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Attachment G

General Methodology Used to Estimate Paperwork Burden Hours and Costs by the Office of Pesticide Programs for Submission of Required Data/Information for Responding to a

Office of Pesticide Programs
October 2007

Contents

Section I. Background

I. What is the purpose of this document?

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, requires federal agencies to estimate the "paperwork burden" for "information collection" activities. Under the PRA, "paperwork burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency. Under the PRA, an "information collection" means any request for information made by a federal agency of ten or more respondents, and may include a request to report, retain records, or disclose information to third parties.

This document describes the methodology used by the Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) to estimate the paperwork burden hours and costs for stakeholders responding to Data Call-In (DCI) Notices issued by OPP under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The methodology is intended to provide a description of the process used by EPA to derive the estimated paperwork burden hours and costs associated with submitting a response to EPA under a DCI. The methodology presented in this document should also enable stakeholders to reproduce the burden estimates made by the Agency for DCI related collection activities. This increased transparency will enable the public to provide more substantive and meaningful feedback during public comment periods. This feedback will better enable the Agency to periodically amend the burden estimates. In addition, since the methodology presented here will be used by the Agency to estimate the paperwork burden for DCI requests, this document will serve as a reference for such calculations in the future.

II. Why does EPA issue DCIs?

With few exceptions, FIFRA requires EPA to evaluate all pesticides marketed and used in the United States to ensure that they will not pose unreasonable risks to human health and the environment. Pesticides that meet the requirements are granted a license or "registration" that permits their distribution, sale, and use according to specific use directions and requirements identified on the label. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA establishes tolerances (defined as maximum allowed pesticide residue levels) to specify the amount of the pesticide residue that can legally remain in or on food or animal feed, using a safety standard of a "reasonable certainty of no harm."

EPA's review and evaluation of a new, amended, or existing pesticide registration or tolerance require data of sufficient quality and quantity to characterize the pesticide's hazards and the potential risk from its intended uses. The data requested by the Agency, including the data requested in the DCI, allow

EPA to evaluate whether a pesticide meets the statutory standard for registration, and allow the Agency to establish the appropriate tolerance(s) for the pesticide under section 408 of the FFDCA.

Under section 3(c)(2)(B) of FIFRA EPA can require pesticide registrants to generate and submit data to the Agency, when such data are required to maintain an existing registration of a pesticide. EPA's determination that additional data are needed could occur for various reasons, with the following four reasons being the most common:

- **The Reregistration Program:** Section 4 of FIFRA requires EPA to re-assess the health and safety data for all pesticide active ingredients registered before November 1, 1984, to determine whether these "older" pesticides meet the criteria for registration that would be expected of a pesticide being registered today for the first time. Section 4 directs EPA to use section 3(c)(2)(B) authority to obtain the required data.
- **The Registration Review Program:** Section 3(g) of FIFRA contains provisions to ensure that each pesticide will be reviewed every 15 years to ensure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. Section 3(g) instructs EPA to use the section 3(c)(2)(B) authority to obtain the required data.
- **The Special Review Program:** Though rare, EPA may conduct a Special Review if EPA believes that a registered pesticide poses risks of unreasonable adverse effects on human health or the environment. Section 3(c)(2)(B) of FIFRA provides a means of obtaining any needed data.
- **Anticipated Residue/Percent Crop Treated Information:** Under FFDCA, EPA can consider information on the anticipated levels of pesticide residues in food (the actual levels of pesticide residues that have been measured in food) and data on the actual percent of food treated with the pesticide chemical. The Agency must also provide for periodic re-evaluation of this information. Under FFDCA section 408(b)(2)(E), EPA can issue a DCI for information relating to anticipated residues, and under section 408(b)(2)(F) EPA can issue a DCI for percent crop treated estimates.

III. How do the PRA requirements relate to DCIs?

The PRA states, "An agency may not conduct or sponsor, and a person is not required to respond to a "collection of information," as defined at 5 CFR 1320.3(c), unless the "collection" displays a currently valid control number issued by the Office of Management and Budget (OMB).[1] EPA's issuance of a DCI under FIFRA section 3(c)(2)(B) is subject to the PRA requirements because the DCI is considered a "collection of information" under the PRA. To comply with

[1] OMB is part of the Executive Office of the President.

the PRA requirements, EPA must submit an Information Collection Request (ICR) that provides specific information to OMB about the data that EPA intends to call in for a given pesticide, including: a list of required studies, the practical utility of the data, the estimated testing costs, and the estimated paperwork burden.

Under the PRA, "practical utility" means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects in a useful and timely fashion.[2] "Burden" means the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal Agency.[3]" including resources to:

- review instructions;
- develop, acquire, install, and use technology and systems;
- search data sources;
- collect, review, validate, and verify information/data;
- process and maintain information/data;
- disclose and transmit/submit information/data;
- change/adjust the existing ways of complying with any previously applicable instructions and requirements to comply with new requirements; and/or
- train personnel.

IV. How does a DCI recipient respond to a DCI?

Response to a DCI can generally be divided into three phases.

- **Phase 1: Initial response:** After receiving a DCI, the recipient has 90 days to provide the initial response, which states how the recipient plans to comply with the DCI. A registrant may avoid generating the data if he qualifies for a generic data exemption (i.e., he uses a registered pesticide as the source of the active ingredient in his own product), cancels the product's registration, submits or cites existing data, or requests a waiver.
- **Phase 2: Data generation:** Unless the DCI recipient can cite existing studies or is granted a waiver by the Agency, the DCI recipient must then generate the required data.
- **Phase 3: Data submission:** DCI recipient submits the studies/information to EPA.

V. DCI burden activities tables

Table 1 illustrates the paperwork activities that would typically be performed by a DCI recipient during each of the three phases. Note that the activities that are

[2] 5 CFR 1320.3(l)
[3] 5 CFR 1320.3(b)

likely to occur have been divided into three categories of duties: managerial, technical and clerical. For this table, it was assumed that the data generation was performed at the request of the DCI recipient by a contract laboratory. Although DCI recipients can certainly choose to generate the data themselves, the Agency believes that the assumption used provides a sufficiently conservative estimate, and does not expect the burden estimate for DCI recipients to be more than the estimate. Table 1 includes ***only*** those duties performed directly by the DCI recipient.

Table 1 – Response Phases

Managerial Duties	Technical Duties	Clerical Duties
PHASE 1: INITIAL RESPONSE		
Read regulations	Read regulations	Complete other required paperwork
Review EPA's DCI notice	Review EPA's DCI notice	
Communicate with EPA		Assist with review of internal company information
Plan DCI response	Search for existing data	Assist with search for existing data
Sign and send initial response forms to EPA		Prepare initial response forms for submission
Oversight of employee activities		
PHASE 2(a): DATA GENERATION USING CONTRACT LABORATORY		
Planning/oversight of employee and contract activities	Plan the data collection activities with the laboratory	Complete/file/archive other required paperwork
Make decisions		Electronic data entry
Secure contract lab services and approve statement of work (SOW)	Create test protocols for SOW	
Communicate with EPA	Ensures contract laboratory maintains records and procedures during testing period in accordance with the Good Laboratory Practices (GLPs)	
Oversight of employee and contract activities	Routine contact with testing laboratory which can include on-	

	site visits	
	Analyze interim report and/or monthly report	
	Proof draft final report	
	Generate acceptance report	
PHASE 3: DATA SUBMISSION TO EPA		
Sign-off on submission to EPA	Draft summary of the data for cover letter	Prepare submission to EPA
Close-out contract		
Oversight of employee activities	Complete other required paperwork	Complete/file/archive other required paperwork

Table 2 represents the PRA activities conducted at a contract laboratory. Data are generated by following standard operating procedures, which involve mostly technical duties. As part of their duties under Good Laboratory Practices (GLP), the scientists and technicians maintain logbooks and other records from which the final report is written. This table lists activities that occur in the conduct of studies where the test subjects are animals. Activities associated with animal care would not occur in studies where the test subject is inanimate, such as product chemistry studies, environmental fate studies or residue chemistry studies.

Table 2

PHASE 2(b): PRA DATA GENERATION ACTIVITIES CONDUCTED AT THE CONTRACT LABORATORY*
Technical Duties
Individual animal care records
Records on the rooms in which animals are housed and procedures are performed
Necropsy records
Equipment logbooks and computer-generated records such as chromatograms
Records on preparation of analytical standards
Freezer and storage area logbooks
Chain-of-custody forms
Quality control/quality assurance forms and review checks for accuracy
Archive and transmittal of data forms

*The Agency recognizes that in certain instances these activities might be conducted “in-house.”

VI. Variations of the response to a DCI

Because there are multiple ways of responding to a DCI, not all DCI recipients participate in all three phases. A registrant would participate only in phase 1 if

they:

- Voluntarily cancel the pesticide registration
- Delete the uses of the product to which the requirements apply
- Qualify for a generic data exemption
- Request and receive a data waiver
- Purchase/cite existing data

A registrant who purchases/cites existing data performs Phase 1 Initial response and Phase 3 Data Submission activities only. The initial response phase and the data submission phase are considered to have more-or-less fixed hours and costs since reading the regulations and preparing submissions to the Agency are independent of the type of information submitted.

Until the Agency receives the 90-day response letters to the DCI notice from the registrants indicating what studies, if any, they will conduct, it is not possible to accurately predict the total cost and burden of developing the data.

This methodology was prepared so that an average burden could be presented for a DCI recipient, regardless of the response they choose. Clearly, by assuming that all DCI recipients engage in all three activities the Agency has chosen to overestimate the burden for a DCI recipient who may not engage in any activities beyond Phase 1. The cost for DCI recipients who engage in a taskforce for data generation, voluntarily cancel the product or affected uses, submit or cite existing data, or are granted a waiver incur fewer burden hours and costs.

a. Data generation in response to a DCI

A registrant who chooses to generate data in response to the DCI may either:

- generate and submit the required data on their own, or
- generate and submit the required data as part of a taskforce.

Data generation is considered the most expensive of the three phases. However, the amount of the expense is highly dependent on the type of data required. Therefore, it is logical to assume that the more expensive the study, the greater the paperwork burden hours and costs. For a DCI recipient to generate and submit the required data on their own is the most expensive of the response scenarios. However, the cost for DCI respondents who pool their resources for data generation with other stakeholders is less than those who engage in data generation activities on their own. Therefore, the Agency encourages cost-sharing agreements among manufacturers of specific pesticide chemicals to minimize the duplication of laboratory tests conducted in response

to a DCI. DCI notices explain the statutory provisions for cost sharing agreements for FIFRA.

b. Phase 1 and Phase 3 response activities for data generaters

Phase I and Phase 3 DCI response activities are a subset of the paperwork burden hours and costs estimates related to generating data to respond to a DCI notice. Unlike the wide variation of the costs for data generation, Phase 1 and Phase 3 response costs are more or less fixed costs. Generally, less than twenty-five (25) burden hours are spent on these activities at a cost of around $2,000 (indexed to 2006 dollars). Section II of this document presents a discussion of these burden hours and costs.

Section II. Estimating Paperwork Activities Of Data Generation

I. What are the key assumptions when estimating PRA burden hours and costs for data generation?

a. Paperwork activities are generally 35% of the cost of the study.

For more than a decade, EPA has been estimating all the paperwork burden hours and costs of responding to a DCI notice as approximately 35% of the cost of the study, see Figure - 1 Relationship of Test Costs to Response Phases. This formula allows the Agency to derive a reasonable estimate of for PRA activities (Phases 1, 2, and 3) by using the average estimated cost of specific tests. This approach was adopted because it allows the Agency to consider the potential for there to be more burdens related to a more complex study. The premise is that a more expensive test may cause the respondent to incur more burden hours and costs than a less expensive test would. This estimate is only applicable to DCI-related data generation. This percentage was developed from numerous sources of information including agency expertise, industry consultation, and repeated review by the public, industry, key stakeholders, and OMB on the Agency's information collection activities.

EPA assumes that 35% of the cost of any given test reflects all burdens and costs necessary for the completion of the paperwork activities. The paperwork burden and cost fall into two general categories of activity burden, administrative and technical:

Administrative Paperwork Burden is defined as the labor time spent communicating and working with the Agency and planning a response to the DCI and the planning of data collection and submittal activities. Generally, the respondent will conduct collection activities listed in the Section 1, Table 1-Response Phases (Phase 1 and Phase 3). The labor cost related to the Administrative category of paperwork burden is assumed to equal 2% of the total test cost (2% of total test cost = Administrative Paperwork Burden Cost).

Technical Paperwork Burden is the labor time needed to complete the paperwork associated with the initiation of testing, collecting and maintaining data, use of laboratory standards, data analysis, data compiling, data entry, oversight of contractor or employee activities, and decision-making. Generally, the respondent will conduct collection activities listed in Table 1-Response Phases (Phase 2(a)). This contract laboratory will conduct collection activities listed in Table 2 (Phase 2(b)). The labor cost for the technical category of paperwork burden is assumed to equal 33% of the total test cost. (33% of total test cost = Technical Paperwork Burden Cost)

Thus, [Administrative paperwork (2% of total test cost)] + [Technical paperwork

(33% of total test cost)] = total test-related paperwork burden hours and costs (35% of total test cost). This aggregate paperwork burden and cost estimate of 35% for data generation activities is used in a number of DCI-related Agency information collection activities, including:

- Data Acquisition for Registration (OMB #2070-0122; EPA #1503);
- Data Generation for Pesticide Reregistration (OMB #2070 - 0107; EPA #1504);
- Data Call-Ins for Special Review and Registration Review Programs (OMB #2070-0057; EPA #0922); and
- Anticipated Residue/Percent Crop Treated (OMB #2070-0164; EPA #1911).

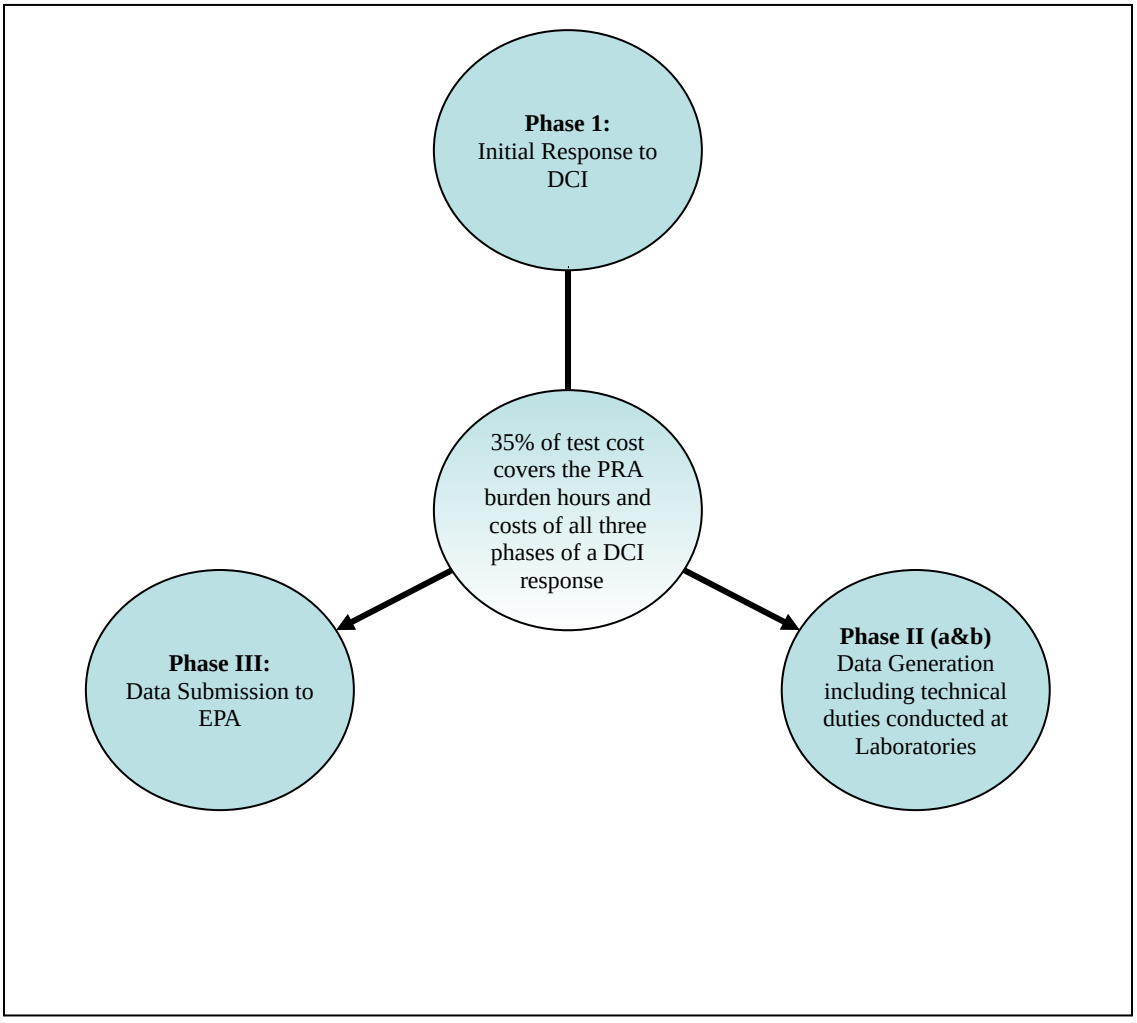

Figure - 1 Relationship of Test Costs to Response Phases

b. All registrants generate all DCI data

The paperwork activity estimates are based on the average cost of generating new data. The total cost of the paperwork burden hours and costs is equal to approximately 35% of the total costs to generate new data. This approach assumes:

- Registrants generate all of the data as specified in the DCI notice.[4]
- All data generation was performed by an independent laboratory.
- Paperwork burden consists of an administrative (2%) and technical (33%) burden. These two categories relate to office and laboratory activities, respectively.
- Paperwork burden is disaggregated by labor category as follows:[5]
    a. Managerial (20%)
    b. Technical (65%)
    c. Clerical (15%)
- Labor rates are derived from the parent ICR
- Labor rates are "fully loaded[6]"

To estimate paperwork activities for each type of labor category (managerial, technical, and clerical), the disaggregated paperwork burden costs are divided by their corresponding labor rates ($/hr). EPA assumes that DCI respondents who generate all requested data on their own is the most expensive of the response options considered and represents the maximum potential estimate of overall burden.

II. How are test cost estimates developed?

The Agency maintains an archive of the basic FIFRA study cost estimates that were developed through surveys of independent testing laboratories, Agency economic analyses, and registrant comments during ICR renewal periods. To the extent possible, EPA uses multiple sources to provide test cost estimates, which are updated as needed. Attachment B contains a listing of the FIFRA study cost estimates currently on file with the Agency. The chart also provides the paperwork burden hour and cost estimates for specific studies.

III. What if test cost estimates are unavailable?

The Agency may request certain special studies or non-guideline studies that

[4] Assumes registrants perform most of the PRA activities highlighted in, Section I-V, "DCI burden activity tables;" Table 1 – Response Phases
[5] See Section I-V, "DCI burden activity tables;" Table 1 – Response Phases; which lists specific managerial, technical, and clerical duties.
[6] "Fully loaded" labor rates are meant to be the estimated costs of wages, overhead, and benefits paid to an employee.

have not been previously required, and for which test cost estimates have not yet been calculated. If the estimated test cost is not readily available to the Agency at the time that a particular test is requested, EPA will estimate the cost on the basis of:

- EPA staff expertise and experience;
- similarity with another study protocol for which cost estimates are available;
- type of study requested (e.g., animal studies, field monitoring, and other possible test parameters);
- level of work that EPA expects will be involved in generating the data (high medium, or low effort required); and/or
- time required to complete the test.

The Agency's estimate would then serve as the default test cost for use in calculating the paperwork burden. EPA will update and revise these default test costs as more reliable estimates are obtained.

IV. What if the available test cost estimates vary?

To the extent possible, EPA uses multiple sources to provide test cost estimates. If several cost estimate exist for a particular study, but the differing estimates fall within an acceptable range, EPA will use the average estimate as its estimate. For example, if test cost estimates for a study were quoted at $20,000, $30,000, and $40,000, these estimates would be considered to fall within an acceptable range, and the average of $30,000 would be used in EPA's estimation of paperwork burden. If EPA finds that the quoted test costs for a given test varies widely among sources (i.e., the variation is not within a reasonable range), then EPA will make a case-by-case decision on how to estimate an average test cost using the criteria listed in section II-III (What if tests costs are unavailable).

V. What are the steps in calculating the paperwork burden (hours and costs)?

a. Calculate test costs

Using the EPA archive information of FIFRA study cost estimates, the Agency calculates the total paperwork burden hours and costs for a test as 35% of the total test cost (administrative paperwork burden as 2% and technical paperwork burden as 33% of the total test cost). This percent-based estimate of paperwork burden is reflective of expert opinion, information from industry, various proprietary information/data, and a general assessment of test costs.

b. Distribute paperwork activities among labor categories.

As an entity prepares a data generating response to the DCI notice, EPA

assumes managerial, technical, and clerical staff will undertake certain activities. Paperwork burden costs are divided among managerial, technical, and clerical staff labor categories (see Table 3, below) to reasonably reflect, on average, the percent of work performed.

Table 3: Distribution of Paperwork Activities Across Labor Categories*	
Labor category	*% of Paperwork Activities Performed*
Managerial	20%
Technical	65%
Clerical	15%

Using this percentage system, EPA can assign a paperwork activity cost to each labor category.

> For example**,** study guideline 850.1735, Whole Sediment Acute Toxicity, has an estimated cost of $20,250. To assign a paperwork activity cost to each labor category, and to eventually arrive at a total estimate of paperwork burden in hours and costs, the steps below are taken.
>
> Labor category activities:
>
> Managerial labor: $1,417.50 = ($7,087.50 * 0.20)
> Technical labor: $4,606.88 = ($7,087.50 * 0.65)
> Clerical labor: $1,063.12 = ($7,087.50 * 0.15)
> Total paperwork activities cost: = $7,087.50

EPA would estimate that $7,087.50 or 35% of the total test cost represents the cost of the total paperwork burden activities.

c. Calculate paperwork burden hours from labor cost distribution.

The second component for estimating DCI PRA activities is to estimate the average amount of time required to complete activities such as obtaining, compiling, preparing and submitting information to EPA. After distributing the paperwork costs among the managerial, technical and clerical labor categories, the paperwork burden hours are then derived by dividing the costs using fully-loaded wage rates ($/hour) compiled from the Department of Labor's Bureau of Labor Statistics which are shown in Table 4.

Table 4: Fully-Loaded Hourly Wage Rates, by Labor Category*	
Labor category	*Rate ($/hour)*
Managerial	$100.86
Technical	$64.80
Clerical	$33.05

To estimate paperwork burden in hours, using the hourly wage rates listed in Table 4, the steps below are taken.

Distribution of paperwork burden hours and costs for labor categories:

Managerial labor: 14.05 hours ($1,417.50)
Technical labor: 71.04 hours ($4,606.88)
Clerical labor: 32.17 hours ($1,063.12)

Total paperwork burden hours = 117.31 hours

VI. Is the burden for those not generating data covered?

As discussed in Section 1-VI, (Variations of the response to a DCI), there are multiple ways of responding to a DCI and not all DCI recipients will generate and submit data as part of the DCI response. Until the Agency receives the 90-day response letters to the DCI notice from the registrants indicating what studies, if any, they will conduct, it is not possible to predict the burden and costs of developing the data. Since the Agency cannot predict the number of DCI recipients who will actually generate data or the amount of data that might be submitted, EPA submits paperwork burden estimates to OMB for DCI response activities under all three Phases (1, 2, and 3). Therefore the Agency uses a default assumption that all DCI recipients will need to generate all of the data requested. The Agency recognizes that using this default assumption inflates the paperwork burden estimates associated with the DCI and renders an overstatement of the burden and cost. The Phase I and Phase 3 response activity burden hours and costs are accounted for in the existing DCI ICRs as a subset of the paperwork burden estimates for information collection activities that are related to generating data to respond to a DCI notice.[7]

In 2006, the Agency conducted a preliminary analysis of existing information from certain collections to estimate the PRA burden of paperwork activities that do not involve data generation, such as Phase 1 responses to DCIs . For the study, the Agency chose two ICRs in which PRA burden hours and costs for paperwork activities that do not involve data generation are clearly defined. The first, the Application for New and Amended Pesticide Registration ICR, OMB No. 2070-0060, (EPA ICR No. 0277.14) represents the majority of paperwork activities that do not involve data generation for applications for pesticide registration and the second ICR, the Data Generation for Pesticide Reregistration ICR, OMB No. 2070-0107, (EPA ICR No. 1504.05) represents all DCI related PRA burden and costs. The subset of paperwork activities that do not involve data generation was tallied and the burden hours and costs from both ICRs were estimated. Finally, information from the Economic Analysis of the Proposed Change to Data Requirements Rule for Biochemical and Microbial Pesticides, September 2, 2005,[8] was also used to extract costs for activities that do not involve data

[7] See Section 1-V "DCI burden activity tables;" Table 1 – Response Phases.

[8] See Environmental Protection Agency proposed rule 40 CFR parts 158 and 172, Subparts L&M:

generation. Of these three studies, the estimates of costs of paperwork that do not involve data generation were 1) $1169.00; 2) $1417.00 and 3) $2000.00 per response respectively. The Agency believes these costs generally represent the range for paperwork burden and cost that registrants who are not generating data might be incur when creating Phase 1 responses. These analyses are discussed in detail in Attachment A.

Data Requirements for Registration of Biochemical and Microbial Pesticides, (45 FR 12072 Wednesday March 8, 2006), section XVII Regulatory Assessment. For specific information refer to the docket EPA-HQ-OPP-2004-0415, document 6, U.S. EPA, 2005, "Economic Analysis of the Proposed Change to Data Requirements Rule for Biochemical and Microbial Pesticides," FEAD/OPP/U.S. EPA, Washington, DC.

Attachment A

Case Studies: Agency Analysis of Response Costs for Phase 1 Responses

1. Study #1: Review of the Application for New and Amended Pesticide Registration, OMB No. 2070-0060, (EPA ICR No. 0277.14) representing burden hours and costs for paperwork activities that do not involve data generation for applications for pesticide registration

In this study, EPA assumes:

1. Paperwork activities for applications for registration for "me-too" pesticides[9] are similar to paperwork activities for developing a DCI response that does not entail generating new data or requesting a waiver.
2. Estimated burden and costs listed in Table A are fixed, consistent costs for every respondent, and are not derived from any test cost estimates.
3. Technical labor efforts are not calculated because the Agency assumes no technical burden would be involved in developing a DCI response that does not entail generating new data or requesting a waiver.[10]
4. The paperwork burden for phase 1 responses that are similar to activities in developing registration applications may be described as follows:
    a. read and discuss test requirements (read the DCI letter to understand what data are to be submitted);
    b. plan activities (includes time for reviewing internal company information);
    c. complete paperwork (prepare necessary correspondence, documents to EPA);
    d. Store/maintain information (maintain information submitted to the Agency in company files).
5. Paperwork burden for such activities may be disaggregated by labor

[9] "Me too" pesticides are pesticides that are substantially similar to an existing pesticide. When applying for a "me-too" registration, a registrant would either cite existing data or claim eligibility for a formulator's exemption. A registrant is eligible for a formulators exemption if he uses a registered pesticide product as the source of the active ingredient in his product. Little or no technical labor is involved for this type of response.

[10] As an example, consider the DCI respondent who claims a generic data exemption (GDE) as their response to a DCI. A generic data exemption is the same as a formulator's exemption. Little or no technical labor burden is involved for this type of response.

category as follows (percentages are approximations):
   a. Managerial (65%)
   b. Technical (0%)
   c. Clerical (35%)
6. Labor rates are derived from the parent ICR.
7. Labor rates are fully loaded.

The supporting statement of the Application for New and Amended Pesticide Registration ICR characterizes the activities that would be needed for an application/notification. These activities are substantially similar to those of Phase 1: Initial Response that do not involve generating data or requesting a data waiver. The applicable activities are reproduced in Table A below:

Table A: Estimated Burden/Cost for Phase 1 Response*

Collection Activity	Burden Hours			Totals	
	Management	Technical	Clerical	Hours	Cost
Read instructions	7	0	0	7	938
Plan activities	0.5	0	0	0.5	67
Complete Paperwork	0	0	3	3	123
Store/maintain data	0	0	1	1	41
Totals	7.5	0	4	11.5	1169

(* Indexed to 2005 dollars)

After distributing the paperwork costs among the managerial and clerical staff labor categories, the paperwork burden hours are then derived by dividing the costs using the fully-loaded wage rates ($/hour) compiled in the parent ICR, Review of the Application for New and Amended Pesticide Registration, OMB No. 2070-0060, (EPA ICR No. 0277.14) approved by Office of Management and Budget, November 8, 2005.

2. Study #2: Data Generation for Pesticide Reregistration ICR, OMB No. 2070-0107, (EPA ICR No. 1504.05).

In this study EPA assumes:

1) The total paperwork burden hours and costs for Phase 1 responses are approximately 7 percent of the estimated average cost to generate new data.
2) Registrant responses to the DCI notice that do not involve data generation include voluntary cancellation, submitting or citing existing data, requesting a data waiver, or claiming eligibilitygeneric data exemption.
3) Paperwork activities that do not involve data generation may be described as follows:
    a. read and discuss test requirements (read the DCI letter to understand what data are to be submitted);
    b. plan activities (developing options for not generating new data includes reviewing internal company information for existing data);
    c. complete paperwork (prepare necessary correspondence, documents and/or waiver requests to avoid having to submitting data to EPA);
    d. record, maintain and file information (maintain information submitted to the Agency in company files).
4) Paperwork burden for Phase 1 DCI responses activities may be disaggregated by labor category as follows (percentages are approximations):
    e. Managerial (50%)
    f. Technical (5%)
    g. Clerical (45%)
5) Labor rates are derived from the parent ICR
6) Labor rates are fully loaded.

a. Calculate Cost of Paperwork**.** Using the EPA maintained database of test cost estimates, the Agency calculates the total paperwork burden cost for a test as 7% of the total test cost because based on the percentage breakdown for paperwork burden applicable to non-data generation activities for this ICR. This percent-based estimate of paperwork burden is reflective of expert opinion, information from industry, various proprietary information/data, and a general assessment of test costs. These activities represent the Phase I DCI response activities discussed in section IV.

b. Distribute Paperwork Costs Among Labor Categories. As an entity prepares a response of non-data generation in response to the DCI notice, EPA assumes certain activities will be conducted by managerial, technical, and clerical staff. Paperwork activities are divided among these labor categories (see Table B below) to reasonably reflect, on average, the percent of work performed. These percentage breakdowns by labor category, derived from the parent ICR Data Generation for Pesticide Reregistration ICR, OMB No. 2070-0107, (EPA ICR No.

1504.05), are consistent for burden activities associated with confirmatory DCIs, product specific DCIs, and submission of voluntary studies cited within the parent ICR.

Table B: Distribution of Burden Across Labor Categories	
Labor category	*% of Paperwork Burden Activities Performed*
Managerial	50%
Technical	5%
Clerical	45%

For example the study guideline 850.1735, Whole Sediment Acute Toxicity, has an estimated cost of $20,250. Estimates for paperwork cost for these non-data generation activities would be:

Managerial labor: $708.75 = ($1,417.50 * 0.50)
Technical labor: $70.88 = ($1,417.50 * 0.05)
Clerical labor: $637.87 = ($1,417.50 * 0.45)
Total labor: $1,417.50

EPA would estimate that $1,417.50 or 7% of the total test cost represents the cost of the total paperwork burden activities.

c. Calculate Paperwork Burden Hours From Labor Cost Distribution. After distributing the paperwork costs among the managerial, technical and clerical staff labor categories, the paperwork burden hours are then derived by dividing the costs using fully-loaded wage rates ($/hour) cited in the parent ICR and listed in Table C.

Table C: Fully-Loaded Hourly Wage Rates, by Labor Category*	
Labor category	*Rate ($/hour)*
Managerial	$130
Technical	$88
Clerical	$40

(Labor costs cited in the parent ICR - Indexed to 2004 dollars)

To estimate paperwork burden in hours, using the hourly wage rates listed in Table C, the steps below are taken.

Managerial labor: 5.45 hours ($708.75 ÷ $130/hr)
Technical labor: 0.81 hours ($70.88 ÷ $88/hr)
Clerical labor: 15.95 hours ($637.87 ÷ $40/hr)
Total hours: 22.21 hours

3. Study #3: Economic Analysis for Proposed Changes in Data Requirements Rule for Biochemical and Microbial Pesticides – Cost Estimates for Data Waivers.

Under 40 CFR 158.45, the Agency may waive data requirements on a case-by-case basis in response to specific requests by applicants. The Agency believes the paperwork burden and cost for developing a data waiver request is a relatively fixed cost. When the Agency analyzed burden and cost for data waivers in the Economic Analysis for Proposed Changes in Data Requirements Rule for Biochemical and Microbial Pesticides in 2005, the cost of applying for waivers was estimated to be approximately $2,000 per firm per registration action, *regardless* of the number of tests a waiver is applied for, if at least one waiver was granted. [11] EPA believes this unit of cost/burden may be applicable to the data waivers submitted to the Agency in response to a DCI. Under this assumption, all non-data generation paperwork activities would be placed at a fixed burden of 20 hours and the burden hours would be distributed as represented in Table D below.

Table D: Industry Estimated Burden/Cost Submitting a Data Waivers Response*

Collection Activity	Burden Hours			Totals	
	Management	Technical	Clerical	Hours	Cost
Research, Literature searches, Calculations & analysis		10		10	1000
Compiling rational		8		8	800
Review document file and submit	1		1	2	200
Total				20	2000

[11] The Biopesticide Industry Alliance Regulatory Committee provided additional informal cost estimates to EPA. Burden breakdown and costs estimates would be: Research, literature searches, calculations, analysis etc. = 10 hours = $1000 writing; compiling the rationale = 8 hours = $800; and managerial/clerical = 2 hours = $200. For a total of $2,000.00 for each waiver. A general $100.00 per hour for consultant costs was provided to EPA.

Attachment B

Chart: FIFRA Estimated Study Costs And Paperwork Burden Hour And Cost Estimates

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	**Test Name**	**AverageTest Cost**	**Total Paperwork Burden Cost**	**Total Paperwork Burden Hours**	**High Test Cost** *(High AVG for 2005 SciReg)*	**Low Test Cost** *(Low AVG for 2005 SciReg)*
Product Performance						
810.1000	Overview, Definitions, and General Considerations	$100,000.0	$35,000.0	443.6	$100,000.0	$100,000.0
810.1550	Product Identity and Disclosure of Ingredients (Composition) (Chemical Identity)	$223.0	$78.1	1.0	$223.0	$223.0
810.2100	Products for hard surfaces -EPA Disinfectant test	$6,600.0	$2,310.0	29.3	$7,200.0	$6,000.0
810.2100	Products for hard surfaces - AOAC Fungicide test	$1,600.0	$560.0	7.1	$2,000.0	$1,200.0
810.2100(b)&(i)	Chemical Analysis	$5,339.0	$1,868.7	23.7	$6,701.0	$3,976.0
810.2100(m)(2)	Products for hard surfaces - AOAC Germicidal, detergent sanitizers	$3,500.0	$1,225.0	15.5	$4,000.0	$3,000.0
810.21000(j)	Products for hard surfaces -Sanitizer test non food	$4,000.0	$1,400.0	17.7	$5,000.0	$3,000.0
810.2100b,c,d or i	Products for hard surfaces -AOAC use dilution test, germicidal	$6,000.0	$2,100.0	26.6	$7,000.0	$5,000.0
810.2100c,d,e	Products for hard surfaces -AOAC Use dilution/germicidal spray/carrier	$6,000.0	$2,100.0	26.6	$7,000.0	$5,000.0
810.2100(f)	Products for hard surfaces - Fungicidal test	$1,600.0	$560.0	7.1	$2,000.0	$1,200.0
810.2100(g)	Products for hard surfaces - Virucidal activity method	$4,000.0	$1,400.0	17.7	$6,000.0	$2,000.0
810.2100(g)	Products for hard surfaces -AOAC Tuberculocidal test	$3,250.0	$1,137.5	14.4	$5,000.0	$1,500.0
810.2100(l)	Products for hard surfaces - Hard inanimate surface non food	$4,000.0	$1,400.0	17.7	$5,000.0	$3,000.0
810.2200	Products for hard surfaces - AVG	$6,187.0	$2,165.5	27.4	$6,187.0	$6,187.0
810.2200 - itemized	Limited disinfectant	$4,201.0	$1,470.4	18.6	$5,010.0	$3,391.0
810.2200 - itemized	Broad spectrum disinfectant	$5,763.0	$2,017.1	25.6	$6,720.0	$4,806.0
810.2200 - itemized	Hospital disinfectant	$5,993.0	$2,097.6	26.6	$7,000.0	$4,986.0
810.2200 - itemized	Fungicidal disinfectant	$4,219.0	$1,476.7	18.7	$4,865.0	$3,572.0
810.2200 - itemized	Virucidal disinfectant	$13,068.0	$4,573.8	58.0	$19,574.0	$6,561.0
810.2200 - itemized	Tuberculocidal disinfectant	$4,691.0	$1,641.9	20.8	$5,633.0	$6,748.0
810.2200 - itemized	Additional bacteria	$4,082.0	$1,428.7	18.1	$4,803.0	$3,361.0

810.2200 - itemized	Non-food contact	$5,198.0	$1,819.3	23.1	$6,026.0	$4,370.0
810.2200 - itemized	Food contact - Halide products	$4,455.0	$1,559.3	19.8	$5,195.0	$3,714.0
810.2200 - itemized	Food contact - Non-halide products	$6,086.0	$2,130.1	27.0	$7,301.0	$4,870.0
810.2200 - itemized	Sanitizers for urinal and toilet bowl water and in-tank sanitizers	$5,672.0	$1,985.2	25.2	$6,902.0	$4,441.0
810.2200 - itemized	Residual self-sanitizing - wet surfaces	$5,210.0	$1,823.5	23.1	$3,969.0	$6,451.0
810.2200 - itemized	Sterilants	$11,803.0	$4,131.1	52.4	$11,936.0	$11,669.0
810.2300b	Products for fabrics/textiles -EPA Carpet Sanitizer	$3,250.0	$1,137.5	14.4	$5,000.0	$1,500.0
810.2400	Products for air sanitizers	$5,500.0	$1,925.0	24.4	$6,500.0	$4,500.0
810.2400(b)(j)	Chemical Analysis	$175.0	$61.3	0.8	$350.0	$0.0
810.2400(b)(l)	Chemical Analysis	$4,000.0	$1,400.0	17.7	$4,000.0	$4,000.0
810.2600	Products for microbial pests associated with human and animal waste	$5,720.0	$2,002.0	25.4	$5,720.0	$5,720.0
810.2700(d)	Products for treating water systems AOAC- water disinfectants pools	$7,500.0	$2,625.0	33.3	$10,000.0	$5,000.0
810.3000	General considerations for Efficacy of invertebrate control agents	$600.0	$210.0	2.7	$600.0	$600.0
810.3100	Soil treatments for imported fire ants	$140,000.0	$49,000.0	621.1	$200,000.0	$80,000.0
810.3200	Livestock,poultry,fur and wool bearing animal treatments	$30,000.0	$10,500.0	133.1	$50,000.0	$10,000.0
810.3300	Treatments to control pests of human and pets	$50,000.0	$17,500.0	221.8	$60,000.0	$40,000.0
810.3400	Mosquito,blackfly and biting midge treatments	$140,000.0	$49,000.0	621.1	$200,000.0	$80,000.0
810.3500	Premises Treatments	$700,000.0	$245,000.0	3,105.3	$800,000.0	$600,000.0
810.3600	Structural Treatments	$1,200.0	$420.0	5.3	$1,200.0	$1,200.0
810.3700	Insect repellants for human skin and outdoor premises	$5,000.0	$1,750.0	22.2	$5,000.0	$5,000.0
810.3800	Methods for efficacy testing of termite baits	$60,000.0	$21,000.0	266.2	$100,000.0	$20,000.0
Product Chemistry						
830.1550	Product identity and composition	$233.0	$81.6	1.0	$223.0	
830.1600	Description of materials used to produce the product	$334.0	$116.9	1.5	$501.0	$167.0
830.1620	Description of production process	$418.0	$146.3	1.9	$167.0	$668.0
830.1650	Description of formulation process	$418.0	$146.3	1.9	$167.0	$668.0
830.1670	Discussion of formulation of impurities	$418.0	$146.3	1.9	$167.0	$668.0
830.1700	Preliminary analysis	$31,715.0	$11,100.3	140.7	$50,054.0	$8,875.0
830.1750	Certified limits	$248.0	$86.8	1.1	$330.0	$165.0
830.1800	Enforcement analytical method	$15,454.0	$5,408.9	68.6	$21,538.0	$9,371.0
830.1900	Submittal of samples	$495.0	$173.3	2.2	$660.0	$330.0
830.6302	Color	$700.0	$245.0	3.1	$1,000.0	$400.0
830.6303	Physical state	$700.0	$245.0	3.1	$1,000.0	$400.0
830.6304	Odor	$700.0	$245.0	3.1	$1,000.0	$400.0
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	$8,250.0	$2,887.5	36.6	$12,000.0	$4,500.0
830.6314	Oxidation/reduction: chemical incompatibility	$2,994.0	$1,047.9	13.3	$3,044.0	$2,944.0
830.6315	Flammability	$2,000.0	$700.0	8.9	$3,000.0	$1,000.0
830.6316	Explodability	$4,163.0	$1,457.1	18.5	$4,163.0	$4,163.0
830.6317	Storage stability	$11,500.0	$4,025.0	51.0	$15,000.0	$8,000.0
830.6319	Miscibility	$1,100.0	$385.0	4.9	$1,500.0	$700.0
830.6320	Corrosion characteristics	$2,750.0	$962.5	12.2	$3,500.0	$2,000.0
830.6321	Dielectric breakdown voltage	$2,525.0	$883.8	11.2	$2,675.0	$2,375.0
830.7000	pH	$750.0	$262.5	3.3	$1,000.0	$500.0

830.7050	UV/visible light absorption	$2,022.0	$707.7	9.0	$2,072.0	$1,972.0
830.7100	Viscosity	$1,400.0	$490.0	6.2	$2,000.0	$800.0
830.7200	Melting point/melting range	$1,200.0	$420.0	5.3	$1,600.0	$800.0
830.7220	Boiling point/boiling range	$1,500.0	$525.0	6.7	$2,000.0	$1,000.0
830.7300	Density/relative density/bulk density	$1,400.0	$490.0	6.2	$2,000.0	$800.0
830.7370	Dissociation constants in water	$4,845.0	$1,695.8	21.5	$4,845.0	$4,845.0
830.7520	Particle size, fiber length, and diameter distribution	$1,333.0	$466.6	5.9	$1,333.0	$1,333.0
830.7550	Partition coefficient (n-octanol/water) - shake flask method	$6,667.0	$2,333.5	29.6	$7,333.0	$6,000.0
830.7560	Partition coefficient (n-octanol/water) -generator column	$6,667.0	$2,333.5	29.6	$7,333.0	$6,000.0
830.7570	Partition coefficient (n-octanol/water) -estimation chromatography	$4,388.0	$1,535.8	19.5	$4,700.0	$4,075.0
830.7840	Water Solubility: column elution/shake flask	$9,635.0	$3,372.3	42.7	$11,322.0	$7,947.0
830.7860	Water solubility	$9,635.0	$3,372.3	42.7	$11,322.0	$7,947.0
830.7950	Vapor pressure	$15,000.0	$5,250.0	66.5	$20,000.0	$10,000.0
Spray Drift						
840.1100	Spray droplet size spectrum	$258,750.0	$90,562.5	1,147.9	$340,000.0	$177,500.0
840.1200	Spray drift field deposition	$16,250.0	$5,687.5	72.1	$25,000.0	$7,500.0
Ecological Effects Tests						
850.1000	Use Profile	$251.0	$87.9	1.1	$334.0	$167.0
850.1010	Aquatic invertebrate acute toxicity, freshwater daphnids	$17,000.0	$5,950.0	75.4	$20,000.0	$14,000.0
850.1020	Gammarid acute toxicity test	$0.0	$0.0	0.0	$0.0	$0.0
850.1025	Oyster acute toxicity test	$32,725.0	$11,453.8	145.2	$32,725.0	$7,550.0
850.1035	Mysid acute toxicity test	$32,725.0	$11,453.8	145.2	$32,725.0	$7,550.0
850.1045	Penaeid acute toxicity test	$32,725.0	$11,453.8	145.2	$32,725.0	$7,550.0
850.1055	Bivalve acute tox larval (embryo/larval)	$32,725.0	$11,453.8	145.2	$32,725.0	$7,550.0
850.1075	Fish acute toxicity (freshwater)	$17,000.0	$5,950.0	75.4	$28,061.0	$10,066.0
850.1075	Fish acute toxicity test (estaurine/marine)	$20,138.0	$7,048.3	89.3	$20,138.0	$20,138.0
850.1300	Daphnid chronic toxicity test	$118,063.0	$41,322.1	523.7	$162,800.0	$73,325.0
850.1350	Mysid chronic tox - aquatic invertebrate life-cycle (saltwater)	$36,333.0	$12,716.6	161.2	$41,000.0	$31,667.0
850.1400	Fish early-life stage toxicity test (freshwater)	$37,279.0	$13,047.7	165.4	$41,379.0	$33,179.0
850.1450	Fish early-life stage toxicity test (saltwater)	$75,000.0	$26,250.0	332.7	$0.0	$0.0
850.1500	Fish life-cycle toxicity	$512,500.0	$179,375.0	2,273.5	$650,000.0	$375,000.0
850.1710	Aquatic Bioavailability/Biomagnification: Oyster BCF	$123,919.0	$43,371.7	549.7	$143,919.0	$103,919.0
850.1730	Aquatic Bioavailability/Biomagnification: Fish BCF	$140,452.0	$49,158.2	623.1	$169,279.0	$111,624.0
850.1735	Whole sediment acute toxicity invertebrates (freshwater)	$20,250.0	$7,087.5	89.8	$21,500.0	$26,000.0
850.1740	Whole sediment acute toxicity invertebrates (marine)	$37,500.0	$13,125.0	166.4	$50,000.0	$25,000.0
850.1790	Chironomid sediment toxicity test	$83,000.0	$29,050.0	368.2	$83,000.0	$83,000.0
850.1800	Tadpole/sediment subchronic toxicity test	$195,856.0	$68,549.6	868.9	$195,856.0	$195,856.0
850.1850	Aquatic food chain transfer - Bioavailability	$325,000.0	$113,750.0	1,441.8	$500,000.0	$150,000.0
850.1900	Generic freshwater microscosm test (laboratory)	$295,000.0	$103,250.0	1,308.7	$360,000.0	$230,000.0
850.1925	Site-specific aquatic microcosm test (laboratory)	$250,000.0	$87,500.0	1,109.0	$250,000.0	$250,000.0
850.1950	Simulated or actual field testing - field animal	$512,500.0	$179,375.0	2,273.5	$650,000.0	$375,000.0
850.1950	Simulated or actual field testing - aquatic	$600,000.0	$210,000.0	2,661.7	$700,000.0	$500,000.0
850.1950	Simulated or actual field testing - insect predators	$87,500.0	$30,625.0	388.2	$100,000.0	$75,000.0
850.1950	Simulated or actual field testing - plants	$62,500.0	$21,875.0	277.3	$75,000.0	$50,000.0
850.2100	Avian acute oral toxicity test	$10,100.0	$3,535.0	44.8	$13,800.0	$6,400.0

850.2200	Avian dietary toxicity test	$6,480.0	$2,268.0	28.7	$6,647.0	$6,313.0
850.2300	Avian reproduction test	$168,250.0	$58,887.5	746.4	$215,500.0	$121,000.0
850.2400	Wild mammal acute toxicity	$35,000.0	$12,250.0	155.3	$50,000.0	$20,000.0
850.2500	Simulated or actual field testing terrestrial wildlife	$527,502.0	$184,625.7	2,340.1	$552,000.0	$502,000.0
850.2500	Simulated or actual field testing - birds	$600,000.0	$210,000.0	2,661.7	$700,000.0	$500,000.0
850.3020	Honey bee acute contact toxicity	$3,175.0	$1,111.3	14.1	$3,175.0	$3,175.0
850.3030	Honey bee toxicity of residues on foliage	$13,368.0	$4,678.8	59.3	$16,670.0	$10,065.0
850.3040	Field testing for pollinators	$47,500.0	$16,625.0	210.7	$65,000.0	$30,000.0
850.4000	Background - Nontarget plant testing	$0.0	$0.0	0.0	$0.0	$0.0
850.4025	Target area phytotoxicity	$0.0	$0.0	0.0	$0.0	$0.0
850.4100	Terrestrial plant toxicity (seedling emergence, Tier I)	$14,625.0	$5,118.8	64.9	$15,625.0	$13,625.0
850.4150	Terrestrial plant toxicity (vegetative vigor, Tier I)	$14,625.0	$5,118.8	64.9	$15,625.0	$13,625.0
850.4200	Seed germination/root elongation toxicity test	$10,292.0	$3,602.2	45.7	$15,875.0	$4,709.0
850.4200	Seed germination/root elongation toxicity test	$25,602.5	$8,960.9	113.6	$30,930.0	$20,275.0
850.4230	Early seed growth toxicity test	$0.0	$0.0	0.0	$0.0	$0.0
850.4225	Seedling emergence, Tier II	$20,375.0	$7,131.3	90.4	$22,000.0	$18,750.0
850.4250	Vegetative vigor, Tier II	$24,500.0	$8,575.0	108.7	$26,500.0	$22,500.0
850.4300	Terrestrial plants field study, Tier III	$111,863.0	$39,152.1	496.2	$126,863.0	$26,500.0
850.4400	Aquatic plant toxicology test using Lemna spp., Tier I	$35,155.0	$12,304.3	156.0	$39,525.0	$18,750.0
850.4400	Aquatic plant toxicology test using Lemna spp., Tier II	$35,155.0	$18,632.2	236.2	$35,155.0	$35,155.0
850.4450	Aquatic plants field study, Tier III	$0.0	$0.0	0.0	$0.0	$0.0
850.5400	Algal Toxicity Tier I and Tier II	$35,155.0	$12,304.3	156.0	$35,155.0	$35,155.0
na	Acute toxicity to aquatic insects	$0.0	$0.0	0.0	$0.0	$0.0
na	Aquatic insect life-cycle study	$0.0	$0.0	0.0	$0.0	$0.0
na	Simulated or actual field testing for aquatic insects	$0.0	$0.0	0.0	$0.0	$0.0
na	Nontarget insect testing - predators and parasites	$0.0	$0.0	0.0	$0.0	$0.0
na	Nontarget insect testing - predators and parasites	$0.0	$0.0	0.0	$0.0	$0.0
Health Effects						
870.1100	Acute oral toxicity (rat)	$3,473.0	$1,215.6	15.4	$4,015.0	$2,932.0
870.1200	Acute dermal toxicity	$2,000.0	$700.0	8.9	$3,000.0	$1,000.0
870.1300	Acute inhalation toxicity (rat)	$2,000.0	$700.0	8.9	$3,000.0	$1,000.0
870.1300	Acute inhalation tox (microbials)	$12,000.0	$4,200.0	53.2	$20,000.0	$4,000.0
870.2400	Acute eye irritation (rabbit)	$2,000.0	$700.0	8.9	$3,000.0	$1,000.0
870.2500	Acute dermal irritation	$2,000.0	$700.0	8.9	$3,000.0	$1,000.0
870.2600	Skin (dermal) sensitization	$8,000.0	$2,800.0	35.5	$10,000.0	$6,000.0
870.3100	90-day oral toxicity in rodents	$138,106.0	$48,337.1	612.7	$142,517.0	$133,695.0
870.3150	90-day oral toxicity in non-rodents	$221,047.0	$77,366.5	980.6	$221,047.0	$221,047.0
870.3200	21/28-day dermal toxicity	$83,240.0	$29,134.0	369.3	$84,681.0	$81,798.0
870.3250	90-day dermal toxicity	$137,094.0	$47,982.9	608.2	$138,114.0	$137,094.0
870.3465	90-day inhalation toxicity (rat)	$300,000.0	$105,000.0	1,330.9	$350,000.0	$300,000.0
870.3700	Prenatal developmental toxicity study (rat and rabbit, preferred)	$76,844.0	$26,895.4	340.9	$77,037.0	$76,844.0
870.3800	Reproduction and fertility effects (multigeneration)	$378,479.0	$132,467.7	1,679.0	$381,233.0	$378,479.0
870.4100	Chronic tox (rodent and non-rodent)	$950,000.0	$332,500.0	4,214.4	$1,100,000.0	$950,000.0
870.4200	Carcinogenicity (rat and mouse, preferred)	$1,730,000.0	$605,500.0	7,674.6	$2,060,000.0	$1,730,000.0
870.4200	Carcinogenicity (microbials)	$922,244.0	$322,785.4	4,091.2	$925,806.0	$922,244.0
870.5100	Bacterial reverse mutation assay	$4,057.0	$1,420.0	18.0	$4,457.0	$4,057.0

870.5300	In vitro mammalian cell gene mutation test	$18,654.0	$6,528.9	82.8	$19,767.0	$18,654.0
870.5375	In vitro mammalian chromosomal aberration test	$0.0	$0.0	0.0	$0.0	$0.0
870.5380	Mammalian spermatogonial chromosomal aberration test	$19,382.0	$6,783.7	86.0	$19,382.0	$19,382.0
870.5385	Mammalian bone marrow chromosomal aberration test	$30,004.0	$10,501.4	133.1	$30,004.0	$30,004.0
870.5395	Mammalian erthrocyte micronucleus test	$20,477.0	$7,167.0	90.8	$20,594.0	$20,477.0
none	Reference list of all studies/papers known to the applicant concerning mutagenicity	$418.0	$146.3	1.9	$418.0	$418.0
870.5450	Rodent dominant lethal assay	$0.0	$0.0	0.0	$0.0	$0.0
870.5500	Bacterial DNA damage or repair tests	$0.0	$0.0	0.0	$0.0	$0.0
870.5550	Unscheduled DNA synthesis in mammalian cells in culture	$30,000.0	$10,500.0	133.1	$0.0	$0.0
870.6100	Acute and 28 day delayed neurotoxicity organophosphorus substances (hen)	$79,375.0	$27,781.3	352.1	$80,625.0	$72,125.0
870.6200	Acute neurotoxicity (rat)	$89,596.0	$31,358.6	397.5	$91,680.0	$87,513.0
870.6200	90-day Neurotoxicity (rat)	$184,039.0	$64,413.7	816.4	$186,410.0	$181,668.0
870.6300	Developmental neurotoxicity study	$406,904.0	$142,416.4	1,805.1	$417,135.0	$396,904.0
870.6500	Schedule-controlled operant behavior	$164,000.0	$57,400.0	727.5	$164,000.0	$164,000.0
870.6850	Peripheral nerve function	$110,000.0	$38,500.0	488.0	$110,000.0	$110,000.0
870.6855	Neurophysiology: sensory evoked potentials	$110,000.0	$38,500.0	488.0	$110,000.0	$110,000.0
870.7200	Companion animal safety	$156,000.0	$54,600.0	692.0	$167,667.0	$144,333.0
870.7485	Metabolism and pharmacokinetics	$182,729.0	$63,955.2	810.6	$217,729.0	$147,729.0
870.7600	Dermal penetration	$147,529.0	$51,635.2	654.5	$175,346.0	$119,711.0
870.7800	Immunotoxicity	$56,648.0	$19,826.8	251.3	$57,731.0	$55,565.0
Occupational and Residential Exposure						
875.1100	Dermal outdoor exposure	$167,857.0	$58,750.0	744.6	$192,143.0	$143,571.0
875.1200	Dermal indoor exposure	$126,429.0	$44,250.2	560.9	$150,714.0	$102,143.0
875.1300	Inhalation outdoor exposure	$164,286.0	$57,500.1	728.8	$181,429.0	$147,143.0
875.1400	Inhalation indoor exposure	$126,429.0	$44,250.2	560.9	$150,714.0	$102,143.0
875.1500	Biological monitoring	$188,393.0	$65,937.6	835.7	$219,256.0	$157,500.0
875.1600	Application exposure data reporting and calculations	$7,500.0	$2,625.0	33.3	$10,000.0	$5,000.0
875.1700	Product use information	$3,000.0	$1,050.0	13.3	$4,000.0	$2,000.0
875.2100	Dislodgeable foliar residue dissipation and turf transferable residues	$55,100.0	$19,285.0	244.4	$56,100.0	$54,100.0
875.2200	Soil residue dissipation	$83,125.0	$29,093.8	368.8	$85,000.0	$81,250.0
875.2300	Indoor surface residue dissipation	$35,000.0	$12,250.0	155.3	$35,000.0	
875.2400	Dermal exposure	$125,500.0	$43,925.0	556.7	$133,000.0	$118,000.0
875.2500	Inhalation exposure	$73,000.0	$25,550.0	323.8	$81,000.0	$65,000.0
875.2600	Biological monitoring	$166,875.0	$58,406.3	740.3	$191,667.0	$142,083.0
875.2700	Product use information	$3,000.0	$1,050.0	13.3	$4,000.0	$2,000.0
875.2800	Description of human activity	$3,000.0	$1,050.0	13.3	$4,000.0	$2,000.0
875.2900	Data reporting and calculations	$3,000.0	$1,050.0	13.3	$4,000.0	$2,000.0
875.3000	Nondietary ingestion exposure	$75,000.0	$26,250.0	332.7	$83,333.0	$66,667.0
Environmental Fate						
none	Use Profile	$251.0	$0.0	0.0	$334.0	$167.0
835.1230	Sediment and soil adsorption/desorption	$23,750.0	$8,312.5	105.4	$24,583.0	$22,917.0
835.1240	Leaching and adsorption/desorption	$46,780.0	$16,373.0	207.5	$51,880.0	$41,680.0
835.1410	Laboratory volatility	$45,000.0	$15,750.0	199.6	$5,000.0	$40,000.0
835.2120	Hydrolysis	$25,230.0	$8,830.5	111.9	$29,900.0	$20,560.0

835.2240	Photodegradation in water	$46,875.0	$16,406.3	207.9	$47,875.0	$47,875.0
835.2370	Photodegradation in air	$110,000.0	$38,500.0	488.0	$120,000.0	$100,000.0
835.2410	Photodegradation on soil	$42,350.0	$14,822.5	187.9	$45,183.0	$39,517.0
835.4100	Aerobic soil metabolism	$94,375.0	$33,031.3	418.7	$98,625.0	$90,125.0
835.4200	Anaerobic soil metabolism	$71,300.0	$24,955.0	316.3	$71,300.0	$71,300.0
835.4300	Aerobic aquatic metabolism	$44,475.0	$15,566.3	197.3	$47,350.0	$41,600.0
835.4400	Anaerobic aquatic metabolism	$80,900.0	$28,315.0	358.9	$86,525.0	$72,275.0
835.6100	Terrestrial field dissipation	$317,767.0	$111,218.5	1,409.7	$366,067.0	$269,467.0
835.6200	Aquatic field dissipation	$267,250.0	$93,537.5	1,185.6	$354,000.0	$180,500.0
835.6300	Forestry dissipation	$275,500.0	$96,425.0	1,222.2	$362,500.0	$188,500.0
835.6400	Combination and tank mixes	$219,200.0	$76,720.0	972.4	$219,200.0	
835.8100	Field volatility	$230,900.0	$80,815.0	1,024.3	$230,900.0	
835.7100	Groundwater Monitoring	$1,225,000.0	$428,750.0	5,434.3	$2,000,000.0	$450,000.0
none	Monitoring of representative U.S. waters	$215,833.0	$75,541.6	957.5	$263,333.0	$168,333.0
none	Leaching study	$43,000.0	$15,050.0	190.8	$48,000.0	$38,000.0
Residue Chemistry						
860.1100	Chemical identity	$1,250.0	$437.5	5.5	$2,000.0	$500.0
860.1200	Directions for use	$4,000.0	$1,400.0	17.7	$5,000.0	$3,000.0
860.1300	Nature of the residue in plants	$100,000.0	$35,000.0	443.6	$105,000.0	$95,000.0
860.1300	Nature of the residue in livestock	$105,833.0	$37,041.6	469.5	$118,333.0	$93,333.0
860.1340	Residue analytical method - plants	$22,125.0	$7,743.8	98.2	$23,250.0	$19,000.0
860.1340	Residue analytical method - livestock	$65,500.0	$22,925.0	290.6	$76,800.0	$54,200.0
860.1360	Multiresidue method	$24,000.0	$8,400.0	106.5	$25,667.0	$22,333.0
860.1380	Storage stability data	$18,500.0	$6,475.0	82.1	$18,500.0	$18,500.0
860.1400	Water	$53,750.0	$18,812.5	238.4	$55,000.0	$52,500.0
860.1400	Fish	$104,000.0	$36,400.0	461.4	$130,000.0	$78,000.0
860.1400	Irrigated crops *(one-crop)*	$18,000.0	$6,300.0	79.9	$20,500.0	$15,500.0
860.1460	Food handling	$205,000.0	$71,750.0	909.4	$230,000.0	$180,000.0
860.1480	Meat/milk/poultry/eggs	$149,000.0	$52,150.0	661.0	$152,333.0	$145,667.0
860.1500	Crop field trials	$163,667.0	$57,283.5	726.1	$177,000.0	$150,333.0
860.1520	Processed food/feed	$35,000.0	$12,250.0	155.3	$37,333.0	$32,667.0
860.1540	Reduction of Residues	$15,000.0	$5,250.0	66.5	$20,000.0	$10,000.0
860.1550	Proposed tolerance	$5,363.0	$1,877.1	23.8	$6,600.0	$4,124.0
860.1560	Reasonable grounds in support of the petition	$10,000.0	$3,500.0	44.4	$15,000.0	$5,000.0
860.1650	Submittal of analytical reference standards	$334.0	$116.9	1.5	$501.0	$167.0
860.1850	Confined accumulation in rotational crops	$249,845.0	$87,445.8	1,108.4	$269,845.0	$229,845.0
860.1900	Field accumulation in rotational crops	$137,500.0	$48,125.0	610.0	$125,000.0	$150,000.0
none	Migration Studies	$105,000.0	$36,750.0	465.8	$120,000.0	$90,000.0
Microbial Pesticides						
880.1100	Product identity	$233.0	$81.6	1.0	$300.0	$165.0
880.1200	Description materials, production, formulation	$908.0	$317.8	4.0	$1,650.0	$165.0
880.1400	Discussion of formation of impurities	$330.0	$115.5	1.5	$495.0	$165.0
880.3800	Immune Response	$85,000.0	$29,750.0	377.1	$100,000.0	$70,000.0
880.4350	Non-target insect testing	$15,000.0	$5,250.0	66.5	$18,000.0	$12,000.0
880.4425	Dispenser - water leaching	$25,000.0	$8,750.0	110.9	$30,000.0	$20,000.0

	Hypersensitivity incidents	$825.0	$288.8	3.7	$1,320.0	$330.0
885.1100	Product Identity	$5,000.0	$1,750.0	22.2	$8,000.0	$2,000.0
885.1200a	Manufacturing process	$3,500.0	$1,225.0	15.5	$5,000.0	$2,000.0
885.1200b	Deposition of samples	$3,500.0	$1,225.0	15.5	$5,000.0	$2,000.0
885.1300	Discussion of formulation of unintentional ingredients	$3,500.0	$1,225.0	15.5	$5,000.0	$2,000.0
885.1400	Analysis of samples	$74,500.0	$26,075.0	330.5	$145,000.0	$4,000.0
885.1500	Certification of limits	$350.0	$122.5	1.6	$500.0	$200.0
885.2000	Background for residue analysis of microbial pest control agents	$0.0	$0.0	0.0	$0.0	$0.0
885.2100	Chemical identity	$660.0	$231.0	2.9	$825.0	$495.0
885.2200	Nature of the residue in plants	$108,333.0	$37,916.6	480.6	$108,333.0	$108,333.0
885.2250	Nature of the residue in animals	$117,144.0	$41,000.4	519.7	$123,750.0	$110,538.0
885.2300	Analytical method - plants	$26,540.0	$9,289.0	117.7	$34,040.0	$19,040.0
885.2350	Analytical method - animals	$43,908.0	$15,367.8	194.8	$56,325.0	$31,492.0
885.2400	Storage stability, plants	$31,017.0	$10,856.0	137.6	$32,683.0	$29,350.0
885.2500	Magnitude of residue in plants	$137,160.0	$48,006.0	608.5	$137,587.0	$136,733.0
885.2550	Magnitude of residue in meat/milk/poultry	$157,663.0	$55,182.1	699.4	$162,425.0	$152,900.0
885.2600	Magnitude of residue in potable water, fish, and irrigated crops	$221,442.0	$77,504.7	982.4	$245,225.0	$197,658.0
885.3000	Background Mammalian Infectivity/pathogenicity analysis	$250,000.0	$87,500.0	1,109.0	$250,000.0	$250,000.0
885.3050	Acute oral toxicity/pathogenicity	$33,500.0	$11,725.0	148.6	$41,000.0	$25,000.0
885.3150	Acute pulmonary toxicity/pathogenicity	$37,500.0	$13,125.0	166.4	$50,000.0	$25,000.0
885.3200	Acute injection toxicity/pathogenicity (intravenous)	$37,500.0	$13,125.0	166.4	$50,000.0	$25,000.0
885.3200	Acute injection toxicity/pathogenicity (intraperitoneal)	$12,500.0	$4,375.0	55.5	$18,000.0	$7,000.0
885.3400	Hypersensitivity incidents	$800.0	$280.0	3.5	$1,300.0	$300.0
885.3500	Cell Culture	$30,000.0	$10,500.0	133.1	$35,000.0	$25,000.0
885.3550	Acute toxicity, TI	$21,500.0	$7,525.0	95.4	$40,000.0	$3,000.0
885.3600	Subchronic toxicity/pathogenicity	$150,000.0	$52,500.0	665.4	$200,000.0	$100,000.0
885.3650	Reproductive/fertility effects	$162,500.0	$56,875.0	720.9	$20,000.0	$125,000.0
885.4050	Avian Oral, TI	$15,000.0	$5,250.0	66.5	$18,000.0	$12,000.0
885.4100	Avian Inhalation toxicity/pathogenicity, TI	$16,000.0	$5,600.0	71.0	$20,000.0	$12,000.0
885.4150	Wild mammal toxicity/pathogenicity,TI	$65,000.0	$22,750.0	288.4	$80,000.0	$50,000.0
885.4200	Freshwater fish toxicity/pathogenicity,TI	$37,500.0	$13,125.0	166.4	$45,000.0	$30,000.0
885.4240	Freshwater invertebrate toxicity/pathogenicity,TI	$37,500.0	$13,125.0	166.4	$45,000.0	$30,000.0
885.4280	Estuarine/marine animal testing, TI	$40,000.0	$14,000.0	177.4	$48,000.0	$32,000.0
885.4280	Estuarine/marine invertebrate testing,TI	$40,000.0	$14,000.0	177.4	$48,000.0	$32,000.0
885.4300	Nontarget plant studies, TI	$30,000.0	$10,500.0	133.1	$40,000.0	$20,000.0
885.4380	Honey bee testing	$4,250.0	$1,487.5	18.9	$5,000.0	$3,500.0
885.4600	Avian chronic pathogenicity and reproduction, TIII	$175,000.0	$61,250.0	776.3	$200,000.0	$150,000.0
885.4650	Aquatic invertebrate range testing,TIII	$75,000.0	$26,250.0	332.7	$1,000.0	$50,000.0
885.4700	Fish life cycle studies,TIII	$250,000.0	$87,500.0	1,109.0	$300,000.0	$200,000.0
885.4750	Aquatic ecosystem test	$350,000.0	$122,500.0	1,552.7	$400,000.0	$300,000.0
885.5200	Terrestrial environmental expression tests	$95,000.0	$33,250.0	421.4	$150,000.0	$40,000.0
885.5300	Freshwater environmental expression test	$0.0	$0.0	0.0	$0.0	$0.0
885.5400	Marine or estaurine environmental expression tests	$95,000.0	$33,250.0	421.4	$150,000.0	$40,000.0

Notes:	Labor Rates in 2003 dollars, but data collected represents 2003 -2007 Clerical: $40/hr Technical: $88/hr Management: $130/hr					
Color Code:						
	Study has no cost estimate, source or year					
	Test cost estimate has no source or year					