that between 40-50, with an average of 45, new plant-pesticides will be registered between years 1-10
- Total plant-pesticide submissions will start out relatively small and will grow slowly, during the next 10 years

2/ The average number of applications received by the Plant Variety Protection Office between 1990-92 was 273. Within those 273 new varieties, plant breeders could potentially develop plants that exhibit pesticidal characteristics similar to plant-pesticide types that are depicted in Case Studies 1-5, as well as Case Study 6 Thus, the 273 new plant varieties have been allocated into Case Studies 6 and 9-12 in the following manner It was assumed that the following allocations remain constant during years 1-10

	Percent	Number
Case Study 6	50%	137
Case Study 9	15%	41
Case Study 10	15%	41
Case Study 11	10%	27
Case Study 12	10%	27
Total submissions		273

/ The total number of VCP submissions between years 1-10 is estimated to be equal to the total number of plant-pesticide submissions (45) during this time period This is based on the observation that the number of VCPs being developed and field tested is about equal to the number of other types of plant-pesticides being developed and field tested It is assumed that nearly equal numbers of VCPs with wild relatives in the U.S and without wild relatives in the U.S. are being developed and thus, the nearly equal split in estimated submissions between the two

Table VII-2. Projected Plant-Pesticide Submissions Under Regulatory Option 1

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	1	1	1	1	2	1	1	1	1	2
Case Study 2 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from the plant family	Case Study 2 not in scope of regulatory Option 1									
Case Study 3 (with wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom		1	1		1	1	1	1	2	2
Case Study 4 (no wild relatives in the U.S. & no info. available)	Pesticidal substance derived from the plant family	Case Study 4 not in scope of regulatory Option 1									
Case Study 5 (with wild relatives in the U.S. & no info. available)	Pesticidal substance derived from animal kingdom				1	1	1		1	1	1
	Total Submissions	**1**	**2**	**2**	**2**	**4**	**3**	**2**	**3**	**4**	**5**

Source: Table VII-1.
Note: The scope of regulatory Option 1 includes submissions of Case Studies 1, 3, and 5.

Table VII-3. Projected Plant-Pesticide Submissions Under Regulatory Option 2

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	1	1	1	1	2	1	1	1	1	2
Case Study 2 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from the plant family			1	1	1	1	2	1	1	1
Case Study 3 (with wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom		1	1		1	1	1	1	2	2
Case Study 4 (no wild relatives in the U.S. & no info. available)	Pesticidal substance derived from the plant family				1	1	1	1	1	2	1
Case Study 5 (with wild relatives in the U.S. & no info. available)	Pesticidal substance derived from animal kingdom				1	1	1		1	1	1
	Total Submissions	**1**	**2**	**3**	**4**	**6**	**5**	**5**	**5**	**7**	**7**

Source: Table VII-1.
Note: The scope of regulatory Option 2 includes submissions of Case Studies 1, 2, 3, 4, and 5

Table VII-4. Projected Plant-Pesticide Submissions Under Regulatory Option 3

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	1	1	1	1	2	1	1	1	1	2
Case Study 2 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from the plant family			1	1	1	1	2	1	1	1
Case Study 3 (with wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom		1	1		1	1	1	1	2	2
Case Study 4 (no wild relatives in the U.S. & no info. available)	Pesticidal substance derived from the plant family				1	1	1	1	1	2	1
Case Study 5 (with wild relatives in the U.S. & no info. available)	Pesticidal substance derived from animal kingdom				1	1	1		1	1	1
Case Study 7 (VCPs without wild relatives in the U.S.)	Pesticidal substance derived from the plant virus	1	1	2	2	2	3	3	3	3	3
Case Study 8 (VCPs with wild relatives in the U.S.)	Pesticidal substance derived from the plant virus	1	1	1	2	2	3	3	3	3	3
	Total Submissions	**3**	**4**	**6**	**8**	**10**	**11**	**11**	**11**	**13**	**13**

NA = Not applicable
Source: Table VII-1.
Note: The scope of regulatory Option 3 includes submissions of Case Studies 1, 2, 3, 4, 5, 7, and 8.

Table VII-5. Projected Plant-Pesticide Submissions Under Regulatory Option 4

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Case Study 1 (no wild relatives in the U S & information available)	Pesticidal substance derived from monera kingdom	1	1	1	1	2	1	1	1	1	2
Case Study 2 (no wild relatives in the U S & information available)	Pesticidal substance derived from the plant family			1	1	1	1	2	1	1	1
Case Study 3 (with wild relatives in the U S. & information available)	Pesticidal substance derived from monera kingdom		1	1		1	1	1	1	2	2
Case Study 4 (no wild relatives in the U.S & no info available)	Pesticidal substance derived from the plant family				1	1	1	1	1	2	1
Case Study 5 (with wild relatives in the U S & no info available)	Pesticidal substance derived from plant kingdom				1	1	1		1	1	1
Case Study 6 (plant varieties developed by traditional breeding)	Pesticidal substance derived from plant kingdom	137	137	137	137	137	137	137	137	137	137
Case Study 7 (VCPs without wild relatives in the U S)	Pesticidal substance derived from plant virus	1	1	2	2	2	3	3	3	3	3
Case Study 8 (VCPs with wild relatives in the U S)	Pesticidal substance derived from the plant virus	1	1	1	2	2	3	3	3	3	3
Case Study 9 (no wild relatives in the U S & information available)	Pesticidal substance derived from the plant virus	41	41	41	41	41	41	41	41	41	41
Case Study 10 (no wild relatives in the U S & information available)	Pesticidal substance derived from the same plant family or genus	41	41	41	41	41	41	41	41	41	41
Case Study 11 (no wild relatives in the U S & no info. available)	Pesticidal substance derived from the same plant family or genus	27	27	27	27	27	27	27	27	27	27
Case Study 12 (with wild relatives in the U S & no info. available)	Pesticidal substance derived from the same plant family or genus	27	27	27	27	27	27	27	27	27	27
	Total Submissions	**276**	**277**	**279**	**281**	**283**	**284**	**284**	**284**	**286**	**286**

NA = Not applicable
Note The scope of regulatory Option 4 includes submissions of Case Studies 1 through 12.
Source Table VII-1

Table VII-6. Summary of Total Estimated Costs of Potential Data Needs by Case Study

Case Study	Total Estimated Data Need Cost		
	Lower Bound 1/	Upper Bound 1/	Mid Point 2/
	($)		
Case Study 1	54,900	72,500	63,700
Case Study 2	89,300	115,500	102,400
Case Study 3	649,500	815,800	732,700
Case Study 4	340,400	433,100	386,800
Case Study 5	945,100	1,196,400	1,070,700
Case Study 6	14,700	18,400	16,600
Case Study 7	15,400	23,100	19,200
Case Study 8	610,000	766,400	688,200
Case Study 9	89,300	115,500	102,400
Case Study 10	649,500	815,800	732,700
Case Study 11	340,400	433,100	386,800
Case Study 12	945,100	1,196,400	1,070,700

1/ From individual case studies: Appendix tables C-1 to C-12. Estimates have been rounded to the nearest hundred.
2/ Calculated: (Lower bound + Upper bound)/2.

Table VII-7. Aggregate Total Compliance Cost Estimates Under Regulatory Option 1, Years 1-10

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
		($)									
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	63,700	63,700	63,700	63,700	127,400	63,700	63,700	63,700	63,700	127,400
Case Study 2 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from the plant family	Case Study 2 not in scope of regulatory Option 1									
Case Study 3 (with wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom		732,700	732,700		732,700	732,700	732,700	732,700	1,465,400	1,465,400
Case Study 4 (no wild relatives in the U.S. & no info. available)	Pesticidal substance derived from the plant family	Case Study 4 not in scope of regulatory Option 1									
Case Study 5 (with wild relatives in the U.S. & no info. available)	Pesticidal substance derived from animal kingdom				1,070,700	1,070,700	1,070,700		1,070,700	1,070,700	1,070,700
AGGREGATE TOTAL COST -- OPTION 1		**$63,700**	**$796,400**	**$796,400**	**$1,134,400**	**$1,930,800**	**$1,867,100**	**$796,400**	**$1,867,100**	**$2,599,800**	**$2,663,500**

Source: Estimates calculated by multiplying the midpoint compliance cost estimate by case study (Table VII-6) by the number of projected plant-pesticide submissions under Option 1 (Table VII-2).

Table VII-8. Aggregate Total Compliance Cost Estimates Under Regulatory Option 2, Years 1-10

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
		($)									
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	63,700	63,700	63,700	63,700	63,700	63,700	63,700	63,700	63,700	127,400
Case Study 2 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from the plant family			102,400	102,400	102,400	102,400	204,800	102,400	102,400	102,400
Case Study 3 (with wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom		732,700	732,700		732,700	732,700	732,700	732,700	1,465,400	1,465,400
Case Study 4 (no wild relatives in the U.S. & no info. available)	Pesticidal substance derived from the plant family				386,800	386,800	386,800	386,800	386,800	773,600	386,800
Case Study 5 (with wild relatives in the U.S. & no info. available)	Pesticidal substance derived from animal kingdom				1,070,700	1,070,700	1,070,700		1,070,700	1,070,700	1,070,700
AGGREGATE TOTAL COST -- OPTION 2		**$63,700**	**$796,400**	**$898,800**	**$1,623,600**	**$2,356,300**	**$2,356,300**	**$1,388,000**	**$2,356,300**	**$3,475,800**	**$3,152,700**

Source: Estimates calculated by multiplying the midpoint compliance cost estimate by case study (Table VII-6) by the number of projected plant-pesticide submissions under Option 2 (Table VII-3).

Table VII-9. Aggregate Total Compliance Cost Estimates Under Regulatory Option 3, Years 1-10

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
		($)									
Case Study 1 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom	63,700	63,700	63,700	63,700	63,700	63,700	63,700	63,700	63,700	127,400
Case Study 2 (no wild relatives in the U S. & information available)	Pesticidal substance derived from the plant family			102,400	102,400	102,400	102,400	204,800	102,400	102,400	102,400
Case Study 3 (with wild relatives in the U.S. & information available)	Pesticidal substance derived from monera kingdom		732,700	732,700		732,700	732,700	732,700	732,700	1,465,400	1,465,400
Case Study 4 (no wild relatives in the U.S & no info available)	Pesticidal substance derived from the plant family				386,800	386,800	386,800	386,800	386,800	773,600	386,800
Case Study 5 (with wild relatives in the U.S & no info available)	Pesticidal substance derived from animal kingdom				1,070,700	1,070,700	1,070,700		1,070,700	1,070,700	1,070,700
Case Study 7 (VCPs without wild relatives in the U S.)	Pesticidal substance derived from the plant virus	19,200	19,200	38,400	38,400	38,400	57,600	57,600	57,600	57,600	57,600
Case Study 8 (VCPs with wild relatives in the U.S)	Pesticidal substance derived from the plant virus	688,200	688,200	688,200	1,376,400	1,376,400	2,064,600	2,064,600	2,064,600	2,064,600	2,064,600
AGGREGATE TOTAL COST – OPTION 3		**$771,100**	**$1,503,800**	**$1,625,400**	**$3,038,400**	**$3,771,100**	**$4,478,500**	**$3,510,200**	**$4,478,500**	**$5,598,000**	**$5,274,900**

NA = Not applicable

Source Estimates calculated by multiplying the midpoint compliance cost estimate by case study (Table VII-6) by the number of projected plant-pesticide submissions under Option 3 (Table VII-4)

Table VII-10. Aggregate Total Compliance Cost Estimates Under Regulatory Option 4, Years 1-10

Case Study (plant-pesticide type)	Source of Pesticidal Substance	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
		($)									
Case Study 1 (no wild relatives in the U S & information available)	Pesticidal substance derived from monera kingdom	63,700	63,700	63,700	63,700	127,400	63,700	63,700	63,700	63,700	127,400
Case Study 2 (no wild relatives in the U S. & information available)	Pesticidal substance derived from the plant family			102,400	102,400	102,400	102,400	204,800	102,400	102,400	102,400
Case Study 3 (with wild relatives in the U S & information available)	Pesticidal substance derived from monera kingdom		732,700	732,700		732,700	732,700	732,700	732,700	1,465,400	1,465,400
Case Study 4 (no wild relatives in the U.S & no info available)	Pesticidal substance derived from the plant family				386,800	386,800	386,800	386,800	386,800	773,600	386,800
Case Study 5 (with wild relatives in the U S. & no info available)	Pesticidal substance derived from plant kingdom				1,070,700	1,070,700	1,070,700		1,070,700	1,070,700	1,070,700
Case Study 6 (plant varieties developed by traditional breeding)	Pesticidal substance derived from plant kingdom	2,274,200	2,274,200	2,274,200	2,274,200	2,274,200	2,274,200	2,274,200	2,274,200	2,274,200	2,274,200
Case Study 7 (VCPs without wild relatives in the U S)	Pesticidal substance derived from plant virus	19,200	19,200	38,400	38,400	38,400	57,600	57,600	57,600	57,600	57,600
Case Study 8 (VCPs with wild relatives in the U.S)	Pesticidal substance derived from the plant virus	688,200	688,200	688,200	1,376,400	1,376,400	2,064,600	2,064,600	2,064,600	2,064,600	2,064,600
Case Study 9 (no wild relatives in the U.S. & information available)	Pesticidal substance derived from the plant virus	4,198,400	4,198,400	4,198,400	4,198,400	4,198,400	4,198,400	4,198,400	4,198,400	4,198,400	4,198,400
Case Study 10 (no wild relatives in the U S & information available)	Pesticidal substance derived from the same plant family or genus	30,040,700	30,040,700	30,040,700	30,040,700	30,040,700	30,040,700	30,040,700	30,040,700	30,040,700	30,040,700
Case Study 11 (no wild relatives in the U S & no info available)	Pesticidal substance derived from the same plant family or genus	10,443,600	10,443,600	10,443,600	10,443,600	10,443,600	10,443,600	10,443,600	10,443,600	10 443,600	10,443,600
Case Study 12 (with wild relatives in the U.S. & no info available)	Pesticidal substance derived from the same plant family or genus	28,908,900	28,908,900	28,908,900	28,908,900	28,908,900	28,908,900	28,908,900	28,908,900	28,908,900	28,908,900
AGGREGATE TOTAL COST – OPTION 4		**$76,636,900**	**$77,369,600**	**$77,491,200**	**$78,904,200**	**$79,700,600**	**$80,344,300**	**$79,376,000**	**$80,344,300**	**$81,463,800**	**$81,140,700**

Source E[illegible] s calculated by multiplying the midpoint compliance cost estimate by case study (Table VII-6) by the number of projected plant-pesticide submissions under Option 4 (Table VII-5)

Table VII-11. Aggregate Incremental Compliance Cost Estimates by Regulatory Option, Years 1-10

Year	Option 1			Option 2			Option 3			Option 4		
	Aggregate Total Costs 1/	Baseline Costs 2/	Aggregate Incremental Costs 3/	Aggregate Total Costs 1/	Baseline Costs 4/	Aggregate Incremental Costs 3/	Aggregate Total Costs 1/	Baseline Costs 5/	Aggregate Incremental Costs 3/	Aggregate Total Costs 1/	Baseline Costs 6/	Aggregate Incremental Costs 3/
	($)											
Year 1	63,700	10,000	53,700	63,700	10,000	53,700	771,100	30,000	741,100	76,636,900	30,000	76,606,900
Year 2	796,400	20,000	776,400	796,400	20,000	776,400	1,503,800	40,000	1,463,800	77,369,600	40,000	77,329,600
Year 3	796,400	20,000	776,400	898,800	30,000	868,800	1,625,400	60,000	1,565,400	77,491,200	60,000	77,431,200
Year 4	1,134,400	20,000	1,114,400	1,623,600	40,000	1,583,600	3,038,400	80,000	2,958,400	78,904,200	80,000	78,824,200
Year 5	1,930,800	40,000	1,890,800	2,356,300	60,000	2,296,300	3,771,100	100,000	3,671,100	79,700,600	100,000	79,600,600
Year 6	1,867,100	30,000	1,837,100	2,356,300	50,000	2,306,300	4,478,500	110,000	4,368,500	80,344,300	110,000	80,234,300
Year 7	796,400	20,000	776,400	1,388,000	50,000	1,338,000	3,510,200	110,000	3,400,200	79,346,000	110,000	79,236,000
Year 8	1,867,100	30,000	1,837,100	2,356,300	50,000	2,306,300	4,478,500	110,000	4,368,500	80,344,300	110,000	80,234,300
Year 9	2,599,800	40,000	2,559,800	3,475,800	70,000	3,405,800	5,598,000	130,000	5,468,000	81,463,800	130,000	81,333,800
Year 10	2,663,500	50,000	2,613,500	3,152,700	70,000	3,082,700	5,274,900	130,000	5,144,900	81,140,700	130,000	81,010,700

1/ From Tables VII-7 to VII-10.
2/ The midpoint cost of product analysis data needs ($10,000) X the projected plant-pesticide submissions under Option 1 (Table VII-2)
3/ Aggregate total costs minus baseline costs.
4/ The midpoint cost of product analysis data needs ($10,000) X the projected plant-pesticide submissions under Option 2 (Table VII-3)
5/ The midpoint cost of product analysis data needs ($10,000) X the projected plant-pesticide submissions under Option 3 (Table VII-4).
6/ The midpoint cost of product analysis data needs ($10,000) X [the projected plant-pesticide submissions under Option 4 (Table VII-5) minus the number of submissions of Case Study 6, 9, 10, 11, and 12 type plant-pesticides (273)]. Option 4 includes Case Studies 6, 9, 10, 11, and 12 (plant varieties developed by traditional breeding). Because plant varieties developed by traditional breeding are not regulated by USDA/APHIS, the product analysis data needs have not already been accounted for and as such ARE attributable to this Rule. Accordingly, the $10,000 product analysis costs remain for the 273 submissions of plant varieties developed by traditional breeding.

Table VII-12. Annualized aggregate incremental compliance costs to the private sector by regulatory Option, constant 1993 dollars, discounted at 10% for 10 years

Year	Option 1 Cash Flow 1/	Option 1 Net Present Value 2/	Option 2 Cash Flow 1/	Option 2 Net Present Value 2/	Option 3 Cash Flow 1/	Option 3 Net Present Value 2/	Option 4 Cash Flow 1/	Option 4 Net Present Value 2/
	($)							
Year 1	53,700	48,813	53,700	48,813	741,100	673,660	76,606,900	69,635,672
Year 2	776,400	641,306	776,400	641,306	1,463,800	1,209,099	77,329,600	63,874,250
Year 3	776,400	583,076	868,800	652,469	1,565,400	1,175,615	77,431,200	58,150,831
Year 4	1,114,400	761,135	1,583,600	1,081,599	2,958,400	2,020,587	78,824,200	53,836,929
Year 5	1,890,800	1,174,187	2,296,300	1,426,002	3,671,100	2,279,753	79,600,600	49,431,973
Year 6	1,837,100	1,036,124	2,306,300	1,300,753	4,368,500	2,463,834	80,234,300	45,252,145
Year 7	776,400	398,293	1,338,000	686,394	3,400,200	1,744,303	79,236,000	40,648,068
Year 8	1,867,100	871,936	2,306,300	1,077,042	4,368,500	2,040,090	80,234,300	37,469,418
Year 9	2,559,800	1,085,355	3,405,800	1,444,059	5,468,000	2,318,432	81,333,800	34,485,531
Year 10	2,613,500	1,008,811	3,082,700	1,189,922	5,144,900	1,985,931	81,010,700	31,270,130
Total NPV		$7,609,038		$9,548,360		$17,911,304		$484,054,947
Annual Industry Revenue Requirement 3/		$1,238,336		$1,553,952		$2,914,982		$78,777,713
Annual Revenue Requirement per Submission 4/		$412,779		$310,790		$323,887		$279,354

1/ From Table VII-11, "Aggregate Incremental Costs" columns.
2/ Amount in "Cash Flow" column X the discount factor.
3/ Annual Revenue Requirement = Capital Recovery Factor (CRF) X Total Net Present Value (NPV).

CRF = (1 + i)^n (i) / (1 + i)^n - 1

Where: i = the real rate of return on invested capital, excluding inflation (10%)

n = the effective operating life of the asset (10 years)

4/ Calculated: Annual Industry Revenue Requirement/Average annual number of plant-pesticide submissions by Option It is predicted that there will be 3, 5, 9, and 282 submissions of plant-pesticides under Options 1, 2, 3, and 4, respectively

Table VII-13. Total EPA Hourly Burden Estimates Under RIA Options 1 to 4, Years 1-10

Year	Option 1 Labor Burden			Option 2 Labor Burden			Option 3 Labor Burden			Option 4 Labor Burden		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	(Hours)											
Year 1	461	952	706	461	952	706	1,425	2,911	2,168	169,894	347,094	258,494
Year 2	964	1,959	1,462	964	1,959	1,462	1,929	3,918	2,923	170,398	348,102	259,250
Year 3	964	1,959	1,462	1,425	2,911	2,168	2,850	5,821	4,335	171,319	350,005	260,662
Year 4	1,533	3,122	2,327	3,065	6,245	4,655	4,994	10,163	7,578	173,463	354,347	263,905
Year 5	2,497	5,081	3,789	4,029	8,204	6,116	5,958	12,122	9,040	174,428	356,306	265,367
Year 6	2,036	4,130	3,083	3,569	7,252	5,410	6,462	13,129	9,795	174,931	357,313	266,122
Year 7	964	1,959	1,462	2,957	6,033	4,495	5,850	11,910	8,880	174,320	356,094	265,207
Year 8	2,036	4,130	3,083	3,569	7,252	5,410	6,462	13,129	9,795	174,931	357,313	266,122
Year 9	2,540	5,137	3,839	5,145	10,430	7,788	8,037	16,307	12,172	176,507	360,491	268,499
Year 10	3,001	6,089	4,545	4,533	9,211	6,872	7,426	15,088	11,257	175,896	359,272	267,584

Source: Appendix tables D-1 to D-4.

Table VII-14. EPA Labor Burden Cost Estimates Under RIA Options 1 to 4, Years 1-10

Year	Option 1 Cost			Option 2 Cost			Option 3 Cost			Option 4 Cost		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	($)											
Year 1	25,207	54,256	39,731	25,207	54,256	39,731	78,601	166,513	122,557	9,353,325	20,009,872	14,681,599
Year 2	53,394	112,258	82,826	53,394	112,258	82,826	106,787	224,515	165,651	9,381,511	20,067,874	14,724,693
Year 3	53,394	112,258	82,826	78,601	166,513	122,557	157,202	333,026	245,114	9,431,926	20,176,385	14,804,156
Year 4	84,425	181,017	132,721	168,850	362,035	265,442	275,637	586,550	431,093	9,550,361	20,429,909	14,990,135
Year 5	137,818	293,275	215,547	222,243	474,293	348,268	329,030	698,808	513,919	9,603,755	20,542,166	15,072,961
Year 6	112,611	239,019	175,815	197,036	420,037	308,536	357,217	756,810	557,013	9,631,941	20,600,168	15,116,055
Year 7	53,394	112,258	82,826	163,026	347,531	255,278	323,206	684,303	503,755	9,597,931	20,527,662	15,062,796
Year 8	112,611	239,019	175,815	197,036	420,037	308,536	357,217	756,810	557,013	9,631,941	20,600,168	15,116,055
Year 9	140,797	297,021	218,909	284,440	604,801	444,620	444,620	941,574	693,097	9,719,345	20,784,932	15,252,138
Year 10	166,005	351,277	258,641	250,429	532,295	391,362	410,610	869,067	639,839	9,685,334	20,712,426	15,198,880

Source: Appendix Tables D-5 to D-8.

Table VII-15. Annualized Aggregate Societal Costs by Regulatory Option, Constant 1993 Dollars, Discounted at 10% for 10 Years

Year	Option 1 Aggregate Costs to Society 1/	Option 1 Net Present Value 2/	Option 2 Aggregate Costs to Society 1/	Option 2 Net Present Value 2/	Option 3 Aggregate Costs to Society 1/	Option 3 Net Present Value 2/	Option 4 Aggregate Costs to Society 1/	Option 4 Net Present Value 2/
	($)							
Year 1	93,431	84,929	93,431	84,929	863,657	785,064	91,288,499	82,981,246
Year 2	859,226	709,721	859,226	709,721	1,629,451	1,345,927	92,054,293	76,036,846
Year 3	859,226	645,279	991,357	744,509	1,810,514	1,359,696	92,235,356	69,268,752
Year 4	1,247,121	851,784	1,849,042	1,262,896	3,389,493	2,315,024	93,814,335	64,075,191
Year 5	2,106,347	1,308,041	2,644,568	1,642,277	4,185,019	2,598,897	94,673,561	58,792,281
Year 6	2,012,915	1,135,284	2,614,836	1,474,768	4,925,513	2,777,989	95,350,355	53,777,600
Year 7	859,226	440,783	1,593,278	817,352	3,903,955	2,002,729	94,298,796	48,375,282
Year 8	2,012,915	940,031	2,614,836	1,221,128	4,925,513	2,300,215	95,350,355	44,528,616
Year 9	2,778,709	1,178,173	3,850,420	1,632,578	6,161,097	2,612,305	96,585,938	40,952,438
Year 10	2,872,141	1,108,646	3,474,062	1,340,988	5,784,739	2,232,909	96,209,580	37,136,898
Total NPV		$8,402,671		$10,931,145		$20,330,754		$575,925,150
Annual Societal Revenue Requirement 3/		$1,367,496		$1,778,993		$3,308,737		$93,729,166
Annual Revenue Requirement per Submission 4/		$455,832		$355,799		$367,637		$332,373

1/ Calculated: Cost to Industry (Table VII-11, "Aggregate Incremental Costs" columns) + Cost to EPA (Table VII-14, "Expected Average" columns).
2/ Calculated: Amount in "Aggregate Costs to Society" column X the discount factor
3/ Annual Societal Revenue Requirement = Capital Recovery Factor (CRF) X Total Net Present Value (NPV).
CRF = (1 + i)^n (i) / (1 + i)^n - 1
Where: i = the real rate of return on invested capital, excluding inflation (10%)
n = the effective operating life of the asset (10 years)
4/ Calculated: Annual Societal Revenue Requirement/Average annual number of plant-pesticide submissions by Option It is predicted that there will be 3, 5, 9, and 282 submissions of plant-pesticides under Options 1, 2, 3, and 4, respectively.

VIII. ECONOMIC IMPACTS AND REGULATORY FLEXIBILITY--INDUSTRY

This chapter discusses the potential economic impacts to the regulated community of the proposed plant-pesticide regulations under FIFRA and FFDCA. The varying compliance costs of the four regulatory options considered are then discussed to demonstrate that the Agency's proposed regulatory scope is not likely to cause "a significant adverse economic impact on a substantial number of small entities."

A. Economic Impacts

The compliance costs of EPA's proposal (Option 2) have been estimated at approximately $311,000 per submission of a plant-pesticide, on an annualized basis. While it is unknown how many plant-pesticide products will be submitted to EPA for registration by a typical firm in an average year, for purposes of discussion it is assumed that small firms submit one and "other"1/ firms submit 2-3 plant-pesticide products. Thus, the associated compliance costs could be approximated at $311,000 per year for small firms (1 product X $311,000), and $622,000 to $933,000 per year for "other" firms (2-3 products X $311,000).

The approximated annual compliance cost ($311,000) for a plant-pesticide is much less than for a traditional chemical pesticide ($5.3 million2/). It is unlikely that there would be adverse impacts on the "other" sized firms that are developing and testing plant-pesticides as

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1/ In this chapter, "other" is equivalent to the medium and large sized firms that were defined in Chapter VI. "Other" firms have sales greater than $300 million and small firms have sales of less than $300 million.

2/ Source: U.S. EPA, DPRA Inc., and W.R. Landis Associates, Inc. 1990 (August 8). Regulatory Impact Analysis: Proposed Testing and Data Requirements for Registering Pesticides Under the Federal Insecticide, Fungicide, and Rodenticide Act as Amended, 1988. DPRA Incorporated, Manhattan, Kansas. Page VI-11: Case study 2 (insecticide) under the moderate-cost scenario, revised estimate.

the annual compliance cost ($622,000 to $933,000) represents less than one percent of annual sales (> $300 million). An industry representative predicted that if compliance costs are similar to the costs of registering microbial or biochemical pesticides, that even the smallest firms would be unlikely to experience adverse impacts (Goldhammer, 1993). Management personnel in many firms developing biotechnology products are aware that any pesticide-expressing product developed will require at least some type of Federal regulation and testing requirements before the product can be commercialized. Some of these firms have planned for registration costs from the initial product planning stages and have adjusted their product research and development budgets accordingly. Considering the historical costs of registering traditional chemical pesticides, it is possible that some biotechnology firms have overestimated the potential costs of plant-pesticide registration, rather than underestimated the costs. However, it is also possible that some small firms--especially those started by individuals new to the industry and to Federal pesticide registration requirements--have not accounted for product registration costs. Management within these companies may need to creatively finance registration costs if their products eventually reach the stage where EPA registration is necessary. (Woodword, 1993)

Any adverse economic impacts that these compliance costs could have on those companies involved with testing and developing plant-pesticides would be very difficult to estimate. Two of the greatest limitations in estimating compliance cost impacts are, (1) the lack of disaggregated financial data for individual biotechnology products within large corporations and, (2) the multitude of business organizations and investment strategies that are the result of large capital needs of companies researching and developing plant-pesticides.

Examples of some business organizations and investment strategies include second mortgages, investment capital from family, joint ventures with national and international firms, corporate alliances, sponsors, equity offerings, and contract agreements. The lack of disaggregated financial data for individual products prevents the analysis of compliance costs as they impact company **biotechnology** sales or net profits--instead the financial data available are for the entire company, including subsidiaries and divisions that are not related to biotechnology.

Additionally, the structure and internal organization of businesses, and the diverse sources of financing allow small companies to incur negative profits, sometimes for three to fours years in a row, and remain in business. For example, small biotechnology companies that are heavy into research and development of promising biotechnology products, commonly receive venture capital from risk-taking investors who believe in the companies employees and/or product(s) despite the companies negative profits. Thus, although small companies are an important component of the regulated community, their frequently reported negative net profits cloud the financial picture and limit quantitative economic impact analyses.

Therefore, due to: (1) uncertainties associated with the unique regulated product of this proposed Rule--plant-pesticides; (2) the fact that agricultural biotechnology is still in its infancy and product commercialization has yet to begun; and (3) the negative profits reported by many small firms involved with agbiotech, a traditional economic impact analysis using quantitative measures to determine this proposed Rule's impact on the regulated industry was not possible.

The remainder of this chapter will identify some of the sources of financing that are commonly used by small firms in the regulated community. These sources of creative financing often allow small firms to operate a business with marginal returns or even losses, while researching, developing, and preparing for market their plant-pesticide products.

Companies involved with biotechnology, as with most other companies, finance their product research, development, and commercialization through investments. Investments can come from the individual(s) starting the firm or from outside sources (public or private). Investing in biotechnology companies is an inherently risky venture--many products are novel and their chance for success in the public marketplace can only be approximated as consumers have mixed feelings towards some biotechnology products. This product novelty and associated public skepticism is especially true with plant-pesticides; consumers have been polled as feeling "cautiously optimistic" regarding food products from transgenic plants including plant-pesticides (Hoban and Kendall, 1992). Consumer skepticism aside, the potential for financial

reward from biotechnology products often justifies the investment risk for certain "risk taking" investors.

Investors can be public entities, such as the U.S. Department of Agriculture or the U.S. Environmental Protection Agency, or they can be private entities, such as individuals or other companies. "Investment" from public entities can take the form of special research grants, low interest loans, or even public ventures. The Small Business Administration is an example of a public entity that offers financial assistance (among other things) to small businesses. The U.S. Department of Agriculture has "invested" in at least one small biotechnology firm with Small Business Innovative Research (SBIR) grants and through the use of joint contracts. Investment from private sources can assume many names or forms: venture capital, stock offerings, equity offerings, debt financing, joint ventures, and corporate alliances are all means by which small biotechnology companies raise or obtain financing (Kelsey, 1993; Radin, 1993; Woodword, 1993; Yonehiro, 1992). All of these public and private sources of investment (and many others) are used throughout the product research, development, registration, and commercialization stages.

B. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) (P.L. 96-354) requires governmental regulators to make a conscious effort to lighten the regulatory burden of their actions on "small entities" within the regulated communities. Regulatory options must be considered in an attempt to avoid "a significant adverse economic impact on a substantial number of small entities."

The regulatory options considered under this proposed Rule were determined after extensive evaluations of the benefit/risk tradeoff between option cost and risk reduction provided. The Agency has structured the resulting options from a narrow regulatory scope (Option 1), to a broad regulatory scope (Option 4) and as such, has provided the basis for a "built in" sensitivity analysis for small firms likely to be affected by this regulation. The tradeoffs

between the benefits and risks of the proposed regulations for plant-pesticides are optimized under regulatory Option 2, EPA's proposed scope.

IX. BENEFITS OF REGULATING PLANT-PESTICIDES

The proposed regulations will generate a wide range of benefits for: the public, the firms that develop and market plants that produce plant-pesticides, the environment, nontarget organisms, and states, tribes, and territories 1/. Benefits to the public include a Federally implemented plant-pesticide registration process that should help alleviate concerns regarding the consumption of transgenic plants that express pesticides and assure the public of a food supply with minimal risks from harmful pesticide residues. The resolution of uncertainty regarding regulatory issues should benefit registrants tremendously. With the promulgation of the proposed regulations, affected firms will no longer need to "hold back" on product research and development; they will be able to plan ahead to allow for timely product development and commercialization. With commercialization, the industry should become attractive to investors who are skeptical to invest in companies without meaningful sales. The environment will benefit by having safety measures in place to protect against unintended environmental effects of accidental and deliberate releases of transgenic plants. Nontarget organisms, including endangered species, will benefit from a registration process that will carefully consider the potential effects that certain plant-pesticides may have upon them. And finally, states will benefit by having a set of standardized Federal regulations that will be more easily conveyed, interpreted, and enforced. Many states may also benefit by not having to establish their own set of regulations pertaining to genetically engineered organisms.

This chapter will discuss the potential benefits of the proposed plant-pesticide regulations to:

- Society: Human Health,
- Society: Environmental,
- Nontarget Organisms,
- Registrants, and
- States

1/ States, tribes, and territories are hereafter referred to as states only.

The potential benefits attributable to this Rule are expressed in qualitative terms due to the lack of data and/or difficulty in assigning quantifiable values to such benefits as improved public perception of biotechnology products, reduced regulatory uncertainty, consistency in regulations, and environmental risk reduction.

A. Benefits to Society: Human Health

The public's apprehension regarding transgenic crops includes concerns about changes in the toxicity and nutrient value of genetically altered food crops (Nazario, 1991; Keehn, 1992). With the implementation of this proposed Rule, registrant's will need to submit data showing that there are no adverse human health effects associated with the consumption of food from the genetically engineered crop. These data will then be used to set tolerance levels, or exemptions from the need for tolerance levels for the transgenic crop that expresses the plant-pesticide. This procedure of testing for health effects and setting tolerance levels has been in practice for traditional chemical pesticides since 1967 and assures the public that any pesticide residues found in the nation's food supply will not exceed tolerance levels. With the implementation of this proposed Rule, this same assurance should also be extended to genetically engineered food crops with pesticidal properties.

B. Benefits to Society: Environmental

The environmental concerns associated with agricultural biotechnology center around the possibility that genetically engineered organisms that are accidentally or deliberately released into the environment, may multiply and become difficult or impossible to control, or may transfer genetic material encoded for superior survival capabilities to plants already in the environment which may thus acquire the ability to outcompete with other organisms in the natural environment. Such an outcome could disturb ecological stability. The result, according to one USDA economist, may be,

> "...a changed environment with fewer wild species, or it could include specific economic control costs. Existing crops could

> become weeds, or the improved crops' characteristics could transfer to weeds, thus increasing their vigor (Reilly, 1989)".

To date, most of the field testing associated with plant-pesticides has been conducted in contained greenhouses and small field plots under USDA/APHIS regulations. Required containment, monitoring, and other protective measures resulting from APHIS requirements have controlled the potential for outcrossing or hybridization between transgenic plants and any cultivated or wild relatives. However, as field testing moves from small plots to larger acreages, the possible sexual transfer, through outcrossing of a plant-pesticide gene to a related plant, is of increasing concern in terms of the potential environmental impacts.

The proposed Rule includes guidance for data needs for registration that would allow EPA to determine, on a case-by-case basis, if the potential exists for outcrossing and/or gene transfer from a transgenic plant expressing a plant-pesticide to a cultivated or wild relative. These informational requirements will greatly reduce the chances of adverse environmental changes due to releases of genetically engineered organisms as speculated by Reilly.

C. Benefits to Nontarget Organisms

Another primary environmental public concern is the toxicity of plant-pesticides to nontarget organisms. One risk consideration for plant-pesticides with toxic modes of action is whether the potential exists for new or significantly different exposures of nontarget organisms to the pesticides. Some plants may be modified to produce pesticidal substances that may be new to the plant and thus present new exposures to organisms that associate with the plant. An important component of the Agency's evaluation of the toxicological properties of the pesticide is the way in which the pesticidal substance acts on the target pest. Because this could also be the way in which the pesticidal substance affects nontarget organisms. Thus, the Agency's review will consider the potential effects that plant-pesticides with toxic modes of action may have on nontarget organisms, particularly endangered species.

D. Benefits to Registrants

The lack of Federally implemented biotechnology regulations has been a significant contributing factor in the sluggish commercialization of agricultural biotechnology products relative to health care (Burrill and Lee, 1992). Many companies in agricultural biotechnology are unsure of what will be needed to secure Federal approval to market their plant-pesticides commercially. This uncertain regulatory environment has prevented companies from devising long-term business plans, has contributed to delays to large-scale transgenic seed production, has stifled university research, and has raised concerns that regulatory holdups may give competing firms marketing advantages (Crawford, 1990). Some policy analysts refer to the risk incurred by biotechnology firms under this regulatory uncertainty as a tax, because it hinders biotechnology product development. Establishing a clear regulatory policy is "...one of the least expensive subsidies that government can provide to biotechnology development..." (Hueth and Just, 1987).

To compound matters, some states have already established regulations pertaining to genetically engineered organisms and industry leaders are concerned that these regulations will not always be consistent among states (Larson and Knudson, 1991).

The industry wants and needs regulatory certainty, and stands to benefit tremendously from these proposed regulations. With the promulgation of this proposed Rule, those companies that have been developing plant-pesticides can move forward to the commercialization stage. With commercialization, the industry should become attractive to investors who have traditionally been skeptical to invest in companies without meaningful sales (Burrill and Lee, 1992). The agricultural biotechnology industry has a promising future with recent valuations declining to levels where the industry is beginning to look appealing from a historical perspective (Yonehiro, 1992).

E. Benefits to States

The promulgation of Federal registration requirements for plant-pesticides should benefit states by diminishing the need for state-specific plant-pesticide regulations. Approximately 22 states are considering developing legislation or regulations regarding plant-pesticides (Crawford, 1990). This proposed Rule would establish Federal registration requirements that would allow states to expend their scarce human and economic resources elsewhere.

States will also benefit by having standardized Federal regulations that will be easy to convey, interpret, and enforce. This proposed Rule is designed to clarify and make more enforceable, registration requirements for transgenic plants that express plant-pesticides, thus simplifying the efforts of compliance monitoring officials, and in some respects, easing their regulatory burden.

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APPENDIX A

SUMMARY OF SELECTED STATE REGULATIONS FOR GENETICALLY ENGINEERED ORGANISMS

Appendix Table A-1. Summary of state regulations in North Carolina, Wisconsin, and Minnesota relevant to pesticide-producing transgenic plants

North Carolina Genetic Engineering Review Board	Wisconsin Dept. of Agriculture, Trade, and Consumer Protection	Minnesota Department of Agriculture (MDA)	Minnesota Environmental Quality Board (EQB)
WHO REGULATES, WHAT IS REGULATED, AND WHAT IS NOT REGULATED			
Genetic Engineering Review Board, comprised of state agency, university, industry, farmer, and other specifically designated members, is responsible for issuing permits.	Department of Agriculture, Trade, and Consumer Protection (DATCP) is lead state agency for all environmental releases regulated under EPA/FIFRA and USDA	A person may not conduct a release of a genetically engineered plant, pesticide, fertilizer, soil amendment, or plant amendment until a permit for the release has been obtained from the commissioner of agriculture	Environmental Quality Board (EQB) is designated the state coordinating organization for state and Federal regulatory activities relating to genetically engineered organisms A permit from the EQB is required for release of any genetically engineered organism, unless some other state agency requires a "significant environmental permit" for that release
Regulates the release and commercial use of genetically engineered organisms in order to protect agriculture, public health, and the environment.	In 1989, state legislature passed an act concerning notifications. This legislation gives the state no regulatory authority and has resulted in the state being characterized as a state with a NOTIFICATION procedure	Regulates the release of certain genetically engineered organisms to protect humans and the environment from the potential for significant adverse effects of those releases	Regulates releases of genetically engineered organisms to protect human health and the environment, allow for the orderly and safe development and use of such organisms, provide information to the EQB and the public, and provide orderly and timely process for making decisions on release permits
Does not regulate the breeding of plants, animals, and other organisms by traditional methods, such as artificial inseminations or hand pollination.	Exempts drugs, cosmetics, medical devices, and biological products intended for human use, DATCP may also waive part or all of the notification requirements for a specified regulated release if DATCP determines such information is not needed to protect the public health or environment, may also exempt a class of regulated releases from part or all of the notification requirements	Does not include selective breeding, hybridization, or nondirected mutagenesis	Does not apply to the direct medical application of genetically engineered organisms to humans or animals, does not include selective breeding, hybridization, or nondirected mutagenesis
GENERAL INFORMATION ON PERMITS			
Review Board may grant, deny, suspend, modify, or revoke permits.	State uses its traditional permitting authority Introduction into the environment of a genetically engineered organism may require a State permit, not specifically because the organism was genetically manipulated, but because the organism falls into a traditionally regulated category This includes biological control agents, broadly defined to include insecticidal plants and disease-resistant plants	The commissioner of the MDA may issue, revoke, or change a permit at any time	For any experimental use, a permit from EQB is required, unless another state agency requires a "significant environmental permit" for the release. For any commercial use, a permit from the appropriate designated agency is sufficient.
Two classes of permits. (1) General permits, for which no permit application is required, includes releases of genetically engineered organisms between 7/1/90 and 12/31/90, which are otherwise in compliance with state and Federal law; releases inside contained facilities; releases from fermentation processes regulated under FDCA, and releases or commercial uses of drugs or devices intended for prophylactic, therapeutic, or diagnostic use in humans if regulated under FDCA. (2) Limited permits, required for the release or commercial use of genetically engineered organisms not covered by a general permit	Each permit requires an environmental assessment	Commissioner may prescribe terms and conditions including, but not limited to, the period for the genetically engineered plants to be used, monitoring activities, department inspection schedules, reporting of experiment results, and experiment termination procedures.	A release permit from EQB is not required if a "significant environmental permit" is required by another agency A "significant environmental permit" means a permit issued by another state agency with the authority to deny modify, revoke, or place conditions on the permit (e g , a permit issued by the MDA) This evidently applies only to permits for commercial use, not permits for experimental use

Appendix Table A-1. Summary of state regulations in North Carolina, Wisconsin, and Minnesota relevant to pesticide-producing transgenic plants (Continued)

North Carolina Genetic Engineering Review Board	Wisconsin Dept. of Agriculture, Trade, and Consumer Protection	Minnesota: Department of Agriculture (MDA)	Minnesota: Environmental Quality Board (EQB)
WHAT PERMIT APPLICATION (OR NOTIFICATION) MUST INCLUDE			
Limited permit must include copy of the Federal submission appended to a Submittal Summary for the Release of a Genetically Engineered Organism, OR if no Federal submission, application on forms or in format prescribed by Review Board, along with a Submittal Summary.	Notification requires a copy of all the information submitted to the Federal regulatory agency which is not confidential business information (CBI), summary of any CBI is required.	Permit application must include (1) name and address of applicant, (2) any EPA, USDA, or other Federal agency regulatory application or approval documents, (3) the purpose or objectives of the plant, (4) name, address, and phone number of cooperators or participants in the state, (5) amount of plants, plant material, or seeds to be shipped or used in state, and (6) other information requested by commissioner.	Permit application must include (1) signed cover letter, (2) title page and table of contents, (3) applicant's name, address, and telephone number, (4) description of proposed release including location, use, and purpose, release date and duration of release, and information necessary to evaluate the proposed release, and any other requested information, (5) list of all known Federal, State, and local agencies that require a permit for the proposed release, and (6) Federal application and Federal CBI-deleted application if they have been prepared. Applicant may make reference to Federal application in completing application
State must issue a permit before a genetically engineered organism may be released into the environment, sold, offered for sale, or distributed for release into the environment.			
To the extent possible, the Review Board shall authorize the use of Federal forms or formats, to the extent possible, the Board shall accept for review and base its decision on the data submitted with the Federal application, Board may require such additional data as it deems necessary to determine potential adverse effects of the release of the organism on agriculture, public health, and the environment.	DATCP may request information on the proposed regulated release in addition to that submitted to a Federal agency, but the affected party does not have to submit that information to DATCP.	The application documents prepared for USDA/APHIS are acceptable documents and usually contain sufficient information.	
Review Board may (1) place restrictions on the number and location of organisms released, method of release, training of persons involved with the release, disposal of organisms, and other conditions of use, (2) require measures to limit dispersal of released organisms or spread of inserted genes or gene products, (3) require monitoring of the abundance and dispersal of the released organism or inserted genes or gene products, and (4) deny, suspend, modify, or revoke permit.			
COMMENTS/PUBLIC NOTICE/PUBLIC HEARING			
The Review Board may submit written comments to any Federal agency reviewing a proposed or completed release, and otherwise participate in any such reviews	DATCP may prepare a formal comment on the regulated release for submission to Federal agency	No provision for preparation of comments to Federal agency	No provision for preparation of comments to Federal agency
Decision shall be made on a permit application within 90 days from the date the completed application is received by the Board, unless a public hearing, Board may extend the time for making a decision by no more 30 days, for good cause			

Appendix Table A-1. Summary of state regulations in North Carolina, Wisconsin, and Minnesota relevant to pesticide-producing transgenic plants (Continued)

North Carolina Genetic Engineering Review Board	Wisconsin Dept. of Agriculture, Trade, and Consumer Protection	Minnesota Department of Agriculture (MDA)	Minnesota Environmental Quality Board (EQB)
Within 15 days of receipt of application, Board shall publish notice and a brief description of the proposed release, unless Board intends to deny application	Within 5 days of receiving notification materials, written notice of receipt must be sent to relevant county and municipal authorities, publication of a legal notice also required in county for which release is proposed.	An Environmental Assessment Worksheet (EAW) is required for each release.	Within 15 days of application acceptance, applicant must publish notice along with Environmental Assessment Worksheet (EAW) in release area newspaper, to certain persons, and to certain governmental units, EQB must publish notice in the EQB Monitor EQB must also publish notice of draft release permit documents in Monitor and provide copies of draft documents to specific parties
Any person may request a public hearing, if public hearing is held, decision on permit application must be made within 120 days after completed application is received, with 30-day extension possible; Board may, with written consent of applicant, extend the period to review the application	When preparing formal comment for Federal regulator, State may hold information meeting and provide an opportunity for the public to comment.	A 30-day public comment period is required for each EAW	30-day period allowed for review and comment on draft release permit documents and EAW, one or more public hearings may be held if EQB determines it necessary or useful, contested case hearing may be held.
No county or municipality shall enact any regulation or ordinance regulating the release of genetically engineered organisms			

Appendix Table A-2. Summary of state regulations in Illinois and Oklahoma relevant to pesticide-producing transgenic plants

Illinois Department of Agriculture	Oklahoma Department of Agriculture
WHO REGULATES, WHAT IS REGULATED, AND WHAT IS NOT REGULATED	
IL requires notification and review; does not permit. The IL Dept of Agriculture is the reviewing department for any regulated release subject to any federal requirement in the coordinated framework, except a TSCA requirement; the IL EPA is the reviewing dept for any regulated release subject to TSCA; if regulated release subject to both TSCA and any other Fed requirement in coordinated framework, both depts review, enter into memorandum of understanding, and designate one dept as the lead reviewing dept.	The State Board of Agriculture shall have the authority to issue, renew, deny, suspend, and revoke any permit issued according to the provisions of the Oklahoma Agriculture Biotechnology Act.
Regulates the release of genetically engineered organisms into the environment if the person proposing to commence the release has to (1) notify a Federal regulator, or (2) has to secure the approval of or a permit or license from a Federal regulator before commencing the release, or (3) secure a determination by a Federal regulator of the need for notification, approval, licensing or issuance of a permit under coordinated framework; other releases not captured in IL.	Regulates the "release into the environment" of any "regulated articles." Release into the environment means the use of a regulated article outside the constraints of physical confinement that are found in a laboratory, greenhouse, fermenter, or other contained structure. Regulated articles are any organisms altered or produced through genetic engineering.
Act does not apply to any drug, cosmetic, medical device or biological product intended for human use and regulated under FFDCA; part or all of notification requirements may be waived; a class of regulated releases may be exempted from part or all of notification requirements.	All persons who have filed Assurances of Compliance with federally established guidelines with their Institutional Biosafety Committee and/or applied for regulatory approval(s) from the appropriate federal agency, is exempt from the provisions of the Act.
GENERAL INFORMATION ON PERMITS	
Permits not required; rather, a notification and review process is required.	No person shall maintain a regulated article without a permit issued by the Board of Ag (unless in compliance with a federal agency).
WHAT PERMIT APPLICATION (OR NOTIFICATION) MUST INCLUDE	
Notification must include (1) copy of all information being submitted to Federal regulatory, except CBI; and (2) summary of CBI sufficient to enable reviewer to prepare comments and to provide information to public.	Permit application shall include (1) information on responsible person and type of permit requested (for importation, interstate movement, or release into the environment), (2) information on donor organism(s), recipient organisms(s), vector or vector agent(s), constituent of each regulated article which is a product, and regulated article, (3) information on persons who developed and/or supplied the regulated article, (4) description of the means of movement, (5) description of anticipated or actual expression of altered genetic material in the regulated article and how it differs from nonmodified parental organism, (6) description of molecular biology of system which is or will be used to produce regulated article, (7) country and locality where

Appendix Table A-2. Summary of state regulations in Illinois and Oklahoma relevant to pesticide-producing transgenic plants (Continued)

Illinois Department of Agriculture	Oklahoma Department of Agriculture
	donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced, (8) description of the purpose for the introduction of the regulated article, (9) quantity of the regulated article to be introduced and proposed schedule and number of introductions, (10) description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in U.S. to prevent contamination, release, and dissemination in the production of the donor organism, recipient organism, vector or vector agent, constituent of each regulated article which is a product, and regulated article, (11) description of the intended destination, uses, and/or distribution of the regulated article, (12) description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations, (13) description of any biological material and (14) description of the proposed method of final disposition of the regulated article.
COMMENTS/PUBLIC NOTICE/PUBLIC HEARING	
Reviewing department may prepare a formal comment for submission to the Federal regulator within time-frame established by Federal regulator To assist in preparation of comment, dept. may (1) hold an information meeting, (2) provide opportunity for public comment, (3) conduct a technical review, and (4) seek assistance of an IL university faculty and staff or the Dept of Public Health No less than 10 days prior to any regulated release, person proposing to commence such release shall send written notice giving summary details to the CEO of the county in which release is proposed and to mayor or president of any municipality in such county if release is within its corporate limits; notice sent to reviewing dept at same time as to local officials	No provisions for comments, public notice, or public hearings.

APPENDIX B

ALTERNATIVE TO THE VIRAL COAT PROTEIN EXEMPTION-- COSTS OF EPA REGULATION OF VIRAL COAT PROTEINS

APPENDIX B

ALTERNATIVE TO THE VIRAL COAT PROTEIN EXEMPTION-- COSTS OF EPA REGULATION OF VIRAL COAT PROTEINS

Some plant varieties are being engineered to express as part of their genome, the coat proteins of viruses that infect them. These engineered proteins (VCPs) assist the plant to resist viral attack and disease. EPA is considering three potential approaches to the regulation of VCPs. The Agency's preferred approach (alternative 1) is to exempt VCPs from regulation under FIFRA and FFDCA. Under one of the alternative approaches (alternative 2), the Agency would establish a series of criteria that, if met, would exempt certain VCPs from FIFRA review. VCPs that would be captured for review under alternative 2, would be those in situations in which the VCPs could spread to wild relatives of the VCP-engineered plant. Under alternative 2, VCPs would be exempted from FFDCA regulation. Under the third approach (alternative 3), all VCPs would be reviewed under FIFRA and exempted under FFDCA.

Although EPA would exempt VCPs under the preferred regulatory scope of Option 2 as described in Chapter IV (alternative 1 discussed above), it is still desirable to estimate the costs of their regulation as the proposed Rule will discuss other options (alternatives 2 and 3 described above). This appendix presents the anticipated data needs under the scenario that VCPs would be regulated by EPA, and the associated compliance costs of these data needs. Two cost analyses are estimated: (1) only VCPs in plants with wild relatives in the United States are regulated (alternative 2), and (2) all VCPs are regulated, i.e., those with **and** without wild relatives in the U.S. (alternative 3).

To estimate compliance costs, it is necessary to 1) determine what kinds or types of tests will be needed for VCPs in plants with wild relatives in the U.S. and for those VCPs in plants without wild relatives in the U.S., 2) obtain the costs for the generation and submittal of testing information, and 3) project the number of potential VCP submissions the Agency may receive for registration.

USDA/APHIS requirements for environmental release permits (ERPs) serve as the existing baseline of Federal requirements for companies that are testing genetically engineered plants (including VCPs) in field tests. Once the costs for certain data currently required by USDA/APHIS are accounted for as the baseline costs, the additional costs associated with the data needs directly attributable to EPA registration needs for VCPs, are the costs of regulating VCPs.

A. General Methodology

The costs of regulating VCPs are developed and compiled in the same manner as were the costs of regulating other plant-pesticides. For a full explanation of the steps involved in estimating compliance costs, please see Chapter VII.

1. Unit or Individual Testing Costs

Cost estimates for performing individual tests were either obtained from secondary sources, EPA experts, or industry specialists. All of the anticipated data needs for VCPs are new to the Agency and as such, none have currently established protocols.

A lower and upper bound for the unit test costs were created. The lower bound test costs were either estimated in today's costs by the Agency or industry contacts, or were obtained from secondary (1989) sources and adjusted for the inflation in test costs since 1989[1/] by a factor of 10 percent for each year up to 1993 to represent the current unit test costs. These 1993 inflation-adjusted direct cost estimates provided the basis for the lower bound test costs. Upper bound test costs were estimated as the lower bound test costs plus 25 percent to account for some of the additional effort needed to revise protocols and endpoints, and to account for the administrative burden associated with consultations with EPA personnel

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1/ According to some industry representatives, recent EPA reregistration requirements for existing chemicals has put an increased demand on private laboratory testing services to complete the new testing requirements. This increased demand for testing services has caused increased costs for these services. The annual increase in test costs is believed to have increased faster than the overall inflation rate and thus, the use of an annual 10% inflation rate.

regarding specific data needs. Midpoint test costs were calculated by summing the lower and upper bound estimates and then dividing by two.

The costs associated with the production of the pesticidal substance and its purification for testing purposes were estimated and included in the case studies. A full discussion of this cost component can be found in Chapter VII.

2. Development of Case Studies

Case studies are used to estimate the potential costs of registering VCPs in plants without wild relatives in the U.S. and VCPs in plants with wild relatives in the U.S.

a. Case Study 1A: Viral coat proteins in plants with no wild relatives in the U.S.

Case Study 1A presents the anticipated data needs and associated costs for the registration of a VCP in plants without wild relatives in the U.S. A tomato plant would be an example of a recipient crop without wild relatives in the U.S. Other examples of transgenic crops with VCPs and no wild relatives in the U.S. that may be developed in the future include alfalfa, corn, potato, and soybean. As shown in Appendix Table B-1, it is estimated to cost a registrant between $15,400 and $23,100 with a midpoint cost of $19,200, to fulfill the anticipated data needs for the registration of Case Study 1A type VCP. Total costs are estimated as a range to account for the varying degrees of test protocol development needed and for the amount of administrative burden that may be incurred by individual registrants.

Many of the data needs for Case Study 1A type VCPs will already have been fulfilled by the time the registrant seeks EPA registration. The costs associated with product analysis and residue analysis data needs are attributable to USDA/APHIS permitting requirements and as such, are not a cost of regulating VCPs (these costs are later subtracted from total costs to obtain incremental costs). Tier I biological fate data needs under the environmental fate subheading, may range from a literature search which would cost approximately $1,500, to minimal testing in a greenhouse that may cost up to $2,000. Terrestrial and aquatic nontarget organisms effects data are also not needed for VCPs.

Appendix Table B-1. Case 1A: Potential data needs for viral coat proteins in plants with no wild relatives in the U.S.

Data Need	When Required 1/	Estimated Data Need Cost Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	N			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I: BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2. Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
IV. Human Health Effects and Mammalian Toxicology				
None needed				
V. Terrestrial and Aquatic Nontarget Organisms Effects				
None needed				
Cost to Produce Pesticidal Substance 8/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 1A		**$15,358**	**$23,072**	**$19,215**

Footnotes.

1/ N = Always needed, SN = Sometimes needed

2/ All estimates have been adjusted annually to 1993 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden

4/ Calculated (Lower bound + Upper bound)/2.

5/ Source for Product Analysis: Federal Register, Vol. 52, No 115

6/ These costs are included in the cost of Product Analysis.

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source EPA, 1990, U.S. Dept. of Commerce, various issues, EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists

8/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

b. Case Study 2A: Viral coat proteins in plants with wild relatives in the U.S.

Case Study 2A presents the anticipated data needs for VCPs in plants that have wild relatives in the U.S. Appendix Table B-2 demonstrates that the data needs and associated costs of registering a VCP in a plant with wild relatives in the U.S. will cost a registrant between $610,000 and $766,400 depending upon the amount of protocol development needed and administrative burden incurred. As with Case Study 1A, several of the data needs in Case Study 2A will have already been incurred by the time the registrant seeks EPA registration.

Not all VCPs in plants with wild relatives in the U.S. will need Tier III biological fate analysis data. It is estimated that only one out of five (20%) submissions of VCPs in plants with wild relatives in the U.S. will need Tier III testing. However, no adjustment in costs have been made to account for only 20 percent of the submissions of Case Study 2A type VCPs needing Tier III biological fate data. This is because at this point, the Agency has no way of knowing which submissions will require Tier III data and which will not, and rather than err on the conservative side of costs, has erred on the high side of costs. Thus, the total cost to register a Case Study 2A type VCP is likely to be overstated for the average submission.

2. Methodology for Determining Total Costs

To estimate the total costs associated with the regulation of VCPs, the total cost of the anticipated data needs by case study were multiplied by the projected number of annual VCP submissions by case study. As with other plant-pesticides, compliance costs for VCPs were estimated for a 10-year period.

Based on the observation that the number of VCPs in development and field testing is about equal to the number of other types of plant-pesticides in development and field testing, it is estimated that the total number of VCP submissions between years 1-10 (45 total submissions) will be equivalent to the number of other types of plant-pesticide submissions between years 1-10 as shown in Appendix Table B-3.

Appendix Table B-2. Case 2A: Potential data needs for viral coat proteins in plants with wild relatives in the U.S.

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	N			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3. Ontogeny/Cultivation	N			
4 Pollination type	N			
TIER II BIOLOGICAL FATE ANALYSIS 8/				
1 Hybrid viability	N	29,440	36,800	33,120
2 Pollen viability	N	7,400	9,250	8,325
TIER III BIOLOGICAL FATE ANALYSIS 8/		557,800	697,250	627,525
1 Selective advantage				
a. Host range	SN			
b Growth and development	SN			
2 Dispersion				
a Field testing	SN			
IV. Human Health Effects and Mammalian Toxicology				
None needed				
V. Terrestrial and Aquatic Nontarget Organisms Effects				
None needed				
Cost to Produce Pesticidal Substance 9/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 2A		**$609,998**	**$766,372**	**$688,185**

Footnotes

1/ N = Always needed, SN = Sometimes needed

2/ All estimates have been adjusted annually to 1993 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden.

4/ Calculated: (Lower bound cost + Upper bound cost)/2

5/ Source for product analysis cost: Federal Register Vol 52, No 115.

6/ These costs are included in the cost of Product Analysis.

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990, U S. Dept. of Commerce, various issues, EPA, 1993). The $2,000 greenhouse testing estimate was provided by industry specialists

8/ Source. 1993 industry estimate.

9/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes

Appendix Table B-3. Projected Viral Coat Protein Submissions by Case Study and Year

Case Study	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Case Study 1A (VCPs in plants without wild relatives in the U.S.)	1	1	2	2	2	3	3	3	3	3	23
Case Study 2A (VCPs in plants with wild relatives in the U.S.)	1	1	1	2	2	3	3	3	3	3	22
Total Submissions 1/	2	2	3	4	4	6	6	6	6	6	45

1/ The total number of VCP submissions between years 1-10 is estimated to be equal to the total number of plant-pesticide submissions (45) during this time period. This is based on the observation that the number of VCPs being developed and field tested is about equal to the number of other types of plant-pesticides being developed and field tested. It is assumed that nearly equal numbers of VCPs in plants with wild relatives in the U.S. and in plants without wild relatives in the U.S. are being developed, thus, the nearly equal split in estimated submissions.

Furthermore, nearly equal numbers of VCPs in plants with wild relatives in the U.S. and in plants without wild relatives in the U.S. are being developed. This observation was used to allocate the total number of VCP submissions between VCPs in plants with wild relatives in the U.S. and those in plants without wild relatives in the U.S. As shown in Appendix Table B-3, approximately 50 percent of the total VCP submissions are estimated to be of the Case Study 1A type (in plants without wild relatives in the U.S.) and 50 percent of Case Study 2A type (in plants with wild relatives in the U.S.).

B. Estimated Direct Compliance Costs

Appendix Table B-4 presents the total compliance cost estimates from years 1-10 for the regulation of (1) VCPs in plants with wild relatives in the U.S., and (2) all VCPs. If EPA regulated only VCPs in plants with wild relatives in the U.S., midpoint total costs would range from $688,200 in year 1 to $2.1 million in year 10. If the Agency decided to regulate all VCPs (those in plants with as well as without wild relatives in the U.S.), compliance costs would range from $707,400 in year 1 to $2.1 million in year 10. Included in these total costs are the midpoint baseline costs (about $10,000) associated with USDA/APHIS permitting requirements.

In year 1, it was predicted that the Agency would receive a total of two VCP submissions; one submission of a VCP in a plant with wild relatives in the U.S. and one submission in a plant without wild relatives in the U.S. (Appendix Table B-3). From Appendix Tables B-1 and B-2 it was estimated that the midpoint cost of the data needs would be approximately $19,200 for VCPs in plants without wild relatives in the U.S. and $688,200 for VCPs in plants with wild relatives in the U.S. Thus, the total cost to regulate VCPs in plants with wild relatives in the U.S. in year 1 is $688,200 (1 X $688,200) and the total cost to regulate all VCPs is $707,400 ([1 X $688,200] + [1 X $19,200]). In year 6, it was predicted that a total of six VCP submissions would be received by the Agency. Again, the midpoint cost to register these types of VCPs are shown in Appendix Tables B-1 and B-2. The total cost to regulate VCPs in plants with wild relatives in the U.S. in year 6 is estimated at $2,064,600 million (3 X $688,200), and for all VCPs the total cost is predicted at $2,122,200 ([3 X

Appendix Table B-4. Total Compliance Cost Estimates for Viral Coat Proteins, Years 1-10

Case Study	Total Compliance Cost Estimate by Case Study 1/									
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
	($)									
Case Study 1A (VCPs in plants without wild relatives in the U.S.)	19,200	19,200	38,400	38,400	38,400	57,600	57,600	57,600	57,600	57,600
Case Study 2A (VCPs in plants with wild relatives in the U.S.)	**688,200**	**688,200**	**688,200**	**1,376,400**	**1,376,400**	**2,064,600**	**2,064,600**	**2,064,600**	**2,064,600**	**2,064,600**
Case Study 1A + 2A (Total cost to regulate all VCPs)	**707,400**	**707,400**	**726,600**	**1,414,800**	**1,414,800**	**2,122,200**	**2,122,200**	**2,122,200**	**2,122,200**	**2,122,200**

1/ Calculated by multiplying the midpoint compliance cost estimate by case study (Appendix Tables B-1 & B-2) by the number of projected viral coat protein submissions by case study (Appendix Table B-3).

$688,200] + [3 X $19,200]). This methodology can be used to determine all total costs by year as shown in Appendix Table B-4.

4. Annualized Incremental Compliance Costs

In order to estimate annualized incremental compliance costs for the regulation of VCPs in plants with wild relatives in the U.S. and the cost for the regulation of all VCPs, it was necessary to 1) subtract baseline costs from total costs, and 2) discount and annualize the resulting incremental costs.

a. Incremental compliance costs

As was previously noted, the costs associated with product analysis and residue analysis data needs are attributable to USDA/APHIS permitting requirements and as such, are considered the baseline costs of regulating VCPs. Looking back at Case Studies 1A and 2A, it can be seen that baseline costs (product analysis data needs) range from $8,858 to $11,072, with a midpoint value of $9,965. Calculating the difference between the projected total compliance costs and the current baseline costs, yields the incremental compliance costs associated with the regulation of VCPs in plants with wild relatives in the U.S. as shown in column one of Appendix Table B-5 and those incremental compliance costs associated with the regulation of all VCPs as shown in column one of Appendix Table B-6.

b. Discounting incremental compliance costs

The 10-year incremental compliance cost estimates as presented in column one of Appendix Tables B-5 and B-6 are nondiscounted costs stated in 1993 dollars. For VCPs, these costs will not be evenly allocated by industry over the 10-year period. Instead, cash flows will be uneven. To account for these uneven cash flows, to allow for the time value of money, and to determine an equivalent, constant-level cost per year (also called an equivalent annual cash flow or annual revenue requirement), discounted cash flow procedures were used. For a full discussion of the procedures used to discount cash flows, please see Chapter VII.

Appendix Table B-5. Incremental and Annualized Compliance Costs to the Private Sector for VCPs in Plants with Wild Relatives in the U.S., Constant 1993 Dollars, Discounted at 10% for 10 Years

	Compliance Costs for VCPs in Plants with Wild Relatives in the U.S.		
Year	Incremental 1/	Cash Flow 2/	Net Present Value 3/
	($)		
1	678,200	678,200	616,484
2	688,200	688,200	568,453
3	688,200	688,200	516,838
4	1,356,400	1,356,400	926,421
5	1,376,400	1,376,400	854,744
6	2,034,600	2,034,600	1,147,514
7	2,034,600	2,034,600	1,043,750
8	2,034,600	2,034,600	950,158
9	2,034,600	2,034,600	862,670
10	2,034,600	2,034,600	785,356
Total NPV			$8,272,389
Annual Revenue Requirement 4/			$1,346,293
Annual Revenue Requirement per Submission 5/			$611,951

1/ Calculated: [Total cost to regulate VCPs in plants with wild relatives in the U.S. (Appendix Table B-4)] - [Baseline costs (Appendix Tables B-1 and B-2) X number of VCP submissions (Appendix Table B-3)].
2/ Cash flow is equivalent to the incremental costs to regulate viral coat proteins.
3/ Amount in "Cash Flow" column X the discount factor.
4/ ARR = Capital Recovery Factor (CRF) X Total Net Present Value (NPV).
CRF = (1 + i)^n (i) / (1 + i)^n - 1
Where: i = the real rate of return on invested capital, excluding inflation (10%)
n = the effective operating life of the asset (10 years)
5/ Calculated: Annual revenue requirement/average annual number of VCP submissions (2.2).

Appendix Table B-6. Incremental and Annualized Compliance Costs to the Private Sector for All Viral Coat Proteins, Constant 1993 Dollars, Discounted at 10% for 10 Years,

	Compliance Costs for All Viral Coat Proteins		
Year	Incremental 1/	Cash Flow 2/	Net Present Value 3/
	($)		
1	687,400	687,400	624,847
2	707,400	707,400	584,312
3	696,600	696,600	523,147
4	1,374,800	1,374,800	938,988
5	1,414,800	1,414,800	878,591
6	2,062,200	2,062,200	1,163,081
7	2,122,200	2,122,200	1,088,689
8	2,122,200	2,122,200	991,067
9	2,122,200	2,122,200	899,813
10	2,122,200	2,122,200	819,169
Total NPV			$8,511,704
Annual Revenue Requirement 4/			$1,385,241
Annual Revenue Requirement per Submission 5/			$307,831

1/ Calculated: [Total cost to regulate all VCPs (Appendix Table B-4)] - [(Baseline costs (Appendix Tables B-1 and B-2) X number of VCP submissions (Appendix Table B-3)].
2/ Cash flow is equivalent to the incremental costs to regulate viral coat proteins.
3/ Amount in "Cash Flow" column X the discount factor.
4/ ARR = Capital Recovery Factor (CRF) X Total Net Present Value (NPV).
CRF = (1 + i)^n (i) / (1 + i)^n - 1
Where: i = the real rate of return on invested capital, excluding inflation (10%)
n = the effective operating life of the asset (10 years)
5/ Calculated: Annual revenue requirement/average annual number of VCP submissions (4.5).

Appendix Tables B-5 and B-6 present the annualized incremental compliance costs (net present value) to the private sector for VCPs. Annual revenue requirements for those firms currently developing and testing plant-pesticides (including VCPs) are estimated at slightly over $1.3 million, or approximately $612,000 per VCP submission per year (based on an annual average of 2.2 VCP submissions per year), if the Agency found it necessary to regulate VCPs in plants with wild relatives in the U.S. If the Agency were to regulate all VCPs, including those in plants without wild relatives in the U.S., the total annual revenue requirement is predicted at approximately $1.4 million for those firms currently developing and testing plant-pesticides, or $307,800 per VCP submission per year (based on an annual average of 4.5 VCP submissions per year).

APPENDIX C

PLANT-PESTICIDE CASE STUDIES

Appendix Table C-1. Case 1: Potential data needs for plant-pesticides in plants with the pesticidal substance derived from the monera kingdom, with no wild relatives in the U.S., and with information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	SN			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
CHEMICAL EXPOSURE 8/				
1 Route	SN			
2 Level	SN			
IV. Human Health Effects and Mammalian Toxicology				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I				
1 Honey bee larval test	N	4,392	5,490	4,941
2 Honey bee toxicity in pollen	N	5,856	7,321	6,588
3 Nontarget insect	N	23,426	29,282	26,354
Cost to Produce Pesticidal Substance 9/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 1		**$54,889**	**$72,486**	**$63,687**

Footnotes.

1/ N = Always needed, SN = Sometimes needed

2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden

4/ Calculated (Lower bound cost + Upper bound cost)/2.

5/ Source for product analysis cost: Federal Register, Vol. 52, No 115

6/ These costs are included in the cost of Product Analysis

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000) The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source. EPA, 1990, U S Dept. of Commerce, various issues, EPA, 1993)
The $2,000 greenhouse testing estimate was provided by industry specialists

8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses

9/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-2. Case 2: Potential data needs for plant-pesticides in plants with the pesticidal substance derived from within the plant kingdom or same plant family, with no wild relatives in the U.S., and with information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2. Gene expression during plant's life cycle	SN			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2. Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
CHEMICAL EXPOSURE 8/				
1 Route	SN			
2 Level	SN			
IV. Human Health Effects and Mammalian Toxicology				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I				
1 Honey bee larval test	N	4,392	5,490	4,941
2 Honey bee toxicity in pollen	N	5,856	7,321	6,588
3 Nontarget insect	N	23,426	29,282	26,354
4 Avian oral LD50 (mallard or bobwhite)	N	6,588	8,236	7,412
5 Avian dietary LC50 (mallard and bobwhite)	N	14,641	18,301	16,471
TIER II.				
1 Field test for pollinators	SN	13,177	16,471	14,824
Cost to Produce Pesticidal Substance 9/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 2		**$89,295**	**$115,494**	**$102,394**

Footnotes

1/ N = Always needed; SN = Sometimes needed

2/ Unless otherwise noted, costs are from a 1990 EPA RIA All estimates were adjusted annually to '93 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden

4/ Calculated (Lower bound cost + Upper bound cost)/2

5/ Source for product analysis cost: Federal Register, Vol. 52, No 115

6/ These costs are included in the cost of Product Analysis

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000) The $1,500 lit search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source. EPA, 1990, U S Dept of Commerce, various issues; EPA, 1993)
The $2,000 greenhouse testing estimate was provided by industry specialists

8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses.

9/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-3. Case 3: Potential data needs for plant-pesticides in plants with the pesticidal substance derived from the monera kingdom, with wild relatives in the U.S., and information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a. Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	SN			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
CHEMICAL EXPOSURE 8/				
1. Route	SN			
2. Level	SN			
TIER II				
BIOLOGICAL FATE ANALYSIS 9/				
1 Hybrid viability	N	29,440	36,800	33,120
2. Pollen viability	N	7,400	9,250	8,325
TIER III				
BIOLOGICAL FATE ANALYSIS 9/		557,800	697,250	627,525
1 Selective advantage				
a. Host range	SN			
b Growth and development	SN			
2. Dispersion				
a Field testing	SN			
IV. Human Health Effects and Mammalian Toxicology				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I				
1 Honey bee larval test	N	4,392	5,490	4,941
2 Honey bee toxicity in pollen	N	5,856	7,321	6,588
3 Nontarget insect	N	23,426	29,282	26,354
Cost to Produce Pesticidal Substance 10/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 3		**$649,529**	**$815,786**	**$732,657**

Footnotes.

1/ N = Always needed, SN = Sometimes needed

2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden

4/ Calculated: (Lower bound cost + Upper bound cost)/2

5/ Source for product analysis cost. Federal Register, Vol 52, No 115.

6/ These costs are included in the cost of Product Analysis

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source EPA, 1990; U S Dept. of Commerce, various issues, EPA, 1993)
The $2,000 greenhouse testing estimate was provided by industry specialists

8/ Will be required when there is a toxicological concern for the gene product This information is part of registrant's R&D expenses

9/ Source: 1993 industry estimate

10/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes

Appendix Table C-4. Case 4: Potential data needs for plant-pesticides in plants with the pesticidal substance derived from within the plant kingdom or same family, with no wild relatives in the U.S., and no information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a. Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	SN			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
CHEMICAL EXPOSURE 8/				
1 Route	SN			
2 Level	SN			
IV. Human Health Effects and Mammalian Toxicology				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
2 Reporting of hypersensitivity incidence and/or specific allergenicity testing	SN	8,200	10,250	9,225
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I.				
1 Honey bee larval test	N	4,392	5,490	4,941
2. Honey bee toxicity in pollen	N	5,856	7,321	6,588
3. Avian oral LD50 (mallard or bobwhite)	N	6,588	8,236	7,412
4. Avian dietary LC50 (mallard and bobwhite)	N	14,641	18,301	16,471
5. Nontarget insect	N	23,426	29,282	26,354
TIER II 9/				
1. Field test for pollinators	SN	13,177	16,471	14,824
2 Freshwater fish LC50 (rainbow trout and bluegill)	SN	24,890	31,112	28,001
3 Acute EC50 freshwater (daphnia)	SN	12,445	15,556	14,000
4 Acute LC50 estuarine and marine organism	SN	13,177	16,471	14,824
TIER III:				
1. Avian reproduction (mallard and bobwhite)	SN	187,405	234,256	210,830
Cost to Produce Pesticidal Substance 10/		10,000	20,000	15,000
TOTAL COST FOR CASE STUDY 4		**$340,411**	**$433,139**	**$386,775**

Footnotes on following page

Appendix Table C-4 footnotes:

1/ N = Always needed; SN = Sometimes needed
2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%.
3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden.
4/ Calculated: (Lower bound cost + Upper bound cost)/2.
5/ Source for product analysis cost: Federal Register, Vol. 52, No. 115
6/ These costs are included in the cost of Product Analysis
7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990, U.S. Dept of Commerce, various issues; EPA, 1993). The $2,000 greenhouse testing estimate was provided by industry specialists.
8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses
9/ Tier II data needs will depend on the recipient crop and the geographic location of the planting.
10/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-5. Case 5: Potential data needs for plant-pesticides in plants with the pesticidal substance derived from the animal kingdom, with wild relatives in the U.S., and no information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1. Product identity				
2. Description of manufactured materials				
a. Source of genetic material				
b. Vector system				
c. Recipient				
II. Residue Analysis 6/				
1. Describe inserted genes expression and estimation of number of gene copies, if appropriate.	N			
2. Gene expression during plant's life cycle.	SN			
3. Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used.	N			
III. Environmental Fate				
TIER I:				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1. Taxonomy	N			
2. Geography	N			
3. Ontogeny/Cultivation	N			
4. Pollination type	N			
CHEMICAL EXPOSURE 8/				
1. Route	SN			
2. Level	SN			
TIER II:				
BIOLOGICAL FATE ANALYSIS 9/				
1 Hybrid viability	N	29,440	36,800	33,120
2. Pollen viability	N	7,400	9,250	8,325
TIER III:				
BIOLOGICAL FATE ANALYSIS 9/		557,800	697,250	627,525
1. Selective advantage				
a. Host range	SN			
b. Growth and development	SN			
2. Dispersion				
a. Field testing	SN			
IV. Human Health Effects and Mammalian Toxicology				
1. Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
2. Reporting of hypersensitivity incidence and/or specific allergenicity testing	SN	8,200	10,250	9,225

Continued

Appendix Table C-5. Case 5: Potential data needs for plant-pesticides in plants with the pesticidal substance derived from the animal kingdom, with wild relatives in the U.S., and no information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I:				
1. Honey bee larval test	N	4,392	5,490	4,941
2. Honey bee toxicity in pollen	N	5,856	7,321	6,588
3. Avian oral LD50 (mallard or bobwhite)	N	6,588	8,236	7,412
4 Avian dietary LC50 (mallard and bobwhite)	N	14,641	18,301	16,471
5. Nontarget insect	N	23,426	29,282	26,354
TIER II 10/				
1 Field test for pollinators	SN	13,177	16,471	14,824
2. Freshwater fish LC50 (rainbow trout and bluegill)	SN	24,890	31,112	28,001
3. Acute EC50 freshwater (daphnia)	SN	12,445	15,556	14,000
4. Acute LC50 estuarine and marine organism	SN	13,177	16,471	14,824
TIER III:				
1 Avian reproduction (mallard and bobwhite)	SN	187,405	234,256	210,830
Cost to Produce Pesticidal Substance 11/		20,000	40,000	30,000
TOTAL COST FOR CASE STUDY 5		**$945,051**	**$1,196,439**	**$1,070,745**

Footnotes:

1/ N = Always needed; SN = Sometimes needed

2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%.

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden.

4/ Calculated: (Lower bound cost + Upper bound cost)/2.

5/ Source for product analysis cost: Federal Register, Vol. 52, No. 115.

6/ These costs are included in the cost of Product Analysis.

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990; U.S. Dept of Commerce, various issues; EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists.

8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses.

9/ Source: 1993 industry estimate.

10/ Tier II data needs will depend on the recipient crop and the geographic location of the planting.

11/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-6. Case 6: Potential data needs for plant-pesticides from sexually compatible plants in new plant varieties

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
II. Residue Analysis 6/				
1 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
None needed unless there are toxicological concerns				
IV. Human Health Effects and Mammalian Toxicology 7/				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TOTAL COST FOR CASE STUDY 6		**$14,714**	**$18,393**	**$16,553**

Footnotes:
1/ N = Always needed; SN = Sometimes needed
2/ All estimates have been adjusted annually to 1993 dollars by an average inflation rate of 10%.
3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden
4/ Calculated (Lower bound cost + Upper bound cost)/2
5/ Cost source Federal Register, Vol 52, No 115
6/ This cost is included in the cost of product analysis
7/ Cost source 1990 EPA RIA.

Appendix Table C-7. Case 7: Potential data needs for viral coat proteins in plants with no wild relatives in the U.S.
Example VCP in tomato

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	SN			
3. Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
IV. Human Health Effects and Mammalian Toxicology				
None needed				
V. Terrestrial and Aquatic Nontarget Organisms Effects				
None needed				
Cost to Produce Pesticidal Substance 8/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 7		**$15,358**	**$23,072**	**$19,215**

Footnotes
1/ N = Always needed, SN = Sometimes needed
2/ All estimates have been adjusted annually to 1993 dollars by an average inflation rate of 10%
3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden
4/ Calculated: (Lower bound + Upper bound)/2.
5/ Source for Product Analysis Federal Register, Vol 52, No 115
6/ These costs are included in the cost of Product Analysis
7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000) The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source EPA, 1990; U S Dept. of Commerce, various issues, EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists
8/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes

Appendix Table C-8. Case 8: Potential data needs for viral coat proteins in plants with wild relatives in the U.S.
Example VCP in squash or melon

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
a Source of genetic material				
b Vector system				
c Recipient				
II. Residue Analysis 6/				
1 Describe inserted genes expression and estimation of number of gene copies, if appropriate	N			
2 Gene expression during plant's life cycle	SN			
3 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
TIER II				
BIOLOGICAL FATE ANALYSIS 8/				
1 Hybrid viability	N	29,440	36,800	33,120
2 Pollen viability	N	7,400	9,250	8,325
TIER III				
BIOLOGICAL FATE ANALYSIS 8/		557,800	697,250	627,525
1 Selective advantage				
a. Host range	SN			
b Growth and development	SN			
2 Dispersion				
a. Field testing	SN			
IV. Human Health Effects and Mammalian Toxicology				
None needed				
V. Terrestrial and Aquatic Nontarget Organisms Effects				
None needed				
Cost to Produce Pesticidal Substance 9/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 8		**$609,998**	**$766,372**	**$688,185**

Footnotes
1/ N = Always needed; SN = Sometimes needed
2/ All estimates have been adjusted annually to 1993 dollars by an average inflation rate of 10%.
3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden
4/ Calculated (Lower bound cost + Upper bound cost)/2.
5/ Source for product analysis cost. Federal Register. Vol 52, No 115
6/ These costs are included in the cost of Product Analysis
7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000) The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source. EPA, 1990, U S. Dept. of Commerce, various issues; EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists
8/ Source: 1993 industry estimate
9/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-9. Case 9: Potential data needs for plant-pesticides in new plant varieties with the pesticidal substance derived from within the plant genus, with no wild relatives in the U.S., and with information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
II. Residue Analysis 6/				
1 Plant-pesticide (PP) expression during plant's life cycle	SN			
2 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2 Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
CHEMICAL EXPOSURE 8/				
1 Route	SN			
2 Level	SN			
IV. Human Health Effects and Mammalian Toxicology				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I				
1 Honey bee larval test	N	4,392	5,490	4,941
2 Honey bee toxicity in pollen	N	5,856	7,321	6,588
3 Nontarget insect	N	23,426	29,282	26,354
4 Avian oral LD50 (mallard or bobwhite)	N	6,588	8,236	7,412
5 Avian dietary LC50 (mallard and bobwhite)	N	14,641	18,301	16,471
TIER II				
1 Field test for pollinators	SN	13,177	16,471	14,824
Cost to Produce Pesticidal Substance 9/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 9		**$89,295**	**$115,494**	**$102,394**

Footnotes

1/ N = Always needed, SN = Sometimes needed

2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocol development burden

4/ Calculated (Lower bound cost + Upper bound cost)/2

5/ Source for product analysis cost Federal Register, Vol. 52, No 115

6/ These costs are included in the cost of Product Analysis

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990; U S Dept. of Commerce, various issues; EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists

8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses

9/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes

Appendix Table C-10. Case 10: Potential data needs for plant-pesticides in new plant varieties with the pesticidal substance derived from within the plant genus, with wild relatives in the U.S., and information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
II. Residue Analysis 6/				
1 Plant-pesticide (PP) expression during plant's life cycle	SN			
2 Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I.				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1 Taxonomy	N			
2. Geography	N			
3 Ontogeny/Cultivation	N			
4 Pollination type	N			
CHEMICAL EXPOSURE 8/				
1. Route	SN			
2 Level	SN			
TIER II				
BIOLOGICAL FATE ANALYSIS 9/				
1 Hybrid viability	N	29,440	36,800	33,120
2 Pollen viability	N	7,400	9,250	8,325
TIER III				
BIOLOGICAL FATE ANALYSIS 9/		557,800	697,250	627,525
1 Selective advantage				
a Host range	SN			
b Growth and development	SN			
2 Dispersion				
a Field testing	SN			
IV. Human Health Effects and Mammalian Toxicology				
1 Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I				
1 Honey bee larval test	N	4,392	5,490	4,941
2. Honey bee toxicity in pollen	N	5,856	7,321	6,588
3 Nontarget insect	N	23,426	29,282	26,354
Cost to Produce Pesticidal Substance 10/		5,000	10,000	7,500
TOTAL COST FOR CASE STUDY 10		**$649,529**	**$815,786**	**$732,657**

Footnotes

1/ N = Always needed; SN = Sometimes needed

2/ Unless otherwise noted, costs are from a '90 EPA RIA. All estimates were adjusted annually to '93 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost + 25% to account for a 10% admin burden and a 15% protocol development burden

4/ Calculated (Lower bound cost + Upper bound cost)/2.

5/ Source for product analysis cost: Federal Register, Vol 52, No. 115.

6/ These costs are included in the cost of Product Analysis.

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990; U.S. Dept. of Commerce, various issues; EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists

8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses.

9/ Source: 1993 industry estimate

10/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-11. Case 11: Potential data needs for plant-pesticides in new plant varieties with the pesticidal substance derived from within the plant genus, with no wild relatives in the U.S., and no information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1. Product identity				
2. Description of manufactured materials				
II. Residue Analysis 6/				
1. Plant-pesticide (PP) expression during plant's life cycle	SN			
2. Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used	N			
III. Environmental Fate				
TIER I:				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1. Taxonomy	N			
2. Geography	N			
3. Ontogeny/Cultivation	N			
4. Pollination type	N			
CHEMICAL EXPOSURE 8/				
1. Route	SN			
2 Level	SN			
IV. Human Health Effects and Mammalian Toxicology				
1. Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
2. Reporting of hypersensitivity incidence and/or specific allergenicity testing	SN	8,200	10,250	9,225
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I:				
1. Honey bee larval test	N	4,392	5,490	4,941
2. Honey bee toxicity in pollen	N	5,856	7,321	6,588
3. Avian oral LD50 (mallard or bobwhite)	N	6,588	8,236	7,412
4. Avian dietary LC50 (mallard and bobwhite)	N	14,641	18,301	16,471
5. Nontarget insect	N	23,426	29,282	26,354
TIER II: 9/				
1. Field test for pollinators	SN	13,177	16,471	14,824
2. Freshwater fish LC50 (rainbow trout and bluegill)	SN	24,890	31,112	28,001
3. Acute EC50 freshwater (daphnia)	SN	12,445	15,556	14,000
4. Acute LC50 estuarine and marine organism	SN	13,177	16,471	14,824
TIER III:				
1. Avian reproduction (mallard and bobwhite)	SN	187,405	234,256	210,830
Cost to Produce Pesticidal Substance 10/		10,000	20,000	15,000
TOTAL COST FOR CASE STUDY 11		**$340,411**	**$433,139**	**$386,775**

Footnotes on following page . .

Appendix Table C-11 footnotes:

1/ N = Always needed; SN = Sometimes needed
2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%.
3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden.
4/ Calculated: (Lower bound cost + Upper bound cost)/2.
5/ Source for product analysis cost: Federal Register, Vol. 52, No. 115.
6/ These costs are included in the cost of Product Analysis.
7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000). The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990; U S. Dept of Commerce, various issues; EPA, 1993). The $2,000 greenhouse testing estimate was provided by industry specialists.
8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses
9/ Tier II data needs will depend on the recipient crop and the geographic location of the planting.
10/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes.

Appendix Table C-12. Case 12: Potential data needs for plant-pesticides in new plant varieties with the pesticidal substance substance derived from within the plant genus, with wild relatives in the U.S., and no information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
I. Product Analysis 5/	N	8,858	11,072	9,965
1 Product identity				
2 Description of manufactured materials				
II. Residue Analysis 6/				
1. Plant-pesticide (PP) expression during plant's life cycle	SN			
2. Concentration (or range estimate) of PP in plant, plant parts, and analytical methods used.	N			
III. Environmental Fate				
TIER I:				
BIOLOGICAL FATE ANALYSIS 7/		1,500	2,000	1,750
1. Taxonomy	N			
2. Geography	N			
3. Ontogeny/Cultivation	N			
4. Pollination type	N			
CHEMICAL EXPOSURE 8/				
1. Route	SN			
2. Level	SN			
TIER II:				
BIOLOGICAL FATE ANALYSIS 9/				
1. Hybrid viability	N	29,440	36,800	33,120
2. Pollen viability	N	7,400	9,250	8,325
TIER III:				
BIOLOGICAL FATE ANALYSIS 9/		557,800	697,250	627,525
1. Selective advantage				
a. Host range	SN			
b. Growth and development	SN			
2. Dispersion				
a. Field testing	SN			
IV. Human Health Effects and Mammalian Toxicology				
1. Acute oral toxicity for rodent and/or in vitro digestibility assay	N	5,856	7,321	6,588
2. Reporting of hypersensitivity incidence and/or specific allergenicity testing	SN	8,200	10,250	9,225

Continued ...

Appendix Table C-12. Case 12: Potential data needs for plant-pesticides in new plant varieties with the pesticidal substance substance derived from within the plant genus, with wild relatives in the U.S., and no information available on the characteristics and function of the gene product

Data Need	When Required 1/	Estimated Data Need Cost: Lower Bound (1993 $) 2/	Upper Bound (1993 $) 3/	Mid Point (1993 $) 4/
V. Terrestrial and Aquatic Nontarget Organisms Effects				
TIER I:				
1 Honey bee larval test	N	4,392	5,490	4,941
2 Honey bee toxicity in pollen	N	5,856	7,321	6,588
3 Avian oral LD50 (mallard or bobwhite)	N	6,588	8,236	7,412
4 Avian dietary LC50 (mallard and bobwhite)	N	14,641	18,301	16,471
5 Nontarget insect	N	23,426	29 282	26,354
TIER II: 10/				
1. Field test for pollinators	SN	13,177	16,471	14,824
2 Freshwater fish LC50 (rainbow trout and bluegill)	SN	24,890	31,112	28,001
3 Acute EC50 freshwater (daphnia)	SN	12,445	15,556	14,000
4 Acute LC50 estuarine and marine organism	SN	13,177	16,471	14,824
TIER III				
1. Avian reproduction (mallard and bobwhite)	SN	187,405	234,256	210,830
Cost to Produce Pesticidal Substance 11/		20,000	40,000	30,000
TOTAL COST FOR CASE STUDY 12		**$945,051**	**$1,196,439**	**$1,070,745**

Footnotes.

1/ N = Always needed; SN = Sometimes needed

2/ Unless otherwise noted, costs are from a 1990 EPA RIA. All estimates were adjusted annually to 1993 dollars by an average inflation rate of 10%

3/ Upper bound cost was estimated as the lower bound cost plus 25% to account for a 10% administrative burden and a 15% protocal development burden

4/ Calculated: (Lower bound cost + Upper bound cost)/2

5/ Source for product analysis cost. Federal Register, Vol 52, No 115

6/ These costs are included in the cost of Product Analysis.

7/ Tier I biological fate analysis data needs may range from a literature search (approximately $1,500) to minimal testing conducted in a greenhouse (approximately $2,000) The $1,500 lit. search cost is based on about 20 hours of work for a literature review & write up at a fully loaded hourly wage of approximately $77 for a "technician" (Source: EPA, 1990, U S Dept. of Commerce, various issues, EPA, 1993) The $2,000 greenhouse testing estimate was provided by industry specialists.

8/ Will be required when there is a toxicological concern for the gene product. This information is part of registrant's R&D expenses

9/ Source 1993 industry estimate.

10/ Tier II data needs will depend on the recipient crop and the geographic location of the planting

11/ EPA cost estimate for the registrant to produce the pesticidal substance and purify it for testing purposes

APPENDIX D

EPA BURDEN ESTIMATE DOCUMENTATION

Appendix Table D-1. Total EPA Hourly Burden Estimates Under RIA Option 1, Years 1-10

Year	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Staff Hours Needed		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	(Hours)											
Year 1	88	288	188	312	537	425	61	127	94	461	952	706
Year 2	197	591	394	653	1126	889	115	242	179	964	1959	1462
Year 3	197	591	394	653	1126	889	115	242	179	964	1959	1462
Year 4	274	996	635	1088	1773	1430	171	353	262	1533	3122	2327
Year 5	471	1587	1029	1741	2899	2320	286	595	440	2497	5081	3789
Year 6	383	1300	841	1428	2362	1895	225	468	347	2036	4130	3083
Year 7	197	591	394	653	1126	889	115	242	179	964	1959	1462
Year 8	383	1300	841	1428	2362	1895	225	468	347	2036	4130	3083
Year 9	492	1603	1047	1769	2951	2360	280	583	431	2540	5137	3839
Year 10	580	1891	1235	2081	3488	2785	340	710	525	3001	6089	4545

Source: EPA estimates.

Appendix Table D-2. Total EPA Hourly Burden Estimates Under RIA Option 2, Years 1-10

Year	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Staff Hours Needed		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	(Hours)											
Year 1	88	288	188	312	537	425	61	127	94	461	952	706
Year 2	197	591	394	653	1,126	889	115	242	179	964	1,959	1,462
Year 3	284	879	581	965	1,663	1,314	176	369	272	1,425	2,911	2,168
Year 4	549	1,992	1,270	2,176	3,546	2,861	341	706	524	3,065	6,245	4,655
Year 5	745	2,583	1,664	2,828	4,672	3,750	456	948	702	4,029	8,204	6,116
Year 6	657	2,296	1,477	2,516	4,135	3,326	396	821	608	3,569	7,252	5,410
Year 7	559	1,875	1,217	2,053	3,436	2,744	346	722	534	2,957	6,033	4,495
Year 8	657	2,296	1,477	2,516	4,135	3,326	396	821	608	3,569	7,252	5,410
Year 9	953	3,308	2,130	3,632	5,961	4,796	560	1,162	861	5,145	10,430	7,788
Year 10	854	2,887	1,870	3,169	5,261	4,215	511	1,063	787	4,533	9,211	6,872

Source: EPA estimates

Appendix Table D-3. Total EPA Hourly Burden Estimates Under RIA Option 3, Years 1-10

Year	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Staff Hours Needed		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	(Hours)											
Year 1	284	879	581	965	1,663	1,314	176	369	272	1,425	2,911	2,168
Year 2	393	1,182	788	1,306	2,252	1,779	230	484	357	1,929	3,918	2,923
Year 3	569	1,757	1,163	1,930	3,326	2,628	351	738	545	2,850	5,821	4,335
Year 4	942	3,174	2,058	3,481	5,798	4,640	571	1,190	881	4,994	10,163	7,578
Year 5	1,138	3,765	2,452	4,134	6,924	5,529	686	1,432	1,059	5,958	12,122	9,040
Year 6	1,247	4,069	2,658	4,474	7,513	5,994	741	1,547	1,144	6,462	13,129	9,795
Year 7	1,148	3,648	2,398	4,011	6,814	5,413	691	1,448	1,070	5,850	11,910	8,880
Year 8	1,247	4,069	2,658	4,474	7,513	5,994	741	1,547	1,144	6,462	13,129	9,795
Year 9	1,542	5,081	3,311	5,590	9,339	7,464	905	1,888	1,396	8,037	16,307	12,172
Year 10	1,443	4,660	3,052	5,127	8,639	6,883	856	1,789	1,322	7,426	15,088	11,257

Source: EPA estimates.

Appendix Table D-4. Total EPA Hourly Burden Estimates Under RIA Option 4, Years 1-10

Year	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Staff Hours Needed		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	(Hours)											
Year 1	31,525	108,433	69,979	118,473	197,214	157,843	19,896	41,448	30,672	169,894	347,094	258,494
Year 2	31,634	108,736	70,185	118,814	197,803	158,308	19,951	41,563	30,757	170,398	348,102	259,250
Year 3	31,810	109,311	70,560	119,438	198,877	159,157	20,072	41,817	30,944	171,319	350,005	260,662
Year 4	32,183	110,729	71,456	120,989	201,349	161,169	20,292	42,269	31,280	173,463	354,347	263,905
Year 5	32,379	111,320	71,849	121,642	202,475	162,058	20,407	42,511	31,459	174,428	356,306	265,367
Year 6	32,488	111,623	72,056	121,982	203,064	162,523	20,461	42,626	31,544	174,931	357,313	266,122
Year 7	32,389	111,202	71,796	121,519	202,365	161,942	20,411	42,527	31,469	174,320	356,094	265,207
Year 8	32,488	111,623	72,056	121,982	203,064	162,523	20,461	42,626	31,544	174,931	357,313	266,122
Year 9	32,783	112,635	72,709	123,098	204,889	163,994	20,626	42,967	31,796	176,507	360,491	268,499
Year 10	32,685	112,214	72,449	122,635	204,190	163,413	20,576	42,868	31,722	175,896	359,272	267,584

Source: EPA estimates.

Appendix Table D-5. EPA Labor Burden Cost Estimates Under RIA Option 1, Years 1-10

	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Labor Burden Costs		
Year	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	($)											
Year 1	6,634	21,735	14,184	17,049	29,320	23,185	1,525	3,200	2,363	25,207	54,256	39,731
Year 2	14,855	44,680	29,768	35,640	61,480	48,560	2,898	6,098	4,498	53,394	112,258	82,826
Year 3	14,855	44,680	29,768	35,640	61,480	48,560	2,898	6,098	4,498	53,394	112,258	82,826
Year 4	20,737	75,305	48,021	59,391	96,817	78,104	4,297	8,896	6,596	84,425	181,017	132,721
Year 5	35,592	119,985	77,789	95,031	158,296	126,664	7,195	14,994	11,094	137,818	293,275	215,547
Year 6	28,959	98,250	63,604	77,982	128,976	103,479	5,670	11,794	8,732	112,611	239,019	175,815
Year 7	14,855	44,680	29,768	35,640	61,480	48,560	2,898	6,098	4,498	53,394	112,258	82,826
Year 8	28,959	98,250	63,604	77,982	128,976	103,479	5,670	11,794	8,732	112,611	239,019	175,815
Year 9	37,180	121,194	79,187	96,574	161,136	128,855	7,043	14,692	10,868	140,797	297,021	218,909
Year 10	43,814	142,929	93,372	113,623	190,456	152,039	8,568	17,892	13,230	166,005	351,277	258,641

Calculated by multiplying the hourly estimates in Appendix Table D-1 by the following adjusted government wage rates (1993 $)

GS Level	Position type	Hourly 1993 wage rate 1/ (1993$/hr)	Adjustments for all benefits & overhead 2/	Government wage rate (1993$/hour)
GS-15	Management	36	2 1	76
GS-13	Technical	26	2.1	55
GS-7	Clerical	12	2 1	25

1/ Source: "Salary Table 93, Executive Branch of the Government". 1993 All salaries based on Step 5

2/ Source: "RIA of Proposed Revisions to Regulations Pertaining to Microbial Pesticides Under FIFRA" 1993 (1/20) EPA/OPP/BEAD

Appendix Table D-6. EPA Labor Burden Cost Estimates Under RIA Option 2, Years 1-10 in 1993 $

Year	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Labor Burden Costs		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	($)											
Year 1	6,634	21,735	14,184	17,049	29,320	23,185	1,525	3,200	2,363	25,207	54,256	39,731
Year 2	14,855	44,680	29,768	35,640	61,480	48,560	2,898	6,098	4,498	53,394	112,258	82,826
Year 3	21,489	66,415	43,952	52,689	90,800	71,744	4,423	9,299	6,861	78,601	166,513	122,557
Year 4	41,474	150,610	96,042	118,782	193,633	156,208	8,593	17,791	13,192	168,850	362,035	265,442
Year 5	56,330	195,290	125,810	154,422	255,113	204,768	11,491	23,890	17,690	222,243	474,293	348,268
Year 6	49,696	173,555	111,625	137,374	225,793	181,583	9,967	20,689	15,328	197,036	420,037	308,536
Year 7	42,226	141,720	91,973	112,080	187,617	149,848	8,719	18,194	13,457	163,026	347,531	255,278
Year 8	49,696	173,555	111,625	137,374	225,793	181,583	9,967	20,689	15,328	197,036	420,037	308,536
Year 9	72,020	250,070	161,045	198,307	325,449	261,878	14,112	29,282	21,697	284,440	604,801	444,620
Year 10	64,551	218,235	141,393	173,014	287,272	230,143	12,865	26,788	19,826	250,429	532,295	391,362

Calculated by multiplying the hourly estimates in Appendix Table D-2 by the following adjusted government wage rates (1993 $):

GS Level	Position type	Hourly 1993 wage rate 1/ (1993$/hr)	Adjustments for all benefits & overhead 2/	Government wage rate (1993$/hour)
GS-15	Management	36	2.1	76
GS-13	Technical	26	2 1	55
GS-7	Clerical	12	2.1	25

1/ Source: "Salary Table 93, Executive Branch of the Government". 1993. All salaries based on Step 5.

2/ Source: "RIA of Proposed Revisions to Regulations Pertaining to Microbial Pesticides Under FIFRA". 1993 (1/20) EPA/OPP/BEAD.

Appendix Table D-7. Total EPA Hourly Burden Estimates Under RIA Option 3, Years 1-10

	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Labor Burden Costs		
Year	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	($)											
Year 1	21,489	66,415	43,952	52,689	90,800	71,744	4,423	9,299	6,861	78,601	166,513	122,557
Year 2	29,711	89,359	59,535	71,280	122,959	97,120	5,796	12,197	8,996	106,787	224,515	165,651
Year 3	42,979	132,829	87,904	105,378	181,600	143,489	8,845	18,598	13,721	157,202	333,026	245,114
Year 4	71,185	239,970	155,577	190,063	316,593	253,328	14,389	29,988	22,189	275,637	586,550	431,093
Year 5	86,040	284,649	185,345	225,703	378,072	301,887	17,287	36,086	26,687	329,030	698,808	513,919
Year 6	94,262	307,594	200,928	244,294	410,232	327,263	18,661	38,984	28,823	357,217	756,810	557,013
Year 7	86,793	275,759	181,276	219,001	372,055	295,528	17,413	36,490	26,951	323,206	684,303	503,755
Year 8	94,262	307,594	200,928	244,294	410,232	327,263	18,661	38,984	28,823	357,217	756,810	557,013
Year 9	116,587	384,108	250,348	305,228	509,888	407,558	22,806	47,578	35,192	444,620	941,574	693,097
Year 10	109,117	352,273	230,695	279,934	471,711	375,823	21,559	45,083	33,321	410,610	869,067	639,839

Calculated by multiplying the hourly estimates in Appendix Table D-3 by the following adjusted government wage rates (1993 $)

GS Level	Position type	Hourly 1993 wage rate 1/ (1993$/hr)	Adjustments for all benefits & overhead 2/	Government wage rate (1993$/hour)
GS-15	Management	36	2.1	76
GS-13	Technical	26	2.1	55
GS-7	Clerical	12	2.1	25

1/ Source: "Salary Table 93, Executive Branch of the Government". 1993. All salaries based on Step 5.

2/ Source: "RIA of Proposed Revisions to Regulations Pertaining to Microbial Pesticides Under FIFRA". 1993 (1/20) EPA/OPP/BEAD

Appendix Table D-8. EPA Labor Burden Cost Estimates Under RIA Option 4, Years 1-10

Year	MANAGEMENT (GS-15)			TECHNICAL (GS-13)			CLERICAL (GS-7)			Total Labor Burden Costs		
	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average	Lower Bound	Upper Bound	Expected Average
	($)											
Year 1	2,383,320	8,197,520	5,290,420	6,468,626	10,767,863	8,618,244	501,379	1,044,490	772,934	9,353,325	20,009,872	14,681,599
Year 2	2,391,542	8,220,464	5,306,003	6,487,217	10,800,022	8,643,620	502,753	1,047,388	775,070	9,381,511	20,067,874	14,724,693
Year 3	2,404,810	8,263,934	5,334,372	6,521,315	10,858,662	8,689,989	505,802	1,053,788	779,795	9,431,926	20,176,385	14,804,156
Year 4	2,433,016	8,371,075	5,402,045	6,605,999	10,993,655	8,799,827	511,346	1,065,179	788,262	9,550,361	20,429,909	14,990,135
Year 5	2,447,871	8,415,754	5,431,813	6,641,640	11,055,135	8,848,387	514,244	1,071,277	792,761	9,603,755	20,542,166	15,072,961
Year 6	2,456,093	8,438,699	5,447,396	6,660,231	11,087,294	8,873,763	515,617	1,074,175	794,896	9,631,941	20,600,168	15,116,055
Year 7	2,448,624	8,406,864	5,427,744	6,634,937	11,049,118	8,842,028	514,370	1,071,680	793,025	9,597,931	20,527,662	15,062,796
Year 8	2,456,093	8,438,699	5,447,396	6,660,231	11,087,294	8,873,763	515,617	1,074,175	794,896	9,631,941	20,600,168	15,116,055
Year 9	2,478,417	8,515,214	5,496,816	6,721,164	11,186,950	8,954,057	519,763	1,082,768	801,266	9,719,345	20,784,932	15,252,138
Year 10	2,470,948	8,483,378	5,477,163	6,695,871	11,148,774	8,922,323	518,515	1,080,274	799,394	9,685,334	20,712,426	15,198,880

Calculated by multiplying the hourly estimates in Appendix Table D-4 by the following adjusted government wage rates (1993 $).

GS Level	Position type	Hourly 1993 wage rate 1/ (1993$/hr)	Adjustments for all benefits & overhead 2/	Government wage rate (1993$/hour)
GS-15	Management	36	2.1	76
GS-13	Technical	26	2.1	55
GS-7	Clerical	12	2.1	25

1/ Source: "Salary Table 93, Executive Branch of the Government". 1993. All salaries based on Step 5.
2/ Source: "RIA of Proposed Revisions to Regulations Pertaining to Microbial Pesticides Under FIFRA". 1993 (1/20). EPA/OPP/BEAD

APPENDIX E

RECORDS OF COMMUNICATION

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[ ] INCOMING
[X] OUTGOING

[ ] MEETING

DATE: January 21, 1993

TIME: 1:30 p.m.

RECORDED BY: Nancy J. Ekart

SUBJECT: Plant Pesticides

PROJECT NO.: 3780.203

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Elizabeth (Beth) Weimar, Biotech Group, U.S. Patent and Trademark Office (703) 308-0254

SUMMARY: Beth Weimar was very helpful in answering my questions about patents. The information she provided is as follows:

- Difference in a "plant patent" and a "utility patent."

  A plant patent is also known as a 161 patent and is based on a 1930 statute. This type of patent is very limited in scope and applies to a single variety. Beth stressed it is one claim to a single described and depicted plant variety. A full botanical description is required, including pictures, etc.

  A utility patent is a "normal" patent. It applies to just about everything such as a chair, shoes, etc. It is the basic patent statute based on the 35-year USC 101. This type of patent is very broad in scope. It is not subject-matter specific. Under a utility patent, claims relevant to transgenic plants may be to the DNA, to the plant cell containing DNA, or to a plant containing heterogenous material (material from a source outside the plant). There is no limit on the variety of a claim.

- Beth says most patents that have been issued relevant to transgenic plants have been utility patents. Plants developed using natural plant breeding via outcrossing are more apt to be patented under a plant patent. But with transgenic plants, there's no attempt usually to try to be variety specific.

- I asked Beth for clarification regarding whether it is the genetic material that is more likely to be patented rather than the entire plant. She said it can be both. Sometimes only one is patentable because the other is "known." She indicated that with Bt, there would be no patent on the protein, because the protein would be "known." The patent is likely to be only on the DNA or on the plant, if the plant was not known.

- A patent gives one the right to exclude others; not to do anything. The party receiving the patent decides to wha extent they want to exclude others, and it's up to them to enforce it. The patent office has nothing to do with licenses given out by a patentee, once the patent has been issued by the Patent Office.

- I asked Beth if there were any bulletins, pamphlets or the like available that would help me better understand the patenting procedure for transgenic plants. She didn't know of any personally, but suggested I call the Public Affairs Office (703-305-8341) and ask them if they have any type of biotech-type overview and for any info they have on plant patents. Beth said I was welcome to call again with any specific questions I might have regarding patents associated with transgenic plants.

Signatures:
Author: Nancy J. Ekart Date: 1-21-93

Participant: _____ Date: _____

Distribution: [X] Author [ ] Participant [X] File [X] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[X] INCOMING
[ ] OUTGOING

[ ] MEETING

DATE: January 28, 1993

TIME: 10:30 a.m.

RECORDED BY: Nancy J. Ekart

SUBJECT Plant Pesticides

PROJECT NO.. 3780 203

PARTICIPANT(S). ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Dr. Art Mason, Minnesota Dept. of Ag, Director of Plant Protection Division (612) 296-8448

SUMMARY: Dr. Mason returned my call of earlier today and provided the following answers to my questions:

- If a person applies for a release permit from MDA (Minnesota Dept. of Ag), do they need to apply for a permit from EQB (the Environmental Quality Board)?

  Dr. Mason indicates that if it's an experimental use, a permit from EQB must be obtained. If it's a commercial use, then a permit from the MDA is enough. He says companies aren't too happy with the situation, and that they're in a "state of flux" right now. The legislature may take action to clarify the situation.

- If a person applies for and receives a permit from USDA/APHIS, do they usually apply for and receive an exemption from a State permit?

  No. A State permit is required. However, the application made to APHIS usually contains sufficient information for MDA.

- Does an Environmental Assessment Worksheet (EAW) have to be prepared for a permit applied for from either the MDA or the EQB? Who prepares the EAW?

  Yes. The EAW is prepared by the MDA, with help from industry. If the findings from the EAW warrant, an Environmental Impact Statement (EIS) must also be prepared. However, no EIS has been required up to this point in time.

Signatures:
Author: _____ Date: _____

Participant: _____ Date: _____

Distribution: [ ] Author [ ] Participant [ ] File [ ] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[ ] INCOMING
[X] OUTGOING

[ ] MEETING

DATE. February 1, 1993

TIME. 10:45 a.m.

RECORDED BY: Nancy J Ekart

SUBJECT: Plant Pesticides

PROJECT NO 3780 203

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT

Toby Jones, Pesticide Registration Division, CA Dept of Agriculture (916) 657-4490

SUMMARY: I contacted Toby to see if California had any biotech regulations relevant to transgenic plants (pesticidal plants). It seems that there are no biotech regs as such. However, "plant permits" are a factor and transgenic plants that are potential plant pests are required to obtain a California permit. Other types of transgenic plants would not require a plant permit. Toby is going to send me an annotated copy of relevant laws and regulations. Evidently, there's some parallelism between various regs, and Toby thought it would be complicated and time-consuming for me to sort through the regs, find the relevant portions, and find the parallelism that occurs. I told her I'd be very grateful for her notes, that it would certainly reduce the time spent in reviewing the regs.

I asked her if there were States in addition to North Carolina, Wisconsin, Minnesota, Illinois and California that might have relevant regulations. She suggested calling both Washington and Oklahoma, and indicated she was going to contact a lady with the last name of Jacobs here in Kansas.

Toby expressed great interest in biotechnology, said she's been following the issue closely, and thinks labeling will be EPA's greatest difficulty in regulating pesticidal plants. Toby was very cooperative, took my phone number, said she was sure we'd be talking again (indicating I'd have questions about the State's regs once I receive the material from her).

Signatures:
Author: Nancy J Ekart Date: 2-1-93

Participant: Date:

Distribution: [X] Author [ ] Participant [X] File [X] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[ ] INCOMING
[X] OUTGOING

[ ] MEETING

DATE: February 4, 1993

TIME: 8:30 a.m.

RECORDED BY: Nancy J. Ekart

PROJECT NO.: 3780.203

SUBJECT: Plant Pesticides

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT

Dr. Steve Kendall, Plant Division, Oklahoma Dept. of Ag (405) 521-3864

SUMMARY: Dr. Kendall told me that Oklahoma has a biotech law, fashioned after that in North Carolina. He said the law has provisions for field testing, but they haven't been used yet because there has not yet been any field testing in the state of transgenic plants. There are 4-5 people in the State with APHIS permits, he says, but their work is still confined to the laboratory. This include 2 to 3 people at Oklahoma State University and 1 to 2 persons at the Noble Foundation. The efforts of these researchers are still under APHIS control. Dr. Kendall says, with Oklahoma Dept. of Ag staff accompanying APHIS staff on all inspections of these labs that have been made.

Dr. Kendall will ask Kevin Holley, the primary person working in the biotech area right now, to send me a copy of Oklahoma's biotech law. I should address any future questions to Mr. Holley. His phone number is the same as Dr. Kendall's.

Signatures:
Author: Nancy J. Ekart Date: 2-4-

Participant: Date:

Distribution: [X] Author [ ] Participant [X] File [X] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[ ] INCOMING
[X] OUTGOING

[ ] MEETING

DATE: March 15, 1993

TIME: 9:00 a.m.

RECORDED BY: Nancy J. Ekart

SUBJECT: Plant Pesticides

PROJECT NO.: 3780.203

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Bill Small, Association of Biotechnology Companies, 1666 Connecticut Ave NW, Suite 330, Washington, D.C. 20009-1039, (202-234-3330; FAX = (202) 234-3565

SUMMARY: I finally was able to talk to Bill; he hadn't returned two previous calls. He was very cooperative, said Joanne was welcome to call him in the future with any additional questions or concerns regarding the impact of registering plant pesticides on biotech firms.

I reminded Bill that I had met him at the Canadian Embassy when I accompanied Sandy Zavolta of EPA to the biotech meeting. He remembered meeting us. I told him that, based on my research, it seemed likely that the biotech firms would develop the technology for plant pesticides, patent the technology, license that technology to seed companies, and NOT come into EPA for registration. I further said it would appear unlikely that biotech firms would be involved in the actual production and marketing of the seed. Bill's response was as follows:

- That scenario will likely hold true for certain biotech firms, but not all. Some biotech firms may come in for registration. The scenario as I described it is more likely to be true of biotech firms today than of biotech firms in the future (with future undefined in terms of how many years).

- Calgene was a small biotech firm just a few years ago. Now it's a large biotech firm that has developed the Flavr Savr tomato nearly ready for marketing. Calgene does not have its own seed company, BUT has subcontracted out to a grower to commercially produce the tomatoes, save some seed, Calgene will get both the toamtoes and the seed back, and Calgene will both market the seed and sell the tomatoes. Some seed companies, however, are challenging Calgene through the Courts.

- So while it may be true today that most biotech firms will license out the technology, it may not be true tomorrow.

- Bill mentioned a "small" biotech firm in South Carolina, Seeds for the Future. It's composed of just one woman with a Ph.D. who has a research assistant working for her. She's doing seed research using genetic modification, and is getting patents. I mentioned it would seem difficult for such a small company to go into large-scale production, given the likely lack of capital. Bill says that may be right, but who knows how she might grow in the future.

In conclusion and based on this one call, I think we may have to consider biotech firms in our economic profile chapter and in the economic impacts analysis. It clearly points out the need for additional research.

Signatures:
Author: Nancy J. Ekart Date: 11/15/93

Participant: Date:

Distribution: [X] Author [ ] Participant [X] File [X] Others Sandra M. Zavolta, U.S. EPA; Joanne Blair

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[ ] INCOMING
[X] OUTGOING

[ ] MEETING

DATE: March 17, 1993

TIME: A.M.

RECORDED BY: Joanne Blair

SUBJECT: Plant Pesticides

PROJECT NO.: 3780.203

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Dr. Alan R. Goldhammer, Director of Technical Affairs, Industrial Biotechnology Association, 1625 K Street N.W., Suite 1100, Washington, D.C. 20006 (202) 857-0244

SUMMARY: I spoke with Dr. Goldhammer about which types of firms will incur the registration costs associated with transgenic plants that express plant pesticides. He reports that whether chemical, biotech, or seed companies incur the costs associated with registration is dependent upon the (1) the type of crop expressing plant pesticides, and (2) the structure of the company that developed the technology.

Companies that have developed specialty vegetable crops (tomatoes, squash, cucumbers, etc.) that express plant pesticides, be they chemical, seed, or biotech, will likely go the route that Bill Small described for Calgene's Flavr Savr tomato. That is, the company will develop the technology, patent it, register the plant pesticide with EPA (paying for all costs of registration), provide the transgenic seed to contractors to grow the vegetables, and receive the market- or processing-ready vegetable back from the contractor, along with any seed harvested. Dr. Goldhammer reports that this is the most likely scenario for vegetables, it is simply an extension of what is occurring today for many of the specialty vegetables grown, i.e., vertical integration from the development of the seed all the way to the market.

With companies that have developed transgenic field and grain crops that express plant pesticides such as cotton and corn, Dr. Goldhammer believes that the patenting of the technology and the responsibility of registration will depend upon the structure of the company, not on the type of company (biotech, chemical, or seed). Major agribusiness firms such as Cargil, Monsanto, and Ceiba-Geigy will likely go the route of companies with transgenic vegetables, i.e., develop the technology to produce PPs, develop the transgenic seed, register with EPA, and sell the seed through subsidiary seed distributors. He estimates that up to 50 percent of the biotech firms that are members of IBA, will go this route--that these biotech firms either already have seed companies to distribute the transgenic seed, or they will acquire the seed companies soon.

Companies that have developed the technology, but do not own seed companies to distribute the PPs may do one or more of several things such as license out the technology, sell the patent, acquire a seed company, etc. Dr. Goldhammer believes that if the cost of registering PPs are in the ballpark of the costs of registering microbial and biochemical pesticides, that even the smallest of seed or biotech companies will have the capital to pay for the costs of registration without adverse impacts.

I asked Dr. Goldhammer if he had anything on the subject of defining "small" biotech companies, or on the structure of the biotech industry (many small firms, many large firms, etc.). He said the only thing he could think of is an accounting (?) report from Earnston-Young. While this report is geared primarily toward privately held medical biotech firms, he did say that there is some info on agricultural biotech companies and he will send me a copy.

Signatures:
Author: [signature] Date: 3/17/93

Participant: Date:

Distribution: [✓] Author [ ] Participant [✓] File [✓] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION (CONT'D)

SUMMARY: (Cont'd)

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION DATE: March 29, 1993

[ ] INCOMING TIME: A.M.
[X] OUTGOING

[ ] MEETING RECORDED BY: Joanne Blair

SUBJECT: Plant Pesticides, Test Costs PROJECT NO.: 3780.203

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Tim Spurgin, ABC Laboratories, Columbia, Missouri. (314) 474-8579

SUMMARY: Tim Spurgin said that the company was currently very busy with budgeting and would not be able to give me any detailed information on test costs for three weeks. He did say that if I was surveying several laboratories that I would get widely varying test cost estimates due to the diversity of analytical methods used in labs.

I asked him if he could give me any information on the relative changes in costs of laboratory tests since 1989 (when we did the Part 158 RIA test cost estimates). He said that while demand for tests has increased since 1989 due to reregistration requirements, that increased competition in the lab testing industry has kept costs from "skyrocketing" as we have heard from others. He guessed that 1993 costs would be 5% - 10% higher than 1989 costs.

He also went on to explain how regulatory burden and paperwork has greatly increased (and gave me several examples) which they have had to account for in their test costs.

If we would like to call back in three weeks we should speak with the company's VP of finance, Greg May at the above number.

Signatures:
Author: Joanne Blair Date: 3/29/93

Participant: Date:

Distribution: [✓] Author [ ] Participant [✓] File [✓] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION DATE: June 15, 1993

[ ] INCOMING TIME: A.M.
[X] OUTGOING

[ ] MEETING RECORDED BY: Joanne Blair

SUBJECT: Immunotoxicity Test Cost PROJECT NO.: 3780.203

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Bob Sherwood, IITRI, 312 567-4845

SUMMARY: Sandy gave me Bob's name and number as a possible contact for an estimate of the cost to do an "Immunotoxicity" test (Tier I, Human Health Effects).

Bob told me that this is a newly required test, that it had only been required for about one year and his company had only done two of them to date. The Immunotoxicity test is a 30-day feeding study with a cost that varies depending upon study design and whether rats or mice are fed. He said the average test runs about $80,000.

He did not know of another testing company that was doing this type of testing. Hazelton Labs and Pharmacon have been advertising that they preform the Immunotoxicity test, but to his knowledge, to date, neither company had actually had a chance to do the test (i.e., no customers).

Signatures:
Author: Joanne Blair Date: 6/1[illegible]

Participant: Date:

Distribution: [✓] Author [ ] Participant [✓] File [✓] Others Sandra M. Zavolta, U.S. EPA

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[X] INCOMING
[ ] OUTGOING

[ ] MEETING

DATE: 11/19/93

TIME: p.m.

RECORDED BY: Joanne S. Blair

SUBJECT: Plant-pesticides EIA

PROJECT NO: 3780 302

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Terry Woodword, Virginia Commonwealth University, Institute of Biotechnology (804) 786-8565

SUMMARY:

Terry used a local biotech firm as an example to explain how small firms are able to remain in business while reporting negative profits, sometimes for up to five years in a row. "Lim Biotech Labs" is a small biotech firm in Richmond, Virginia. Although Lim Labs is not currently researching and developing transgenic plants, it has just registered a microencapsulated Bt product with EPA

When Lim Labs started out, they received financing from USDA through the SBIR program and from joint contracts with USDA. They also received funds from many private, local investors that recognized the potential of the companies products. When the company made good progress with a particular product they were developing, investors would usually increase their monetary investment in the company.

Another local firm called "Croptech" was established by a husband and wife team from Virginia Polytechnic Institute. Terry referred to Croptech as a "paper" company. Much of this companies financing has come from family sources and from a second mortgage taken out by the couple.

Apparently, small biotech firms can become quite creative when seeking financial support. I asked Terry if to his knowledge, small biotech firms have budgeted for the costs of EPA registration, which is certain to occur If the small company is the result of an individual starting up a firm, or from someone that's from academia, then no, they usually have no idea of what the registration costs might be, and don't budget them in. However, if the small firm is a "breakoff" from another, large firm, then yes, they probably have a handle on a registration cost estimate and have accounted for this cost in their R & D budgets.

He suggested that I call Lim Labs, Richmond VA at (804) 780-3855 and speak with the president, Jarel Kelsey. Also, try CropTech, Blacksberg, VA at (703) 231-4325 and speak with either Dr. Carol Cramer or Dr. David Radin.

Signatures:
Author: _____ Date: _____

Participant: _____ Date: _____

Distribution: [ ] Author [ ] Participant [ ] File [ ] Others Sandy Zavolta, BEAD

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[ ] INCOMING
[X] OUTGOING

[ ] MEETING

DATE: 11/22/93

TIME. a.m.

RECORDED BY: Joanne S. Blair

SUBJECT Plant-pesticides EIA

PROJECT NO.: 3780.302

PARTICIPANT(S), ORGANIZATION/DEPARTMENT, ADDRESS, TELEPHONE/EXT.

Jerel Kelsey, President, Lim Laboratories, Richmond, VA (804) 780-3855

SUMMARY: Although Lim Labs is not researching transgenic plants, they have researched microencapsulated Bt and just recently received EPA registration. They are also considered a small biotech firm.

I asked Mr. Kelsey how small biotech companies finance themselves while waiting for their product to reach commercialization. He reports that Lim Labs "has used it all":

- Private and equity offerings
- Debt financing
- Venture capital (from the risk taking investor)
- Public ventures with Canadian boards
- Sponsoring by Canadian investment bankers

For interim financing, they turn to shareholders and board members. Basically, they try to receive financing where ever its available. He related that the toughest part of starting up a biotech firm or keeping a small biotech firm going, is trying to pay the employees their salaries when the company doesn't have a product.

He believes that the greatest hurdle to staying in business for small firms is in dealing with environmental regulations and EPA. The delays in regulations, delays in getting a product registered, and the bureaucracy associated with EPA is incredible. He is "really surprised that the internal delays within EPA due to the administration change" have been so extensive. These delays have trickled down to his company, causing incredible delays in product registration and commercialization.

He believes that it will be even worse for companies developing and attempting to register transgenic plants because EPA has no experience in this area, likely leading to uncertain registration requirements. He told of a biological product that Lim Labs attempted to register with EPA, that even with EPA's experience with biologicals, it took forever and was very "painful" for his company. He believes the internal confusion at EPA is tremendous. He can't even imagine the problems that will come with transgenic plant registration.

It's Mr. Kelsey's opinion that only companies with "deep pockets" will be able to afford the registration requirements for transgenic plants, not because the tests will be necessarily expensive, but because of the internal delays that are an everyday occurrence with the Agency. Ideally, someday, biotech firms will be able "to make it through the regulatory maze in a cost effective manner so they can make payroll".

Mr. Kelsey welcomes any calls from Agency staff to discuss improving the regulatory process.

Signatures:
Author: _____ Date: _____

Participant: _____ Date: _____

Distribution: [ ] Author [ ] Participant [ ] File [ ] Others Sandy Zavolta, BEAD

DPRA INCORPORATED

RECORD OF COMMUNICATION

[X] TELEPHONE CONVERSATION

[X] INCOMING
[ ] OUTGOING

[ ] MEETING

DATE 12/2/93

TIME. am

RECORDED BY: Joanne S Blair

SUBJECT: Plant-pesticides EIA

PROJECT NO : 3780.302

PARTICIPANT(S), ORGANIZATION/DEPARTMENT. ADDRESS. TELEPHONE/EXT

David Radin Ph D., CropTech. Blacksburg, VA (703) 231-4325

SUMMARY: Dr. Radin, along with his wife, Carol Cramer. Ph.D . have founded a small biotechnology firm in Blacksburg, Virginia called "CropTech" Although they both work in the Department of Biotechnology at VPI, CropTech is a "spinoff" from the university and was created to market a biotechnology product that they have developed. While he didn't think he should tell me what his product was. I believe he said that they were working on plants that produced beneficial products. Their company will be one year old tomorrow

Dr Radin told me that "hightech" biotech firms commonly go through 3 stages of financing as their products are researched and developed. The first stage is a government program grant. called **Small Business Innovative Research grants (SBIRs)**. These grants are available from any federal department/agency to small businesses which are formally defined as <500 employees. In reality, due to the relative small size of the grants and the elaborate procedure necessary to procure a grant, only businesses with < 50 employees ever apply for them. Despite the size of the grants (an average figure was quoted as $75K), this program is very important for two reasons: (1) it gets the business started. and (2) it establishes credibility in the business, which is important when the business seeks funding elsewhere.

The second stage involves **private financing** sources. These can be self-financed, family financed. bank loans, etc.

The third stage is where firms seek **venture capital**. This usually occurs in the 2nd to 3rd year in a products development and can continue to be a source of funding through the 4th year when up to $1 million can be raised. **Foundations** are another source during this time period. By the 5th to 7th year in product development, a business usually considers an **initial public offering**. IPOs can bring upwards of $20-30 million into a promising business.

I asked Dr. Radin if he had thought about budgeting for the costs of EPA registration, once his product reaches the commercialization stage. The EPA hasn't even entered his mind, he told me. He has been working solely with USDA. He said that once EPA published their registration requirements for transgenic plants and he had a chance to see them. he really didn't currently have the funds to begin budgeting for compliance costs. His budgeting "horizon" is only about 2 years into the future.

Signatures:
Author: _____ Date: _____

Participant: _____ Date: _____

Distribution: [ ] Author [ ] Participant [ ] File [ ] Others Sandy Zavolta, BEAD