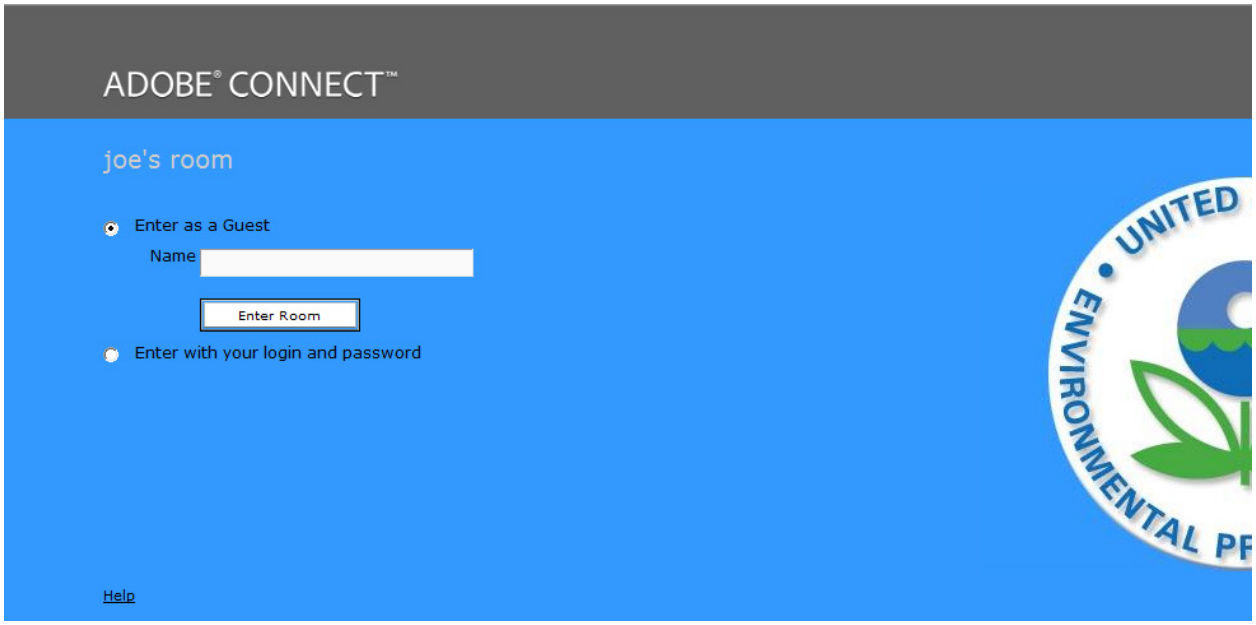
Attachment D
EPA materials from the DCI Response Burden Assessment
Workshop, December 12, 2013

Instructions for Accessing the Webinar

December 12th, 2013 @ 11:00 AM

Invitees are asked to log into the webinar **at 11:00 AM** on December 12th by visiting this url: https://epa.connectsolutions.com/jhogue. At the login prompt (Fig. 1), select 'Enter as a Guest' and enter your first and last name, then, click "Enter Room." The room will load and bring you into the web conference once the meeting has been opened.

Fig. 1



The audio for the meeting will be handled via teleconference. Please call the teleconference line at **1-866-299-3188** and, when prompted, enter the conference code **703-308-9069**. If you have any questions or issues connecting to the webinar, we can address them by phone at the beginning of the webinar.

Agenda
Pesticide Data Call In (DCI) Information Collection Request (ICR)
Industry Consultation Workshop
12/12/13

11:00 Introduction

- Welcome and introductions — Martha Shimkin
- Conduct of workshop
- Purpose of workshop
- Brief overview of ICRs and consultation process — Angela Hofmann

11:15 Burden methodology, assumptions, and estimates — Elizabeth Hill

- Programs involving DCIs, and DCI response types
- Burden estimation methodology:
    - Overview of basic methodology
    - Registration Review
        - DCIs
        - Voluntarily submitted data (low- and high-burden studies)
    - Reregistration
        - Confirmatory data
        - Product specific data
        - Voluntarily submitted data (low- and high-burden studies)
    - Tolerance Assessment Program
        - Anticipated Residue DCIs: Base Set of Data
        - Anticipated Residue DCIs: Verification of Use Data
        - Anticipated Residue DCIs: Updated Public Source Monitoring Data
        - DCIs for Percent Crop Treated Estimates
    - Special Review DCIs
    - DCI recipients – initial (90-day) response

12:45 Additional questions for participants — Cameo Smoot

1:00 Wrap-up — Martha Shimkin

- Questions and comments from participants
- Request for written comments by January 13

1:30 Adjourn

Office of Pesticide Programs

Draft Methodology and Assumptions for Estimating Response Burden for Pesticide Data Call Ins: Data Call In Response Burden Assessment Workshop
December 12, 2013

Introduction

The Environmental Protection Agency (EPA) through the Office of Pesticide Programs (OPP) is currently redefining the Data Call-In (DCI) recipient groups and calculations for those groups to reassess the Paperwork Reduction Act (PRA) burden. Under the PRA, 44 U.S.C. 35, the Agency is required to ensure that the information collected from the public minimizes the burden and maximizes the public utility of the information collected. Prior to collecting the information from the public, EPA must have Office of Management and Budget (OMB) approval. Several programs under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) authorize EPA to seek additional data from pesticide registrants to ensure compliance with statutory standards for the protection of human health and the environment.

The OPP is conducting a reassessment of the information collections obtained through the DCI process. As part of this reassessment, OPP is consulting with industry about the Agency burden assumptions, the methodology used to estimate the burden, the time estimates for conducting PRA activities, and the accuracy of and appropriate distribution of the labor rates. The focus of the DCI Response Burden Assessment Workshop and OPP's burden reassessment of the DCI ICR are limited only to PRA burdens for the following types of DCIs: Reregistration, Registration Review, Endangered Species Protection Program, Special Review Program and the Tolerance Assessment Program (Anticipated Residue/Percent Crop Treated Information).

Section I: Background on Programs Involving Data Call-Ins (DCIs)

The following programs involve reviews of existing registrations that could result in a determination that additional data are necessary for a decision, which would be sought through the issuance of a DCI under FIFRA §3(c)(2)(B).

A. Reregistration Program

FIFRA §4[1] 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. FIFRA §4 directs EPA to use FIFRA §3(c) (2) (B) authority to obtain the required data. While, the reregistration program reassessment process was completed by 2006 for food-use pesticide ingredients and 2008 for non-food use pesticide ingredients, the Agency will still issue certain types of product-specific DCIs (PDCIs) in the future.

[1] 7 USC 136a-1

B. Registration Review Program

FIFRA §3(g)[2] directs EPA to establish by regulation procedures for periodically reviewing pesticide registrations, and to complete each pesticide's registration review at least every 15 years to assure that the pesticide continues to pose no unreasonable adverse effects on human health or the environment. The purpose of this review is to assure that a pesticide continues to meet the FIFRA standard for registration. The procedural regulations were promulgated in 2006 as 40 CFR part 155, subpart C.[3] The Pesticide Registration Improvement Act[4] requires EPA to complete registration review decisions for all currently-registered pesticides by October 1, 2022. FIFRA §3(g) instructs EPA to use the FIFRA §3(c)(2)(B) authority to obtain data determined to be necessary to complete the assessment, reviews, and decisions called for under FIFRA §3(g).

In addition, EPA intends these reviews to involve the review of data related to endangered species and endocrine effects:

- Endangered Species Protection Program (ESPP): EPA regards the ESPP, which concerns endangered species assessments (effects determinations) required under the Endangered Species Act (ESA)[5], as part of the risk characterization of the pesticide under Registration Review. FIFRA §3(g) instructs EPA to use the FIFRA §3(c) (2) (B) authority to obtain the required data.

- Endocrine Disruptor Screening Program (EDSP): EPA intends to consider endocrine effects pursuant to FFDCA §408(p)[6] as part of the risk characterization of the pesticide under Registration Review. [7] FFDCA §408(p) mandates the issuance of Orders requiring screening of substances for their potential endocrine disruptor effects. FIFRA §3(c) (2) (B) also provides a means of obtaining needed data for pesticides. Thus, under the EDSP program two types of data collection authorities allow the Agency to address endocrine disruptor screening and testing data needs: DCIs and 408(p) orders. In establishing the policy and procedures for issuing 408(p) orders under the EDSP, EPA will integrate the considerations under the EDSP with the Registration Review activities whenever possible. EPA believes that doing this will provide efficiencies for everyone involved. Please note, however, the information collection activities associated with the issuance of 408(p) orders are already covered by another ICR, identified under EPA ICR No. 2249.03 and approved under OMB Control No. 2070-0176. As such, the issuance of 408(p) orders for Registration Review chemicals is not currently covered by this ICR.

DRAFT

[2] 7 USC 136a(g)
[3] 71 FR 45719, August 9, 2006.
[4] Public Law 112-177- September 28, 2012, 112th Congress (126 Stat. 1327)
[5] 16 USC 1531 *et seq*. For information about the ESPP, go to http://www.epa.gov/espp/.
[6] 21 USC 346a(p).
[7] For information about the EDSP, go to http://www.epa.gov/scipoly/oscpendo/index.htm.

C. Special Review Program

Though it does not occur often, the Special Review process is set in motion when EPA has reason to believe that the continued use of a registered pesticide may result in unreasonable adverse effects to people or the environment. The criteria for initiating a Special Review, which are found in 40 CFR 154.7, include the following:

- Acute toxicity to humans or domestic animals.
- Potential chronic or delayed toxic effects in humans.
- Potential hazards to non-target organisms.
- Risk to the continued existence of any threatened or endangered species.
- Risk of destruction or other adverse modification of a critical habitat of any threatened or endangered species.
- Any other adverse effect to humans or the environment which may outweigh the benefits that justify initial or continued registration.

Should data and information be needed as part of Special Review, EPA may use the authority in FIFRA §3(c) (2) (B) to issue a DCI to obtain the necessary data.[8]

D. Tolerance Assessment Program (Anticipated Residue/Percent Crop Treated Information)

Under FFDCA §408, before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or establish an exemption from the requirement to have a tolerance. In order to conduct the required evaluation, a Pesticide Registrant may be required to submit specific data necessary to demonstrate that residues do not exceed the residue levels used to establish the tolerance. Under the authority of FIFRA §3(c) (2) (B), the Agency will issue a DCI to obtain any additional data that is determined to be necessary for the decisions that must be made under this program. FFDCA §408(b)(2)(E) and (F) authorize the use of anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. FFDCA requires that if AR data are used, data must be reviewed five years after a tolerance is initially established. If PCT data are used, FFDCA affords EPA the discretion to obtain additional data if any or all of several conditions, including but not limited to the following, are met:

- The existing data have been found unreliable;
- Exposure estimates underestimate exposures for any significant population group; and
- Dietary exposure must be re-evaluated periodically.

Section II: Data Collections Using a DCI

The data that EPA may collect and review under this ICR will likely vary for each DCI because the DCI is tailored to address the specific needs of the individual chemical or active ingredient under review. However, the data requested will be primarily based on the data requirements that are found in 40 CFR part 158. In codifying the requirements in 40 CFR part 158, EPA provided

[8] For additional information about Special Review, go to http://www.epa.gov/oppsrrd1/special_review/index.htm.

substantiation and support to demonstrate the need and practical utility for the data in terms of its use to assess the risks for particular chemicals based on the different use patterns and pesticides, and in order to make the required registration decisions about those pesticides. 40 CFR part 158 also includes a provision that allows the Agency to seek additional non-codified data if it is determined to be necessary to make the risk-based decisions mandated by federal law.

A. History of the Methodology Used to Estimate the Paperwork Burden and Costs for DCIs

DCI Test Cost Burden Calculation Assumptions

Prior to 2007, EPA calculated the paperwork burden and costs for the data generation activities as a percentage of the testing costs. This percent-based estimate of paperwork associated with conducting a test was initially established in consultation with OMB in the 1980's in an effort to provide a reasonable estimate of the burden associated with the paperwork component of data generation, which may vary based on the complexity of the test performed. In 2007, EPA solicited public comment on this approach as described in detail in the document entitled "*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 Data Call-In Notice*"[9] see Attachment 1). Based on feedback received, EPA concluded that this approach appears to be a reasonable and fair alternative to simply setting a single estimate for data generation burden or using set criteria of high, medium or low burden, neither of which may fairly reflect potential differences in burden.

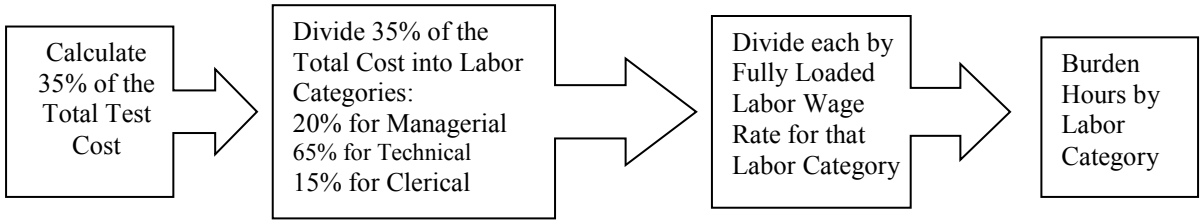
In summary, to calculate the burden and costs associated with the paperwork activities involved in conducting the tests, the Agency starts with the cost of the test, typically the market price for the test as identified by laboratories that offer testing services. The Agency maintains an archive of the 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 greatest extent possible, EPA uses multiple sources to provide test cost estimates, which are updated as needed.

EPA uses 35% of the estimated total test cost to calculate the total potential cost for the paperwork activities related to data generation. The 35% of test cost is disaggregated by labor category, and then burden hours are extrapolated by using the loaded labor rates. To disaggregate by labor category, the Agency considered the estimated distribution of paperwork activity across the labor categories represented and the existing methodology assumption that paperwork activities for data generation mostly involve the technical staff to perform the tests, with fewer activities related to management and clerical staff.

See Figure 1 for an illustrated outline of the Agency burden calculation process for data generation.

9 This document was originally published as Attachment G to a DCI ICR renewal document posted under the docket identification #EPA-HQ-OPP-2007-0923-0005. See Regulations.gov

Figure 1 – Method for Calculating Paperwork Burden from Test Costs



This approach assumes and incorporates the following core considerations:

(1) Recipients generate all of the data as specified in the DCI and without any changes.

(2) All data generation is performed by an independent laboratory.

(3) Paperwork burden is disaggregated by labor category as follows:

a. Managerial (20%)

b. Technical (65%)

c. Clerical (15%)

(4) Labor rates are fully loaded, meaning that they include the estimated costs of wages, overhead, and benefits paid to an employee.

Note that for certain types of DCIs, paperwork burden calculations do not follow the current methodology—that is, they are not broken out by 20%-65%-15% Managerial-Technical-Clerical as is typically the case. This is because certain types of DCIs have paperwork burden that falls disproportionately on different labor categories and thus do not follow the EPA methodology for estimating paperwork burden hours for DCIs. For more information of such instances, see Appendix B.

B. Methodology for Calculating Labor Wage Rates

The Agency updates the estimated wages, benefits and overhead for all labor categories for affected industries, state government, and EPA employees based on publicly available data from the U.S. Bureau of Labor Statistics. The formulas used to estimate the labor rates and formulas used to derive the fully loaded rates and overhead costs for the new ICR renewal are listed in Table 1,

Table 1: EPA Methodology Used to Determine Labor Rates

Methodology	The methodology uses data on each sector and labor type for an *Unloaded wage rate* (hourly wage rate), and calculates the *Loaded wage rate* (unloaded wage rate + benefits), and the *Fully loaded wage rate* (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This renewal uses 2012 base data.

DRAFT

Unloaded Wage Rate	Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm.
Sectors	The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm).
Loaded Wage Rate	Unless stated otherwise, all benefits represent 43% of unloaded wage rates, based on benefits for all civilian non-farm workers, from http://www.bls.gov/news.release/ecec.t01.htm. However, if other sectors are listed for which 43% is not applicable; the applicable percentage will be stated.
Fully Loaded Wage Rate	We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to calculate overhead costs and add this to the loaded wage rate to get the fully loaded wage rate.

C. Information Collection Groups

Information Collection (ICs) Groups are a way of categorizing similar DCI requests into subprogram groupings. EPA currently uses 12 IC Groups which are outlined in Table 2. In the previous DCI ICR, IC Group, "DCIs for Enforcement and Unanticipated Incidents" was included but EPA plans to remove this group in future ICRs because EPA has not issued and does not foresee issuing any DCIs for this category. Detailed information about the specific IC program groups is in Section 1: Programs Involving Data Call-ins.

Table 2: Information Collection (IC) Groups by Program

IC Group	Program
1. Reregistration DCIs: Confirmatory Data	Reregistration Program
2. Reregistration: Voluntarily Submitted Data (Low Burden Studies)	
3. Reregistration: Voluntarily Submitted Data (High Burden Studies)	
4. Reregistration DCIs: Product Specific Data	
5. Special Review DCIs	Special Review Program
6. Registration Review DCIs	Registration Review
7. Registration Review: Voluntarily Submitted Data (Low Burden Studies)	
8. Registration Review: Voluntarily Submitted Data	

IC Group	Program
(High Burden Studies)	
9. Anticipated Residue DCIs: Base Set of Data	Tolerance Assessment Program (Anticipated Residue/Percent Crop Treated)
10. Anticipated Residue DCIs: Verification of Use Data	
11. Anticipated Residue DCIs: Updated Public Source Monitoring Data	
12. DCIs for Percent Crop Treated Estimates	

Section III: Redefining the DCI Recipient Groups to Better Define Paperwork Burden

The Agency is redefining the DCI recipient groups to better classify the activities and burdens associated with each group. While each DCI involves the same basic paperwork activities, which are grouped into the following three information collection categories for purposes of presenting the burden and costs in this ICR, the burden associated with each group can be very different. The groups are:

1. DCI Recipients
2. Data Generators
3. Consortium Participants

DCI Recipients –After receiving a DCI, each recipient has 90 days to provide the initial response indicating how the recipient plans to comply with the DCI. A registrant may avoid generating the data if they qualify for a generic data exemption, i.e., they use a registered pesticide as the source of the active ingredient in their own product, cancel the product's registration, submit or cite existing data, or is granted a waiver by EPA in response to their request. Not all DCI recipients will generate data in response to a DCI. The DCI recipient is assumed to be involved in the four activities listed in Table 3. The burden for dDCI recipients will be lower than the burden estimates for the data generation group.

Data Generators **-** Regardless of the response option that the DCI recipient might select, the Agency has assumed that some data will be generated for each chemical. The data generator is assumed to be involved in the nine activities listed in Table 3. While Agency records indicate that not all the studies requested in a DCI are, in fact, generated (data generators can request waivers, submit or cite existing data like the DCI recipients), for the most part the data generator group will assume the highest DCI response burden among the three respondent groups.

Consortium Participants - The Agency will assume that whenever more than one company receives identical DCIs for the same chemical, the companies will work together to generate one set of data and participate in a consortium or task force. Generally, the Agency calculations for these paperwork burdens are accounted for as part of the 35% of the cost of generating studies.[10]

10 As part of the 2007 methodology, the Agency identified three response phases: Phase 1: the initial response; Phase 2: data generation and Phase 3: data submission to EPA. The Phase 1, Phase 2 and Phase 3 response activity burden hours and costs are accounted for as subsets of the paperwork burden estimates for information collection activities that are related to generating data to respond to a DCI. These burdens are accounted for as part of the 35% of the test burden and cost.

However, in addition to the cost of data generation, consortium participants are subject to costs associated with operating a consortium or task force (e.g., communication, attending meetings, etc.). Thus, consortium participants are also assumed to be involved in the four consortium activities listed in Table 3.

Table 3: New Recipient Groups - Collection Activities and Corresponding Collection Category.

DCI Recipient	
Collection Activity	**Collection Category**
1) Read Instructions	Reporting
2) Plan Activities	
3) Complete Paperwork	
4) Store/maintain Data	Recordkeeping
Data Generator	
Collection Activity	**Collection Category**
1) Read and discuss test requirements	Reporting
2) Discuss test and protocol with Agency	
3) Plan activities	
4) Create information	
5) Gather information	
6) Process, compile, review information for accuracy	
7) Complete written forms	
8) Record, disclose, display information	Recordkeeping
9) Store, file, or maintain information	
Consortium Participants	
Collection Activity	**Collection Category**
1) Negotiate/establish consortium/task force agreements	Reporting
2) Participate in consortium discussions	
3) Plan logistics for calls or meetings	
4) Store/maintain consortium information	Recordkeeping

Section IV: Estimating the Burden and Cost for the Redefined DCI Recipient Groups

The estimated paperwork burden and costs for DCI recipients vary from DCI to DCI because of the variations in the individual studies that are part of the DCI and the combination of activities (waivers, exemptions, etc.) each DCI manifests. As discussed, 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 accurately

estimate the burden and costs of developing the data. Nor can the Agency accurately predict the number of DCI recipients who will generate data or the amount of data that might be submitted to EPA. The Agency's burden estimates are based on past patterns of DCI response activities.

DCI Recipients - DCI recipients are subject to burden from having to provide an initial response to the EPA for a DCI regardless of whether or not they generate data. The methodology EPA used for calculating the burden for this group is derived from the 2007 Methodology, Phase 1 requirements outlined in Case Study #1, Attachment A, which reflects the activities that all DCI recipients would have to conduct regardless of whether or not they must generate data.

Given that a single DCI can be sent to several companies, DCI recipient burden is calculated at the company level—not at the DCI level. To estimate the number of companies that are DCI recipients, EPA conducted a search of companies that received a DCI request in its Pesticide Registration Information System (PRISM) to determine the average annual number of impacted entities. The Agency estimates that 122 companies will receive a DCI request annually. For more information on methodologies used in estimating the total number of DCI recipients and burdens to DCI recipients, see Appendix A.

Data Generators - The paperwork burden and costs for data generators are based in part on the average cost for paying a laboratory to conduct the test(s) necessary to generate the data requested in the DCI. To estimate paperwork activities for each type of labor category (managerial, technical, and clerical), the disaggregated paperwork burden costs are multiplied by their corresponding labor wage rates ($/hr). As mentioned previously, some DCIs do not follow the Agency's methodology of paperwork being 20%-65%-15% Managerial-Technical-Clerical as certain IC Groups have paperwork burden that falls disproportionately on different labor categories. For details regarding the methodology used for calculating data generation paperwork burden for each of the IC Groups, refer to Appendix B.

EPA has also assumed that for each DCI, companies are combining resources when responding to a DCI and data generation is necessary—thus it is expected that only one set of data is being submitted to the EPA in response to each DCI request. EPA understands that this assumption may not be accurate and solicits industry input to clarify this assumption.

EPA expects to issue approximately 120 DCIs annually over the next three years that will require data generation. This is nearly all of the 122 companies that are data recipients annually. This estimate for data generators does not include voluntarily submitted data as they are not DCIs (i.e., IC Groups 2, 3, 7, and 8 in Table 4 are excluded from this estimate).

Consortium Participants - Although consortium members encumber burden from consortium activities, the cost savings from avoiding study generation are expected to far exceed the burden from such activities. Furthermore, EPA assumes that no business would opt to join a consortium if the cost of consortium activities would result in a higher cost per DCI. Thus for each consortium member, the upper bound (i.e., maximum) total cost per DCI submitted by a consortium is expected to be less than or equal to the per DCI burden incurred by a recipient who chooses to submit their DCI data independently. In this case, the burden per consortium member would be equal to that in Table 5 for DCI Generators. EPA is currently requesting additional

information from industry to better understand costs incurred by consortium participants and has left a placeholder for consortium burden in Tables 5 and 6.

The breakdown of the regulatory decisions for DCIs that EPA expects to make over the next three years is as follows:

Table 4: Estimated Number of DCIs by IC Group

IC Number	IC Group	Total DCIs 1-Year Period*	Total DCIs 3-Year Period*
1	Reregistration DCIs: Confirmatory Data	23.7	71
2	Reregistration: Voluntarily Submitted Data (Low Burden Studies)	0.3	1
3	Reregistration: Voluntarily Submitted Data (High Burden Studies)		
4	Reregistration DCIs: Product Specific Data	20.3	61
5	Special Review DCIs	0.3	1
6	Registration Review DCIs	92.3	277
7	Registration Review: Voluntarily Submitted Data (Low Burden Studies)	0.3	1
8	Registration Review: Voluntarily Submitted Data (High Burden Studies)		
9	Anticipated Residue DCIs: Base Set of Data	0.3	1
10	Anticipated Residue DCIs: Verification of Use Data	0.3	1
11	Anticipated Residue DCIs: Updated Public Source Monitoring Data	0.3	1
12	DCIs for Percent Crop Treated Estimates	0.3	1
	Total DCIs*	**119.3**	**358**
	Total Voluntarily Submitted Data	**0.7**	**2**

* Counts for IC Groups 2, 3, 7, and 8 are for voluntarily submitted data—i.e., they are not DCIs. Therefore, the total DCI count does not include these estimates.

DRAFT

A. DCI-Related Respondent Burden and Cost Estimates

Tables 5 and 6 provide information on the burden and costs faced by DCI recipients, DCI data generators, and DCI consortiums. Respondent costs are based on managerial, technical and clerical wage rates estimated at $117.54, $62.58, and $37.33 per hour, respectively. These wage rates are based on wage rates estimated by the Bureau of Labor Statistics (BLS) for the North American Industry Classification System (NAICS) for pesticide registrants (NAICS code 325300).

Table 5 outlines burden and cost to these three groups per company of DCI—that is, for data recipients, burden is estimated by company since companies are responsible for responding to the 90-day notice; for data generators, it is assumed that only one data package is being submitted by one or more companies for each DCI. As mentioned, EPA is currently requesting additional information from industry to better understand costs incurred by consortium participants and therefore has a placeholder for consortium burden in Tables 5 and 6.

Table 5: Estimated Common DCI-Related Annual Respondent Burden and Costs per Company/DCI*

	Clerical		Technical		Manager		Totals	
Activity Category	Hrs.	$37.33/hr.	Hrs.	$62.58/hr.	Hrs.	$117.54/hr.	Burden (hrs)	Costs ($)
IC Category – DCI Recipients								
Reporting	3	$112	0	$0	7.5	$882	11.5	$994
Recordkeeping	1	$37	0	$0	0	$0	1	$37
IC Category – Data Generators								
Reregistration Program DCIs								
1) Confirmatory DCIs								
Reporting	962	$35,909	4,662	$291,760	620	$72,892	6,244	$400,561
Recordkeeping	842	$31,420	0	$0	144	$16,880	985	$48,301
2) Product Specific DCIs								
Reporting	146	$5,458	709	$44,348	93	$10,927	948	$60,734
Recordkeeping	128	$4,776	0	$0	23	$2,718	151	$7,494
3) Reregistration: Voluntarily Submitted Low Burden Studies								
Reporting	88	$3,300	428	$26,814	57	$6,699	574	$36,813
Recordkeeping	77	$2,888	0	$0	13	$1,551	91	$4,439
4) Reregistration: Voluntarily Submitted High Burden Studies								
Reporting	549	$20,495	2,661	$166,523	349	$40,976	3,559	$227,994
Recordkeeping	480	$17,933	0	$0	87	$10,262	568	$28,195
Special Review and Registration Review DCIs								
5) Special Review DCIs								
Reporting	137	$5,127	666	$41,655	88	$10,295	891	$57,077
4Recordkeeping	120	$4,486	0	$0	21	$2,521	142	$7,007

DRAFT

Activity Category	Clerical		Technical		Manager		Totals	
	Hrs.	$37.33/hr.	Hrs.	$62.58/hr.	Hrs.	$117.54/hr.	Burden (hrs)	Costs ($)
6) Registration Review DCIs								
Reporting	3,688	$137,662	17,873	$1,118,502	2,340	$275,009	23,901	$1,531,173
Recordkeeping	3,227	$120,454	0	$0	588	$69,145	3,815	$189,599
7) Registration Review: Voluntarily Submitted Low Burden Studies								
Reporting	88	$3,300	428	$26,814	57	$6,699	574	$36,813
Recordkeeping	77	$2,888	0	$0	13	$1,551	91	$4,439
8) Registration Review: Voluntarily Submitted High Burden Studies								
Reporting	549	$20,495	2,661	$166,523	349	$40,976	3,559	$227,994
Recordkeeping	480	$17,933	0	$0	87	$10,262	568	$28,195
Anticipated Residue/Percent Crop Treated DCIs								
9) AR DCIs: Base Set of Data								
Reporting	2	$75	13,624	$852,590	9	$1,058	13,635	$853,722
Recordkeeping	1	$37	0	$0	0	$0	1	$37
10) AR DCIs: Verification-of-use Data								
Reporting	8	$299	32	$2,003	28	$3,291	68	$5,592
Recordkeeping	1	$37	0	$0	0	$0	1	$37
11) AR DCIs: Updated Public Source Monitoring Data								
Reporting	8	$299	100	$6,258	28	$3,291	136	$9,848
Recordkeeping	1	$37	0	$0	0	$0	1	$37
12) DCIs for Percent Crop Treated Estimates								
Reporting	2	$75	53	$3,317	3	$353	58	$3,744
Recordkeeping	1	$37	0	$0	0	$0	1	$37
IC Category – Consortium Participants								
Reporting	TBD							
Recordkeeping	TBD							
Third Party Disclosure Activities	Estimates outlined above represent the maximum paperwork burden that a consortium participant is expected to face.							

***** Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table. Note that these estimates reflect burden and costs per company when referring to DCI recipients and per DCI when referring to data generators. Methods used for calculating the cost and burden for cases under each IC Group vary. For a review of methods used in these calculations, refer to Appendix A and B.

Table 6 presents the total annual respondent burden hours for data recipients, data generators, and consortium members (excluding voluntary data submissions). These calculations reflect recordkeeping, reporting, and total burden numbers for each IC group universe. Refer to Appendices A and B for methodologies and formulas demonstrating how these estimates were calculated. For example, the supporting text under Table A-1 in Appendix A demonstrates how the total burden hours and costs were calculated for data recipients. Tables in Appendix B provide the same information for data generators by IC group. Total bottom-line paperwork

burden is estimated at 2,758,896 burden hours which equates to $171,333,146 in paperwork burden costs. Of this, 1,403 burden hours ($125,782) are incurred by the entire universe of data recipients.

DRAFT

Table 6: Summary of Annual DCI Paperwork Burdens and Costs

	Burden Hours			Costs		
	Reporting	Recordkeeping	Total	Reporting	Recordkeeping	Total
Data Recipients (Table A-1_	1,281	122	**1,403**	$121,227	$4,554	**$125,782**
Data Generators						
Reregistration Program DCIs						
Confirmatory DCIs (Table B-1)	147,781	23,319	**171,100**	$9,479,935	$1,143,113	**$10,623,048**
Product Specific DCIs (Table B-4)	19,273	3,072	**22,345**	$1,234,916	$152,387	**$1,387,303**
Voluntarily Submitted Low Burden Studies (Table B-2)	191	30	**221**	$12,271	$1,480	**$13,751**
Voluntarily Submitted High Burden Studies (Table B-3)	1,186	189	**1,375**	$75,998	$9,398	**$85,396**
Special Review and Registration Review DCIs						
Special Review DCIs (Table B-5)	297	47	**344**	$19,026	$2,336	**$21,361**
Registration Review DCIs (Table B-6)	2,206,818	352,252	**2,559,070**	$141,378,303	$17,506,330	**$158,884,633**
Registration Review: Voluntarily Submitted Low Burden Studies (Table B-7)	191	30	**221**	$12,271	$1,480	**$13,751**
Registration Review: Voluntarily Submitted High Burden Studies (Table B-8)	1,186	189	**1,375**	$75,998	$9,398	**$85,396**
Anticipated Residue/Percent Crop Treated DCIs						
AR DCIs: Base Set of Data (Table B-9)	4,545	0.3	**4,545**	$284,574	$12	**$284,587**
AR DCIs: Verification-of-use Data (Table B-10)	23	0.3	**23**	$1,864	$12	**$1,877**
AR DCIs: Updated Public Source Monitoring Data (Table B-11)	45	0.3	**46**	$3,283	$12	**$3,295**
DCIs for Percent Crop Treated Estimates (Table B-12)	19	0.3	**20**	$1,248	$12	**$1,260**
DCI Data Generator Total	**2,378,801**	**378,691**	**2,757,493**	**$152,403,149**	**$18,804,215**	**$171,207,364**
Consortium Members	**TBD**	**TBD**	**TBD**	**TBD**	TBD	**TBD**
Total Annual Burden	**2,380,082**	**378,813**	**2,758,896**	**$152,524,376**	**$18,808,769**	**$171,333,146**

Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table. Methods used for calculating the cost and burden for cases under each IC Group vary. For a review of methods used in these calculations, refer to Appendix A and B.

Appendix A:
Estimated Burden Hours and Costs for DCI Recipients

This Appendix outlines the burden hours and costs for DCI recipients. The methodology EPA used for calculating the burden for this group is derived from the 2007 document entitled 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 Data Call-In Notice, see Attachment 1, Case Study #1, Attachment A.

To calculate the universe of DCI recipients, EPA conducted a search of its Pesticide Registration Information System (PRISM) for all companies that received DCI requests in 2013. This number was 82; however, an influx of DCIs under reregistration are expected for antimicrobials starting in 2014, with an estimated average of 20 confirmatory and 20 product-specific DCIs being sent out annually for the next three years. This would result in 122 DCIs being expected annually from 2014 to 2017.

EPA has made the assumption that the annual average is the three-year average of companies receiving DCIs with a final due date in 2014-2016, which is 215 annually.

Annual burden and costs is estimated at 11.5 hours or $1,031 for each DCI recipient; with 122 companies receiving DCIs annually, the total annual burden is 1,403 hours or $125,782.

Table A-1: Annual Burden and Costs per DCI Recipients

Activity	Burden Hours			Total	
	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Hours	Costs
1) Read Instructions	7.0	0.0	0.0	7.0	$822
2) Plan Activities	0.5	0.0	0.0	0.5	$59
3) Complete Paperwork	0.0	0.0	3.0	3.0	$111
4) Store/maintain Data	0.0	0.0	1.0	1.0	$37
5) Totals	7.5	0.0	4.0	11.5	$1,031

Estimated Total Burden & Costs Across all DCI Recipients:
Reporting (Collection Activities 1-3):
Burden: 10.5 hours per response x 122 responses = 1,281 burden hours.
Costs: $993.67 per response x 122 responses = $121,227
Recordkeeping (Collection Activity 4):
Burden: 1 hour per response x 122 responses = 122 burden hours
Costs: $37.33 per response x 122 responses = $4,554
Total (Reporting + Recordkeeping):
Burden: 11.5 hours per response x 122 responses = 1,403 burden hours
Costs: $1,031 per response x 122 responses = $125,782
** Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table.*

Appendix B:
Estimated Burden Hours and Costs for DCI Collection Activities for Data Generators, by IC Group

The estimated burden hours, collection activity costs, and total cost per DCI by IC Group using loaded labor rates for the labor categories are outlined in this Appendix. Please see Section 1(b) (i): Methodology Used to Estimate the Paperwork Burden and Costs for DCIs for an overview of how paperwork burden estimates in this section were calculated.

Section B-1: Estimating Respondent Burden – Reregistration

Over the next three years, EPA expects to issue 123 reregistration DCIs and 9 import tolerances for confirmatory and product specific data; a maximum of one voluntarily data submission is expected to be received by the Agency. This is a substantial decrease from previous DCI estimates as the reregistration process is switching over to registration review; however, EPA's Antimicrobials Division in the Office of Pesticide Programs still has several chemicals that are subject to reregistration which accounts for a majority of the reregistration DCIs to be issued.

Section B-1.1: Paperwork Burden Related to the Submission of Confirmatory Data Reregistration

Confirmatory data are required of registrants to complete registrant databases and to assist in the evaluation of risk findings. For DCIs involving confirmatory studies, EPA assumes that only one respondent will provide the data requested. The total cost for the most burdensome confirmatory data DCI that the EPA has issued in the past three years was $1,282,460. The paperwork cost associated with this (35% of the total cost) is $448,861 or 7,230 total burden hours. EPA expects to issue 71 confirmatory DCIs over the next three years, which is an average of 23.7 confirmatory DCIs annually. Total annual burden across all Confirmatory Data DCIs is 171,100 burden hours or $10,623,048. See Table B-1 below for burden activity details.

Table B-1: Annual Respondent Burden per DCI Involving Confirmatory Studies

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	78	0	0	78	$9,207
2. Discuss test and protocol with Agency	39	72	0	111	$9,104
3. Plan activities	157	72	0	229	$22,915
4. Create information	118	3,584	721	4,422	$265,000
5. Gather information	0	360	0	360	$22,501
6. Process, compile, review information for accuracy	228	575	0	804	$62,856

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
7. Complete written forms	0	0	240	240	$8,977
8. Record, disclose, display information	72	0	481	553	$26,395
9. Store, file, or maintain information	72	0	361	433	$21,906
Total	*764*	*4,662*	*1,804*	*7,230*	*$448,861*

Estimated Total Annual Burden & Costs Across All Confirmatory Study DCI Data Generators:

Reporting (Collection Activities 1-7):
Burden: 6,244 hours per response x 1 response per DCI x 23.7 DCIs = 147,781 burden hours.
Costs: $400,561 per response x 1 response per DCI x 21.7 DCIs = $9,479,935.
Recordkeeping (Collection Activities 8-9):
Burden: 985 hours per response x 1 response per DCI x 23.7 DCIs = 23,319 burden hours.
Costs: $48,301 per response x 1 response per DCI x 23.7 DCIs = $1,143,113.
Total (Reporting + Recordkeeping):
Burden: 7,230 hours per response x 1 response per DCI x 23.7 DCIs = 171,100 burden hours.
Costs: $448,861 per response x 1 response per DCI x 23.7 DCIs = $10,623,048.
** Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table.*

Section B-1.2: Paperwork Burden Related to Voluntarily Submitted Data - Reregistration

Submission of voluntary data consist of studies not required by the Agency but are submitted by registrants to supplement a pesticide database. The Agency does not expect to receive more than one voluntary data submission over the next three years under the reregistration program. Despite the low chance of such an occurrence, the Agency has provided high and low burden estimates given the variable nature of the expected cost of voluntarily submitted data.

Given that there have been no recent voluntary submissions under reregistration, the Agency used the burden hour cost calculated in the previous DCI ICR—adjusted for wage rate changes—to back out the proportional burden hour estimates for each of the three labor groups (i.e., 20% managerial, 65% technical, 15% clerical). This method was used both for low and high burden voluntary submission burden hour estimate. Updating for 2012 labor wage rates, the total data cost per voluntary submission is expected to range from $117,862 to $731,969. This translates to paperwork burden estimates for voluntary submissions ranging from 664 to 4,126 burden hours, or $41,252 to $256,189 per voluntary submission. Since only one submission is expected every three years, the expected range of potential annual burden from a voluntary submission is 221 to 1,375 burden hours or $13,751 to $85,396 in burden cost.

Table B-2. Annual Respondent Burden per Submission of Voluntary Studies (Low Burden)

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	7	0	0	7	$846
2. Discuss test and protocol with Agency	4	7	0	10	$837
3. Plan activities	14	7	0	21	$2,106
4. Create information	11	329	66	406	$24,355
5. Gather information	0	33	0	33	$2,068
6. Process, compile, review information for accuracy	21	53	0	74	$5,777
7. Complete written forms	0	0	22	22	$825
8. Record, disclose, display information	7	0	44	51	$2,426
9. Store, file, or maintain information	7	0	33	40	$2,013
Total	*70*	*428*	*166*	*664*	*$41,252*

Estimated Total Annual Burden & Costs Across All Voluntary Low Burden Studies:

Reporting (Collection Activities 1-7):

Burden: 574 hours per response x 1 response per DCI x 0.33 DCIs = 191 burden hours.

Costs: $36,813 per response x 1 response per DCI x 0.33 DCIs = $12,271.

Recordkeeping (Collection Activities 8-9):

Burden: 91 hours per response x 1 response per DCI x 0.33 DCIs = 30 burden hours.

Costs: $4,439 per response x 1 response per DCI x 0.33 DCIs = $1,480.

Total (Reporting + Recordkeeping):

Burden: 664 hours x 1 response x 0.33 submissions = 221 hours

Costs: $41,252 x 1 response x 0.33 submissions = $13,751

** Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table.*

Table B-3. Annual Respondent Burden per Submission of Voluntary Studies (High Burden)

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	44	0	0	44	$5,131
2. Discuss test and protocol with Agency	22	41	0	63	$5,134
3. Plan activities	87	41	0	128	$12,830

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
4. Create information	65	2,045	412	2,523	$151,064
5. Gather information	0	205	0	205	$12,842
6. Process, compile, review information for accuracy	130	328	0	459	$35,869
7. Complete written forms	0	0	137	137	$5,124
8. Record, disclose, display information	44	0	275	318	$15,378
9. Store, file, or maintain information	44	0	206	250	$12,817
Total	*436*	*2,661*	*1,029*	*4,126*	*$256,189*

Estimated Total Annual Burden & Costs Across All Voluntary High Burden Studies:

Reporting (Collection Activities 1-7):

Burden: 3,559 hours per response x 0.33 submissions = 1,186 burden hours.

Costs: $227,994 per response x 0.33 submissions = $75,998.

Recordkeeping (Collection Activities 8-9):

Burden: 568 hours per response x 0.33 submissions = 189 burden hours.

Costs: $28,195 per response x 0.33 submissions = $9,398.

Total (Reporting + Recordkeeping):

Burden: 4,126 hours x 1 response x 0.33 submissions = 1,375 hours

Costs: $256,189 x 1 response x 0.33 submissions = $85,396

** Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table.*

Section B-1.3: Paperwork Burden Related to the Submission of Product-Specific Data – Reregistration

The Agency projects 61 Product-Specific DCIs (PDCIs) will be called-in over the next three years (20.3 annually) and that each PDCI will generate one response**.** Table B-4 provides details for each burden activity. Although a PDCI has not been issued recently, total test cost estimates are available from 2011 for four product chemicals. The average total test cost for each of these chemicals is $194,937. Using the updated 2007 EPA burden estimate methodology, the paperwork cost associated with this (35% of the total cost) is $68,228 or 1,099 burden hours. Total annual paperwork burden across all PDCI's is 22,345 burden hours or $1,387,303. See Table B-4 below for burden activity details.

Table B-4. Annual Respondent Burden Estimates per Product Specific DCI

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	12	0	0	12	$1,359
2. Discuss test and protocol with Agency	6	11	0	17	$1,377
3. Plan activities	23	11	0	34	$3,402
4. Create information	17	545	110	672	$40,234
5. Gather information	0	55	0	55	$3,420
6. Process, compile, review information for accuracy	35	87	0	122	$9,577
7. Complete written forms	0	0	37	37	$1,365
8. Record, disclose, display information	12	0	73	85	$4,088
9. Store, file, or maintain information	12	0	55	66	$3,406
Total	*116*	*709*	*274*	*1,099*	*$68,228*

Estimated Total Annual Burden & Costs Across All Product-Specific DCI Data Generators:

Reporting (Collection Activities 1-7):
Burden: 948 hours per response x 1 response per DCI x 20.3 DCIs = 19,273 burden hours.
Costs: $60,734 per response x 1 response per DCI x 20.3 DCIs = $1,234,916.
Recordkeeping (Collection Activities 8-9):
Burden: 151 hours per response x 1 response per DCI x 20.3 DCIs = 3,072 burden hours.
Costs: $7,494 per response x 1 response per DCI x 20.3 DCIs = $152,387.
Total (Reporting + Recordkeeping):
Burden: 1,099 hours per response x 1 response per DCI x 20.4 DCI = 22,345 burden hours.
Costs: $68,228 per response x 1 response per DCI x 20.3 DCI = $1,387,303.
Numbers may not add due to rounding. Please refer to text for information on calculations presented in this table.

Section B-2: Estimating Respondent Burden – Special Review

Special Reviews, though rare, are conducted when the Agency determines such a review is warranted. In the Special Review Program, EPA focuses on specific hazards or uses of a pesticide. Special Reviews are not intended to be comprehensive evaluations of the pesticide; instead, the DCIs address specific hazard or exposure concerns.

Over a three-year ICR approval period, one response is expected. Since the Agency has not requested a Special Review in recent history, no high-end estimates could be obtained to represent the upper bound burden estimate for a DCI associated with this IC Group. Instead, the Agency used the burden hour cost calculated in the previous DCI ICR—

adjusted for wage rate changes—to back out the proportional burden hour estimates for each of the three labor groups (i.e., 20% managerial, 65% technical, 15% clerical). Total DCI test cost is estimated at $183,097 when adjusting for 2012 wage rates, making the total DCI paperwork burden $64,084 (1,032 burden hours) per DCI when assuming paperwork burden is 35% of total DCI burden. With only one DCI expected every three years, this equates to a total annual paperwork burden of 344 burden hours or $21,361annually across all Special Review DCIs. Table B-6 details the estimated annual respondent burden hours and costs for Special Review DCIs.

Table B-6: Estimated Annual Burden Hours and Cost Estimates for Special Review DCIs per Respondent

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	11	0	0	11	$1,261
2. Discuss test and protocol with Agency	5	10	0	16	$1,273
3. Plan activities	0	10	0	10	$642
4. Create information	22	512	103	637	$38,454
5. Gather information	17	51	0	68	$5,173
6. Process, compile, review information for accuracy	0	82	0	82	$5,140
7. Complete written forms	33	0	34	67	$5,134
8. Record, disclose, display information	0	0	69	69	$2,563
9. Store, file, or maintain information	21	0	52	73	$4,444
Total	*109*	*665*	*258*	*1,032*	*$64,084*

Estimated Total Annual Burden & Costs Across All Special Review DCI Data Generators:

Reporting (Collection Activities 1-7):

Burden: 891 hours per response x 1 response per DCI x 0.33 DCIs = 297 burden hours

Costs: $57,077 per response x 1 response per DCI x 0.33 DCIs = $19,026

Recordkeeping (Collection Activities 8-9):

Burden: 142 hours per response x 1 response per DCI x 0.33 DCIs = 47 burden hours

Costs: $7,007 per response x 1 response per DCI x 0.33 DCIs = $2,336

Total (Reporting + Recordkeeping):

Burden: 1,032 hours per response x 1 response per DCI x 0.33 DCI = 344 burden hours

Costs: $64,084 per response x 1 response per DCI x 0.33 DCI = $21,361

** Numbers may not add due to rounding.*

Section B-3: Estimating the Respondent Burden – Registration Review Program

Data that is submitted under the Registration Review Program includes that submitted through DCIs for Registration Review and Voluntarily Submitted Data. As the burden associated with Voluntarily Submitted Data can be highly variable, low and high burden estimates are provided.

Section B-3.1: Estimating Respondent Burden – Registration Review

The estimated total cost for all studies requested under the most burdensome registration review DCI that EPA has issued in the past three years was $4,916,432. The paperwork cost associated with this (35% of the total cost) was $1,720,772 or 27,716 total burden hours. EPA expects to issue 277 Registration Review DCIs over the next three years, which equals an average of 92 registration review DCIs annually. See Table B-7 below for burden activity details. Across all Registration Review DCIs, this would be $158,884,633 annually or 2,559,070 burden hours.

Table B-7: Estimated Annual Respondent Burden Hours and Costs for Registration Review DCIs

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	294	0	0	294	$34,573
2. Discuss test and protocol with Agency	147	276	0	423	$34,538
3. Plan activities	588	276	0	864	$86,397
4. Create information	441	13,738	2,766	16,945	$1,014,828
5. Gather information	0	1,378	0	1,378	$86,260
6. Process, compile, review information for accuracy	869	2,205	0	3,074	$240,162
7. Complete written forms	0	0	922	922	$34,415
8. Record, disclose, display information	294	0	1,844	2,138	$103,403
9. Store, file, or maintain information	294	0	1,383	1,677	$86,196
Total	*2,928*	*17,873*	*6,914*	*27,716*	*$1,720,772*

Estimated Total Annual Burden & Costs Across All Registration Review DCI Data Generators:

Reporting (Collection Activities 1-7):

Burden: 23,901 hours per response x 1 response per DCI x 92.33 DCIs = 2,206,818 burden hours

Costs: $1,531,173 per response x 1 response per DCI x 92.3 DCIs = $141,378,303

Recordkeeping (Collection Activities 8-9):

Burden: 3,815 hours per response x 1 response per DCI x 92.33 DCIs = 352,252 burden hours

Costs: $189,599 per response x 1 response per DCI x 92.3 DCIs = $17,506,330

Total (Reporting + Recordkeeping):
Burden: 27,716 hours per response x 1 response per DCI x 92.33 DCIs = 2,559,070 burden hours
Costs: $1,720,772 per response x 1 response per DCI x 92.33 DCIs = $158,884,633
* *Numbers may not add due to rounding.*

Section B-3.2: Estimating the Respondent Burden – Registration Review: Voluntary Submission of Data

Given that the Agency has completed all Reregistration Eligibility Decisions (REDs), voluntary data submissions to the EPA are now being received under the Registration Review Program. The Agency has provided high and low burden estimates as the expected cost of voluntarily submitted data is variable in nature.

Since no data is available on the burden per submission for voluntary data under Registration Review, burden hours and cost were adopted from estimates for voluntary data under Reregistration Review. The method used for Reregistration Review burden calculations used the burden hour cost calculated in the previous DCI ICR—adjusted for wage rate changes—to back out the proportional burden hour estimates for each of the three labor groups (i.e., 20% managerial, 65% technical, 15% clerical). Updating for 2012 labor wage rates, the total test cost per voluntary submission is expected to range from $117,862 to $731,969. This translates to paperwork burden estimates for voluntary submissions ranging from 664 to 4,126 burden hours, or $41,252 to $256,189 per voluntary submission. This method was used both for low and high burden voluntary submission burden hour estimates. See Tables B-8 and B-9 for details.

Table B-8: Estimated Annual Respondent Burden Hours and Costs for Registration Review: Voluntarily Submitted Data (Low Burden)

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	7	0	0	7	$846
2. Discuss test and protocol with Agency	4	7	0	10	$837
3. Plan activities	14	7	0	21	$2,106
4. Create information	11	329	66	406	$24,355
5. Gather information	0	33	0	33	$2,068
6. Process, compile, review information for accuracy	21	53	0	74	$5,777
7. Complete written forms	0	0	22	22	$825
8. Record, disclose, display information	7	0	44	51	$2,426
9. Store, file, or maintain information	7	0	33	40	$2,013
Total	*70*	*428*	*166*	*664*	*$41,252*

Estimated Total Annual Burden & Costs Across All Registration Review Voluntary Low Burden Studies:

Reporting (Collection Activities 1-7):
Burden: 574 hours per response x 0.33 submissions = 191 burden hours.
Costs: $36,813 per response x 0.33 submissions = $12,271.
Recordkeeping (Collection Activities 8-9):
Burden: 91 hours per response x 0.33 submissions = 30 burden hours.
Costs: $4,439 per response x 0.33 submissions = $1,480.
Total (Reporting + Recordkeeping):
Burden: 664 hours x 0.33 submissions = 221 hours
Costs: $41,252 x 0.33 submissions = $13,751
** Numbers may not add due to rounding.*

Table B-9: Estimated Annual Respondent Burden Hours and Costs for Registration Review: Voluntarily Submitted Data (High Burden)

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements	44	0	0	44	$5,131
2. Discuss test and protocol with Agency	22	41	0	63	$5,134
3. Plan activities	87	41	0	128	$12,830
4. Create information	65	2,045	412	2,523	$151,064
5. Gather information	0	205	0	205	$12,842
6. Process, compile, review information for accuracy	130	328	0	459	$35,869
7. Complete written forms	0	0	137	137	$5,124
8. Record, disclose, display information	44	0	275	318	$15,378
9. Store, file, or maintain information	44	0	206	250	$12,817
Total	*436*	*2,661*	*1,029*	*4,126*	*$256,189*

Estimated Total Annual Burden & Costs Across All Registration Review Voluntary High Burden Studies:

Reporting (Collection Activities 1-7):
Burden: 3,559 hours per response x 0.33 submissions = 1,186 burden hours.
Costs: $227,994 per response x 0.33 submissions = $75,998.
Recordkeeping (Collection Activities 8-9):
Burden: 568 hours per response x 0.33 submissions = 189 burden hours.
Costs: $28,195 per response x 0.33 submissions = $9,398.
Total (Reporting + Recordkeeping):
Burden: 4,126 hours x 0.33 submissions = 1,375 hours
Costs: $256,189 x 0.33 submissions = $85,396
** Numbers may not add due to rounding.*

Section B-4: Estimating Respondent Burden – Anticipated Residues/Percent Crop Treated DCIs (AR/PCT)

The Anticipated Residue and Percent Crop Treated (AR/PCT) review programs requires the Agency to reevaluate of previous Agency decisions regarding the establishment of a tolerance (maximum residue limit) for pesticide residues on food or feed crops. The law also requires that tolerance decisions based on ARs or PCT data be verified to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance.

Section B-4.1: Estimating Respondent Burden - Anticipated Residues/Percent Crop Treated DCIs

There are four IC groups associated with AR/PCT, including:

- DCI for anticipated residues requiring a base set of data,
- DCI for anticipated residues for verification of use data
- DCI for anticipated residues collected from publicly available sources, and
- DCI for percent crop treated using existing information.

After reevaluating the burden hours from the last DCI ICR, the Agency is not changing the burden hour estimates. Thus, it does not follow the 20%-65%-15% Managerial-Technical-Clerical breakout assumption as is typically the case. This is because given the nature of data requests that occur in an AR/PCT DCI, paperwork burden falls disproportionately on technical labor, i.e., 72%-99% technical labor versus the standard 65% technical labor—with the exception of anticipated residues verification of use data, where paperwork burden disproportionately falls on management (approximately 40% managerial labor versus the standard 20% managerial labor).

Furthermore, the previous collection activities associated with the AR/PCT DCIs are less detailed than collection activities associated with different IC groups. The Agency has altered these less defined groupings to coordinate with the collection activities associated with other IC groups. Table B-11 provides a breakdown of how these categories compare.

Table B-11: Change in Collection Activity Groupings for Anticipated Residues/Percent Crop Treated DCIs

Previous Collection Activity Groupings for AR/PCT DCI IC Groupings	New Collection Activity Groupings for AR/PCT DCI IC Groupings
1. Read Instructions	1. Read and discuss test requirements
	2. Discuss test and protocol with Agency
2. Plan Activities	3. Plan activities
3. Create Information	4. Create information
4. Gather Information	5. Gather information

Previous Collection Activity Groupings for AR/PCT DCI IC Groupings	New Collection Activity Groupings for AR/PCT DCI IC Groupings
5. Compile and Review	6. Process, compile, review information for accuracy
6. Complete Paperwork	7. Complete written forms
7. Maintain and file	8. Record, disclose, display information
	9. Store, file, or maintain information

The following presents the Agency's burden estimates for each type of DCI.

Section B-4.2: Anticipated Residue DCIs: Base Set of Data

As explained in Section B-4.1, the Agency is not changing the burden hour estimates for any of the AR/PCT DCIs from the original (20%-65%-15% Managerial-Technical-Clerical) paperwork burden breakouts breakout. For base set of data, the Managerial-Technical-Clerical paperwork burden breakout for each type of labor is 0.07% managerial, 99.91% technical, and 0.02% clerical.

The total test cost for an anticipated residue DCI requiring a base set of data is estimated at $2,439,314. Respondent burden hours for generating and submitting data in response to a DCI for anticipated residues requiring a base set of data to be submitted are estimated at 13,636 burden hours, or $853,760, per response.

In most cases, registrants will be able to get the information from federal and state monitoring programs, thus the Agency estimates that no more than one registrant might generate their own monitoring data in response to the DCI every three years which would result in 4,545 burden hours or $284,587 in costs annually, as shown in B-12.

Table B-12: Anticipated Residue DCIs: Base Set of Data Annual Burden/Cost Estimates, per DCI

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements					
2. Discuss test and protocol with Agency	2	0	0	2	$235
3. Plan activities	4	0	0	4	$470
4. Create information	0	13,600	0	13,600	$851,088
5. Gather information	0	16	0	16	$1,001
6. Process, compile, review information for accuracy	1	8	0	9	$618
7. Complete written forms	2	0	2	4	$310

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
8. Record, disclose, display information	0	0	1	1	$37
9. Store, file, or maintain information					
Total	*9*	*13,624*	*3*	*13,636*	*$853,760*

Estimated Total Annual Burden & Costs Across All Anticipated Residue (Base Set of Data) DCIs:

Reporting (Collection Activities 1-7):
Burden: 13,635 hours per response x 1 response per DCI x 0.33 DCIs = 4,545 burden hours.
Costs: $853,722 per response x 1 response per DCI x 0.33 DCIs = $284,574.
Recordkeeping (Collection Activities 8-9):
Burden: 1 hour per response x 1 response per DCI x 0.33 DCIs = 0.3 burden hours.
Costs: $37 per response x 1 response per DCI x 0.33 DCIs = $12.
Total (Reporting + Recordkeeping):
Burden: 13,636 hours per response x 1 response per DCI x 0.33 DCIs = 4,545 burden hours.
Costs: $853,760 per response x 1 response per DCI x 0.33 DCIs = $284,587.
** Numbers may not add due to rounding.*

Section B-4.3: Anticipated Residue DCIs: Verification of Use Data

As explained in Section B-4.1, the Agency is not changing the burden hour estimates for any of the AR/PCT DCIs from the original (20%-65%-15% Managerial-Technical-Clerical) paperwork burden breakouts breakout. For verification of use data, the Managerial-Technical-Clerical paperwork burden breakout for each type of labor is 41% managerial, 46% technical, and 13% clerical.

The total test cost for an anticipated residue DCI requiring a verification of use data is estimated at $16,085. The Agency estimates that the verification for updating use information is 69 burden hours or $5,630 per response and that no more than one respondent every three years will comply with a DCI by submitting a base set of data for updating use information, which equates to 23 burden hours annually ($1,877). Refer to Table B-13 for details.

Table B-13: Anticipated Residue DCIs: Verification of Use Data Annual Burden/Cost Estimates, per DCI

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements					
2. Discuss test and protocol with Agency	8	0	0	8	$940
3. Plan activities	16	0	0	16	$1,881

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
4. Create information	0	0	0	0	$0
5. Gather information	0	16	0	16	$1,001
6. Process, compile, review information for accuracy	2	16	0	18	$1,236
7. Complete written forms	2	0	8	10	$534
8. Record, disclose, display information					
9. Store, file, or maintain information	0	0	1	1	$37
Total	*28*	*32*	*9*	*69*	*$5,630*

Estimated Total Annual Burden & Costs Across All Anticipated Residue (Verification of Use) DCIs:

Reporting (Collection Activities 1-7):
Burden: 68 hours per response x 1 response per DCI x 0.33 DCIs = 23 burden hours.
Costs: $5,592 per response x 1 response per DCI x 0.33 DCIs = $1,864.
Recordkeeping (Collection Activities 8-9):
Burden: 1 hour per response x 1 response per DCI x 0.33 DCIs = 0.3 burden hours.
Costs: $37 per response x 1 response per DCI x 0.33 DCIs = $12.
Total (Reporting + Recordkeeping):
Burden: 69 hours per response x 1 response per DCI x 0.33 DCIs = 23 burden hours.
Costs: $5,630 per response x 1 response per DCI x 0.33 DCIs = $1,877.
** Numbers may not add due to rounding.*

Section B-4.4: Anticipated Residue DCIs: Updated Public Source Monitoring Data

As explained in Section B-4.1, the Agency is not changing the burden hour estimates for any of the AR/PCT DCIs from the original (20%-65%-15% Managerial-Technical-Clerical) paperwork burden breakouts breakout. For updated public source monitoring data, the Managerial-Technical-Clerical paperwork burden breakout for each type of labor is 20% managerial, 73% technical, and 7% clerical.

The total test cost for an anticipated residue DCI requiring public source monitoring data is estimated at $28,242. The average respondent burden for submitting a base set of data for updating monitoring information is estimated at 137 burden hours or $9,885 per year. The Agency estimates that an average of one respondent every three years is likely to be able to comply with a DCI by submitting data from publicly available sources. As such, the total annual respondent burden for this type of DCI is estimated to be 46 burden hours ($3,295). See Table B-14.

Table B-14: Anticipated Residue DCIs: Updated Public Source Monitoring Data Annual Burden/Cost Estimates, per DCI

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements					
2. Discuss test and protocol with Agency	8	0	0	8	$940
3. Plan activities	16	0	0	16	$1,881
4. Create information	0	0	0	0	$0
5. Gather information	0	60	0	60	$3,755
6. Process, compile, review information for accuracy	2	40	0	42	$2,738
7. Complete written forms	2	0	8	10	$534
8. Record, disclose, display information					
9. Store, file, or maintain information	0	0	1	1	$37
Total	*28*	*100*	*9*	*137*	*$9,885*

Estimated Total Annual Burden & Costs Across All Anticipated Residue (Public Source Monitoring Data) DCIs:

Reporting (Collection Activities 1-7):
Burden: 136 hours per response x 1 response per DCI x 0.33 DCIs = 45 burden hours
Costs: $9,848 per response x 1 response per DCI x 0.33 DCIs = $3,283
Recordkeeping (Collection Activities 8-9)
Burden: 1 hour per response x 1 response per DCI x 0.33 DCIs = 0.3 burden hours
Costs: $37 per response x 1 response per DCI x 0.33 DCIs = $12
Total (Reporting + Recordkeeping):
Burden: 137 hours per response x 1 response per DCI x 0.33 DCIs = 46 burden hours
Costs: $9,885 per response x 1 response per DCI x 0.33 DCIs = $3,295
** Numbers may not add due to rounding.*

Section B-4.5: DCIs for Percent Crop Treated Estimates

As explained in Section B-4.1, the Agency is not changing the burden hour estimates for any of the AR/PCT DCIs from the original (20%-65%-15% Managerial-Technical-Clerical) paperwork burden breakouts breakout. For percent crop treated estimates, the Managerial-Technical-Clerical paperwork burden breakout for each type of labor is 5% managerial, 90% technical, and 5% clerical.

The estimated total test cost for a DCI requiring percent crop treated estimates is $10,802. The annual per respondent burden for generating percent crop treated estimates using existing information is estimated to be 59 burden hours ($3,781). Percent crop treated estimates are generally conducted within the Agency, and only in rare instances would a

registrant need to gather the information; one DCI every three years impacting one respondent is likely an overestimation. If this were the case, however, the annual burden estimates is 20 hours or $1,260 in paperwork burden cost. The estimated costs assume that the cost of purchasing or obtaining percent crop treated information is obtaining data from existing, contracted data sources. See Table B-15.

Table B-15: DCIs for Percent Crop Treated Estimates Annual Respondent Burden/Cost Estimates, per DCI

Collection Activity	Mgmt. ($117.54)	Tech. ($62.58)	Cler. ($37.33)	Total	
				Hours	Costs
1. Read and discuss test requirements					
2. Discuss test and protocol with Agency	1	1	0	2	$180
3. Plan activities	0	2	0	2	$125
4. Create information	0	8	0	8	$501
5. Gather information	0	22	0	22	$1,377
6. Process, compile, review information for accuracy	1	20	0	21	$1,369
7. Complete written forms	1	0	2	3	$192
8. Record, disclose, display information					
9. Store, file, or maintain information	0	0	1	1	$37
Total	*3*	*53*	*3*	*59*	*$3,781*

Estimated Total Annual Burden & Costs Across All Anticipated Residue (Public Source Monitoring Data) DCIs:

Reporting (Collection Activities 1-7):
Burden: 58 hours per response x 1 response per DCI x 0.33 DCIs = 19 burden hours.
Costs: $3,744 per response x 1 response per DCI x 0.33 DCIs = $1,248.
Recordkeeping (Collection Activities 8-9):
Burden: 1 hour per response x 1 response per DCI x 0.33 DCIs = 0.3 burden hours.
Costs: $37 per response x 1 response per DCI x 0.33 DCIs = $12.
Total (Reporting + Recordkeeping):
Burden: 59 hours per response x 1 response per DCI x 0.33 DCIs = 20 burden hours.
Costs: $3,781 per response x 1 response per DCI x 0.33 DCIs = $1,260.
* *Numbers may not add due to rounding.*

Attachment 1
(Originally 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 Data Call-In Notice

Draft Document for Public Review - EPA is releasing this draft document solely for the purpose of public review and comment. This draft document is not now, and has not yet been, formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination. Please submit comments to **Docket ID # EPA-HQ-OPP-2007-0923** at *www.regulations.gov*.

Office of Pesticide Programs
October 2007

Contents

Article I. 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).[11] 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 the PRA requirements, EPA must submit an Information Collection Request

11 OMB is part of the Executive Office of the President.

(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.[12] "Burden" means the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal Agency.[13]" 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

12 5 CFR 1320.3(l)
13 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.

- **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).

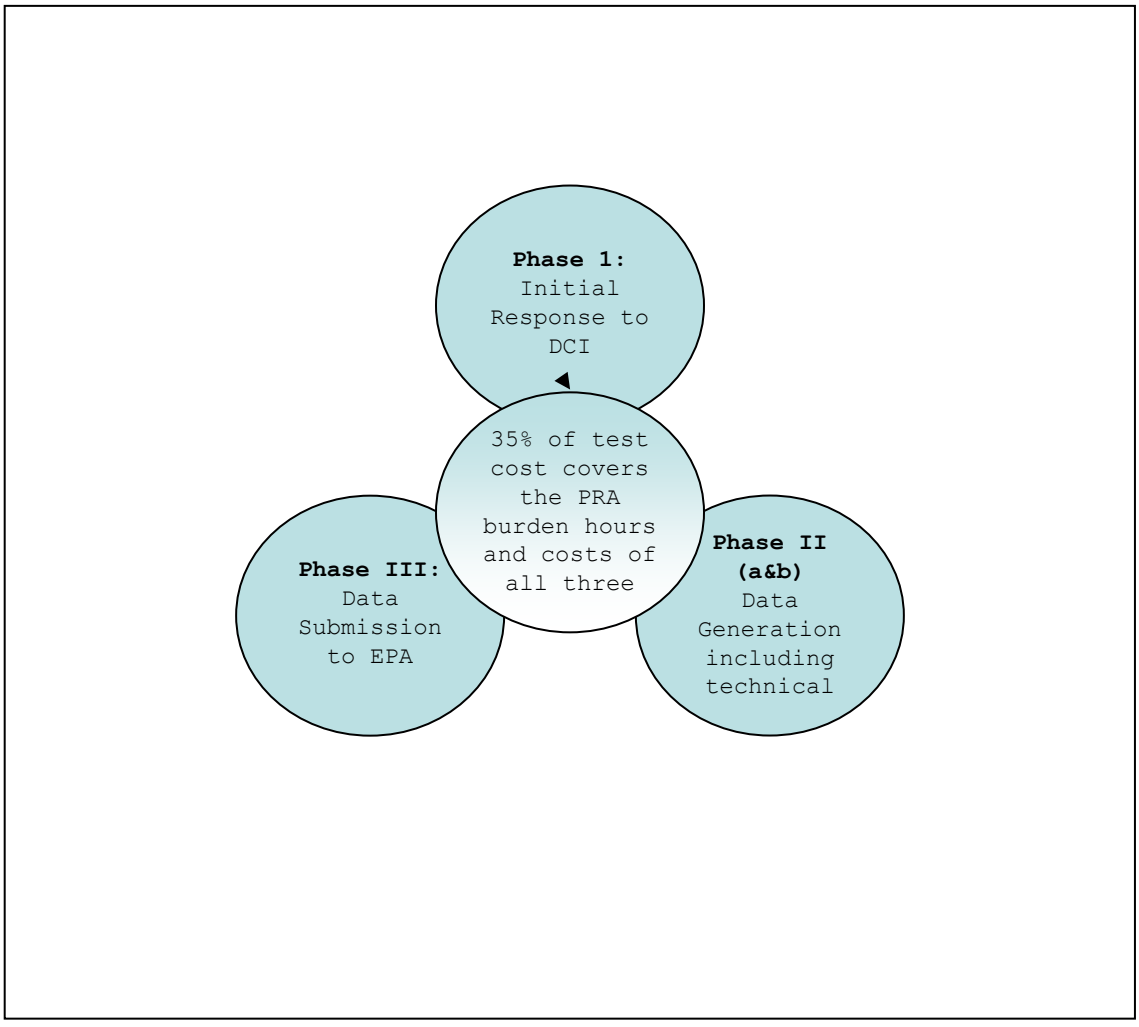


Figure - 1 Relationship of Test Costs to Response Phases

-
- **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.[14]
- 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:[15]
    a. Managerial (20%)
    b. Technical (65%)
    c. Clerical (15%)
- Labor rates are derived from the parent ICR
- Labor rates are "fully loaded[16]"

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 have not been previously required, and for which test cost estimates have not yet

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

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 estimates 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.[17]

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,

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

2005,[18] was also used to extract costs for activities that do not involve data 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.

18 See Environmental Protection Agency proposed rule 40 CFR parts 158 and 172, Subparts L&M: 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[19] 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.[20]
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

19 "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.

20 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 does 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.

(i) 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 eligibility generic 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

(ii) 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. [21] 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

21 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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	**Test Name**	**Average Test 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)*
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						

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	**Test Name**	**Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	**Test Name**	**Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	Test Name	Average Test 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)*
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

Test Information			Paperwork Burden Totals (35% of study cost)			
Test Guideline/ Section	**Test Name**	**Average Test 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)*
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					

Office of Pesticide Programs
Questions for DCI Response Burden Assessment Workshop Participants
Response to questions due to OPP by January 13, 2014

The list of questions below relate to the OPP discussion paper presented to the participants of the DCI Response Burden Assessment Workshop held December 12, 2013. During the DCI ICR renewal process, OPP will assess responses received from Workshop participants and, if rational and sufficient data is provided, modify the agency's estimates of the paperwork burden and cost of responding to a DCI as necessary. After the consultation period is complete, Industry will have two more opportunities to comment on the methodology as it is being developed in conjunction with the new DCI ICR. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Non CBI materials submitted to OPP will be placed in the docket for the DCI ICR renewal when the docket is created. Data estimates or data stated in ranges or other summary statements are acceptable. If you feel you must submit CBI or other information whose disclosure is restricted by statute, please contact one of the program contacts below to assist you with the CBI data submission.

Burden Questions

Consortium participants

1. The EPA encourages companies/registrants to combine resources when responding to a DCI—thus it is assumed that only one set of data (a.k.a. "data set,") and all of the data requested is submitted to the EPA in response to each DCI. However, this is not always the case.
    - The agency is interested in obtaining estimates of and a basis for supporting:
        - How many datasets are typically submitted per DCI [for each Information Collection (IC) group, if possible—see Table 2 for a list of IC groups].
        - The typical number of participants in the consortium that your company participates in (by IC group, if possible).
        - The total number of consortiums your company has participated in on an annual basis.

Office of Pesticide Programs
Questions for DCI Response Burden Assessment Workshop Participants
Response to questions due to OPP by January 13, 2014

- Any other information you feel would support the EPA in estimating consortium participant burden.

  - Since waiver requests and other exemptions are *not* data sets can you estimate the percentage of the DCI response that will be generated studies?

1a. *Trade Associations

Does your Trade Association track membership participation in a number of consortiums? Can you provide information on the total number of consortiums your membership has participated in on an annual basis?

2. Does your company track the activities and costs for consortium participation? EPA would like to derive an estimate for the average cost for participating in a consortium (e.g., communication, meetings, and any other activities needed to coordinate the consortium), in addition to the cost of, data generation/purchasing (e.g., communication, meetings, and any other activities needed to coordinate the consortium). If possible, please provide data on the typical per entity *annual* cost of consortium participation.

3. When participating in a consortium, EPA is assuming that the cost for participating varies among involved entities. Do you have any information supporting how costs are distributed among participants and their typical variation?

Office of Pesticide Programs
Questions for DCI Response Burden Assessment Workshop Participants
Response to questions due to OPP by January 13, 2014

DCI recipients

4. Are the types of initial DCI burden response activities correct? (See Table 3).

5. Are the initial response activities to the DCI (e.g., 90 day response) for planning, generating and submitting data in response to a DCI correct? Are the total burden and breakout percentages of the Industry labor force used to respond to a DCI (i.e., managerial, technical and clerical) correct? (See Table A-1, Appendix A).

6. Do you have information to support a different estimate for the expected number of DCIs recipients? By IC group, if possible.

Data generators

7. Are the types of initial DCI burden response activities correct? (See Table 3).

8. Are the total burden and breakout percentages of the Industry labor force used to respond to a DCI (i.e., managerial, technical and clerical) correct?

9. Do you have information to support a different estimate for the expected number of DCIs for which data generation will be necessary? By IC group, if possible. For example: Your company receives a DCI request. The request suggests that a total of 10 studies are to be submitted to OPP. You believe that your company will only have to generate 8 studies (data generation) and will seek waivers (or other non-data generating actions) for the other two

studies. In this example your company only anticipates generating 80% of the requested studies for this DCI request.

Consultation activities

10. Does your company track time and labor estimates for consultation activities? How would you define the burden activities (i.e., meeting logistics, meeting preparation, travel, meeting follow-up including debriefing management)?

General Questions:

11. When you receive a DCI, are the instructions and process for responding understandable? Do you clearly know what is required of you?

12. If there are records to maintain, are you familiar with your record keeping requirements?

13. Are the forms that are used to report the data gaps, clear, logical, and easy to comprehend and/or complete?

14. Do you normally submit your response as part of a DVD or other electronic file only? Or is your response a mix of electronic media and paper?

15. Do you have any suggestions to offer to the Agency to clarify the instructions or the forms?

Office of Pesticide Programs
Questions for DCI Response Burden Assessment Workshop Participants
Response to questions due to OPP by January 13, 2014

Response to OPP

Thank you for your participation in the DCI Response Burden Assessment Workshop. We would like to receive your comments by **January 13, 2014**. We ask that each company submit one set of consolidated comments. Please forward your non-CBI responses via email to Cameo Smoot, Field and External Affairs Division, OPP smoot.cameo@epa.gov, phone (703)305-5454.

If you have additional questions, or would like to follow-up with OPP staff. Staff contact numbers are as follows:

BEAD – Elizabeth Hill, 703-308-8150
PRD – Joe Nevola, 703-308-8037
AD – Rose Kyprianou, 703-305-5354

Pesticide Data Call In (DCI) Information Collection Request (ICR)
Industry Consultation Workshop

December 12, 2013, 11:00am – 1:30pm

List of Participants

Industry	**EPA**
David Swayne – Scientific and Reg Consultant (SRC)	Lily Negash
Erin Ahlers – Monsanto	Joe Hogue
Erin Tesch – Tech Sciences Group	Martha Shimkin
Abigail – Tech Sciences	Elizabeth Hill
Abbey Trubblewood – Dow	Michelle Ranville
Janelle Kay – Texas Reg Consulting	Tim Kiely
John Abbot –	Mike Goodis
Charlotte Sanson – BASF	Angela Hoffman
Kristy Keating – BASF	Joe Nevola
Robert Butz –	Cameo Smoot
Rachel Calliers – SC Johnson	Rose Kyprianou
Seth Goldberg – Steptoe	Rich Dumas
Elizabeth Brown – Steptoe	Kathryn Boyle
Mike Kelly –	Stephen Smearman
Has Shah – American Chemistry Council (ACC)	Lance Wormel
	Kathryn Boyle
	Steve Smearman