1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Information Collection – Title and Numbers

Title: Pesticide Data-Call-In Program

ICR Numbers: OMB Control No.: 2070-0174; EPA ICR No.: 2288.03

EPA Form Numbers: 8570-4, 8574-27, 8570-28, 8570-32, 8579-34, 8570-35, 8570-36, 8570-37, 6300-3, 6300-4

Docket ID Number: EPA-HQ-OPP-2016-0109

1(b). Executive Summary

ICR Status: This information collection request (ICR) is a renewal of a currently approved ICR under the Paperwork Reduction Act (PRA)[1] that is scheduled to expire on August 31, 2017. Before submitting the ICR to the Office of Management Budget (OMB) for review and approval under the PRA, EPA is soliciting comments pursuant to PRA §3506(c)(2)(A) and 5 CFR 1320.8(d)(1).

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the ***Federal Register***, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

Short Characterization/Abstract: This ICR covers the information collection activities associated with the issuance of data-call-ins (DCIs) under §3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[2]

EPA regulates the use of pesticides under the authority of two federal statutes: FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA)[3]. In general, before manufacturers can sell pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. EPA grants a "registration" or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with the use of the product. Applicants, or potential registrants, must generate or provide the scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide. The data allow EPA to evaluate whether a pesticide has the potential to cause

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1 44 USC 3501 *et seq.*
2 7 USC 136 *et seq.*
3 21 USC 346a

harmful effects on certain non-target organisms and endangered species that include: humans; wildlife; plants; and surface water or ground water.

Through a rigorous scientific and public process, EPA specifies the kinds of data and information necessary to make regulatory judgments about the risks and benefits of pesticide products under FIFRA §§ 3, 4 and 5, as well as the data and information needed to determine the safety of pesticide chemical residues under FFDCA §408. The regulations in 40 CFR part 158 describe the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process (e.g., as used in the registration review program); or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

As described in 40 CFR 158.30, however, FIFRA provides EPA with flexibility to require, or not require, data and information for the purposes of making regulatory judgments for individual pesticide products, thereby allowing for the data required to be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process. In addition, the Agency cautions applicants that the data routinely required by the regulations may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment. EPA may, therefore, require the submission of additional data or information beyond that specified in the regulations if such data or information are needed to evaluate a pesticide product as required by FIFRA and FFDCA.

EPA uses the DCIs issued under this ICR to acquire the data that has been deemed necessary for the Agency's statutorily mandated review of a pesticide's registration, which require it to assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment and whether the Agency will pursue appropriate regulatory measures. The key program areas are described in more detail in this ICR, along with the Agency's estimates of the information collection burden and costs associated with issuing DCIs under those key program areas.

Respondents/Affected Entities: Entities potentially affected by this ICR are pesticide registrant and are identified by the North American Industrial Classification System (NAICS) code 325320 (Pesticide and Other Agricultural Chemical Manufacturing).

Respondent's Obligation to Respond: Response to a DCI is mandatory under FIFRA section 3(c)(2)(B).

Estimated Number of Respondents: 122

Frequency of Response: On occasion.

Estimated Burden: The response burden is estimated to range between 20 and 8182 hours per response, depending on the specific data gap associated with the individual DCI. The total annualized burden for this ICR is estimated to be 625,669 hours (per year). The burden is defined at 5 CFR 1320.3(b).

Estimated Cost: The total annualized cost for this ICR is estimated to be $44,890,390. Mailing costs for DCIs are not included in the estimates below as electronic submissions are now accepted, and it is typical practice for registrants to submit data using this method. See http://www.epa.gov/pesticide-registration/e-submission-resource-documents-assembly-electronic-packages-and-discs. In the case that DCI responses are submitted using certified mail, it is estimated that the cost to submit an individual DCI would be no more than $20.[4]

Changes in Burden Estimates: This ICR represents an increase of 362,368 hours (625,669 – 262,301) in the total estimated annualized burden compared with that currently approved by OMB. The burden increase is a cumulative result of the program implementing new methodologies to calculate respondent burden, the inclusion of a new IC group - consortium participants - to more accurately reflect the respondent burden, renaming and recalculating an existing IC group from Enforcement and Unanticipated Incident activities to Maintenance DCIs, and the acceleration of the Registration Review Program. All of these activities have contributed to the significant increase in number of DCIs to be issued (221 versus 45) annually. This change represents a program adjustment.

2. AUTHORITY FOR THE COLLECTION

FIFRA §§3(a) and 12(a)(1) require a person to register a pesticide product with the EPA before the pesticide product may be lawfully sold or distributed in the United States. A pesticide registration is a license that allows a pesticide product to be sold and distributed for specific uses under specified terms and conditions such as use instructions and precautions. The proponent of initial or continued registration always bears the burden of demonstrating that a pesticide product meets the statutory standard for registration.

A pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA §3(c)(5), which is as follows:

(A) Its composition is such as to warrant the proposed claims for it.

4 EPA's Pesticide Re-evaluation Division found that typical GDCI packets averaged 40 pages; certified mailing cost for this size package are approximately $20.

(B) Its labeling and other material required to be submitted comply with the requirements of this Act.
(C) It will perform its intended function without unreasonable adverse effects on the environment.
(D) When used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

FIFRA §2(bb) defines “unreasonable adverse effects on the environment" as follows:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug and Cosmetic Act.

FIFRA §3(c)(2) directs EPA to publish guidelines specifying the kinds of data that applicants and registrants must submit to support the EPA regulatory determinations established under FIFRA. EPA identifies the majority of the data requirements in 40 CFR part 158, and in the context of individual actions as allowed by FIFRA §3(c)(2).

EPA regulations at 40 CFR part 152, subpart E, describe a variety of means by which an applicant may satisfy EPA’s data requirements and requests for data. Persons submitting data must request inclusion on an Agency-maintained Data Submitters list as the means for asserting their rights to offers of compensation from applicants who cite their data. Procedures also allow an applicant to cite to data previously submitted by another person that are relevant to that applicant’s product. When the latter option is selected, an applicant may be required to either obtain permission or offer compensation to cite the data, depending upon whether the data at issue are entitled to the exclusive use or data compensation provisions of FIFRA §3(c)(1)(F).

In addition, 40 CFR part 152, subpart E spells out the circumstances under which certain applicants are exempt from data submission or citation obligations (i.e., the formulators’ exemption provided by FIFRA §3(c)(2)(D)).

All the programs and DCI activities represented in this ICR share a common statutory authority, FIFRA § 3(c)(2)(B), which authorizes EPA to require pesticide registrants to generate and submit data to the Agency, when such data are needed to maintain an existing registration of a pesticide.

Before the Agency determines that specific data are needed under this ICR, the Agency will first search for available information (i.e., EPA databases for information that may have been submitted to EPA under another ICR, submitted

voluntarily, or submitted by another respondent; information that has otherwise published in the literature; or information that is otherwise publicly available).

EPA has also established a transparent and participatory process that allows for public dialogue on EPA's risk characterizations under these pesticide registration review programs, including the consideration related to the need for other data or information in order to make the required statutory determinations for that pesticide. Only if the needed data are not found to be otherwise available will EPA require the submission or generation of the specific data needed in a particular case. Such data, which are described in more detail later in this document, may include toxicology studies, fish and wildlife studies, environmental fate studies, chemistry studies, endocrine disruptor screening data and/or other data needed to analyze the potential risks and benefits associated with pesticide chemicals.

3. INFORMATION COLLECTION (IC) ACTIVITIES

Several programs involve the issuance of DCIs and share both a common statutory authority, FIFRA § 3(c)(2)(B), and the same basic information collection activities. As such, this section of the ICR will present the basic information collection activities and estimates common to all the DCIs that are addressed in this ICR, followed by a presentation of the program specific activities and estimates.

3(a). Basic IC Activities Common to all DCIs

This section of the ICR will address the basic IC activities common to all DCIs, including:

- The collection methodology used to collect the data;
- The data that may be collected using a DCI; and
- The Agency's estimated burden and costs associated with the related paperwork activities.

3(a)(i). Common DCI Collection Methodology

The IC activities and procedures associated with the issuance of a DCI are a subset of the overall activities related to DCIs generally. The following is a brief list of the overall activities common to DCIs and the basic IC activities covered by this ICR:

1) EPA identifies the chemical as part of the related program.
2) EPA identifies the potential need for data.
3) Registrant & public involvement/comment as part of the related program.
4) EPA completes final data needs determination.
5) EPA issues the DCI to the chemical's registrants of the chemical.
6) Registrant submits an initial response to EPA, indicating how they plan to comply with the DCI.

7) As appropriate, the registrant may consult with EPA on their plans, e.g., data requested, protocols for studies, timeframes for submissions, etc.
8) If multi-year studies are involved, the registrant may be asked to submit an annual status report to EPA, reporting on progress towards compliance with DCI due date(s).
9) Registrant submits the data/final study reports identified in the DCI to EPA.
10) EPA reviews submission to determine if it satisfies the DCI.
11) EPA processes the data for consideration and uses in applicable assessments and decision-making.

The collection methodology for these IC activities, including the initial response options, is diagramed in Attachment B.

The data requirements are organized in 40 CFR part 158 in a series of subparts to address an individual scientific disciplines or data types; and describes general policies and procedures associated with the submission of data in support of a pesticide regulatory action, including the definitions, applicability, flexibility, CBI, how to submit data, use of other data, format of data submissions, flagging of studies for potential adverse effects, waivers, minor use data policies, etc. By applying the data requirements based both on the pesticide type and identified use patterns, the data collected can be tailored to ensure that the relevant data is available to support the regulatory decisions for that registration.

In establishing the data requirements in 1984, EPA adopted a step-wise approach to assist the applicant in determining the data needed to support the registration of a particular product. This approach, which is described in 40 CFR part 158, subpart B, involves the use of “data tables” to facilitate the identification of the applicability of the data requirements. In essence, the data requirements illustrate the questions the registrant will need to answer regarding the safety of the pesticide product before the Agency can register it. Because of the variety of chemicals and use patterns, and because EPA must retain the flexibility to tailor data requirements as appropriate, only qualitative descriptors are in the tables. Test notes provide more specific information on the applicability of specific data requirements.

The table descriptors NR (not required), R (required), and CR (conditionally required) should be viewed as a general presentation, indicating the likelihood that the data requirement applies.

- The use of R does not necessarily indicate that a study is always required, but that it is more likely to be required than not. For example, if the applicant wanted to apply his pesticide to apples, then crop field trials would be required almost always on apples. However, if the physical/chemical properties of the chemical did not lend themselves to the test, such as performing an inhalation test with a chemical that is a solid and has an extremely low vapor pressure, then a waiver might be

granted. Generally, test notes for R studies discuss any particular circumstances when the testing might not be required.

- The use of CR means a study is less likely to be required. Triggers in the test notes indicate the circumstances under which the Agency has learned through experience that the information is needed. Although only an approximation, if percentages were to be assigned to indicate the need for a particular study, then R could be viewed as representing the submission of a study 50% to 100% of the time and CR would be up to 50%.

Thus, NR, R, and CR are used for convenience to make the table format feasible but serve only as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual need for the data.

The table format includes a column heading entitled “Guideline," which refers to the OCSPP Harmonized Test Guidelines[5]. Guideline numbers are provided as information/guidance to applicants. These Guidelines set forth recommended instructions and test methods for performing a study to generate the required data. Since these are guidance documents, the applicant is not required to use these Guidelines, but may instead seek to fulfill the data requirement by other appropriate means such as alternative test methods, submission of an article from open literature, or use of modeling. The applicant may submit a protocol of his own devising for the Agency to review. However, the OCSPP Harmonized Guidelines have been developed through a rigorous scientific process, including extensive peer review by the FIFRA Scientific Advisory Panel. Additionally, many of the Guidelines have been harmonized internationally. As such, they represent the recommended approach to developing high-quality data that should satisfy EPA's data needs for risk assessment.

Since it is not possible to sufficiently delineate all circumstances in test notes, consultation with EPA is encouraged. Applicants are encouraged to visit the Agency's website at http://www.epa.gov/pesticide-registration/data-requirements

The Agency may also require a study to generate data that are not codified in 40 CFR part 158 be conducted to provide critical information about the risks and benefits of the pesticide in support of its registration. Agency requests for these studies are based on the particular characteristics of the chemical, and the Agency’s need for the information in order to make the required statutory finding. In some cases, where the Agency has determined that there is a need for specific data not yet codified in 40 CFR part 158, EPA is already requesting or accepting the voluntary submission of the data in order to facilitate making sound regulatory decisions, while minimizing the burden and costs associated with a

5 The OCSPP Harmonized Test Guidelines are available at http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/master-list-test-guidelines-pesticides-and-toxic

delayed or conditioned decision. A listing of the non-codified studies which EPA has recently or is currently requesting for certain call-ins (DCIs) issued or expected to be issued by the EPA along with a rationale for requiring the data and an explanation of the practical utility of the data is contained in Appendix E. The studies are grouped by scientific discipline.

3(a)(ii). Data That May Be Collected 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 request will be primarily based on the data requirements that are found in 40 CFR part 158, which includes a provision that allows the Agency to seek additional non-codified data that is determined to be necessary to make the risk-based decisions mandated by federal law. In codifying the requirements in 40 CFR part 158, EPA provided 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.

Section 4 of this ICR includes a discussion of how the data are used in EPA decision-making.

3(a)(iii). Methodology Used to Estimate the Paperwork Burden and Costs for DCIs

The Agency uses two basic approaches to calculating the potential burden and costs for this ICR: 1) For the data generation activities, EPA calculated the paperwork burden as a percentage of the testing costs; and 2) For the rest of the paperwork activities EPA estimated the average amount of time required to complete the specific activity, considering estimates provided in other approved ICRs involving the same activity, feedback from stakeholders, and EPA's overall experience with such activities.

Method Used to Calculate the Burden and Costs for Data Generation. EPA calculates 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.

This methodology as described in detail in 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."[6] Based on feedback received at the time, EPA concluded the methodology was a reasonable and fair alternative to simply setting a single estimate for data generation burden or perhaps using some set criteria like a high, medium or low burden, neither of which may fairly reflect potential differences in burden.

In December 2013, the Agency held a DCI Response Burden Assessment Workshop with industry stakeholders. As part of the reassessment, EPA consulted 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.[7] As a result, the Agency redefined some of the 2007 methodologies by revising the number of DCI recipient groups and calculations for those groups to reassess the PRA burden. For more detail on the revised burden methodology, see Attachment B.

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. For this ICR, 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.

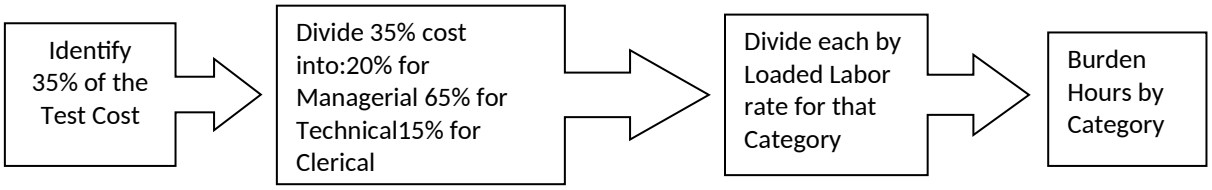
Based on the existing methodologies, EPA used 35% of the estimated total test cost to calculate the total potential cost of the paperwork activities related to data generation. The 35% of test cost is disaggregated by labor category, and then burden hours are extrapolated by using the loaded labor rates. To disaggregate by labor category, the Agency considered the estimated distribution of paperwork activity across the labor category represented and the existing methodology assumption that paperwork activities for data generation mostly involve the technical staff to perform the tests, with a few activities related to management and clerical. See Figure 1 for an illustrated outline of the Agency burden calculation process for data generation.

Figure 1 – Method for Calculating Paperwork Burden from Test Costs

6 See Appendix D.

7 On December 12, 2013, The Office Pesticide Programs sponsored a DCI Response Burden Assessment Workshop. Industry participants included, but were not limited to: representatives from BASF, the DOW Chemical Company, the American Chemistry Council Biocides Panel, Steptoe and Johnson, LLP, Technology Sciences Group Inc., Monsanto, and SC Johnson. Meeting materials and Industry comments are part of the docket for the ICR renewal at**:** EPA-HQ-OPP- 2016-0109.

This approach assumes and incorporates the following core considerations:



(1) Recipients generate all of the data as specified in the DCI 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.

See Attachment B, Section II, B. Methodology for Calculating Labor Wage Rates, for more details about this method.

Method Used to Calculate the Burden and Costs for Other Activities. For the other activities, EPA estimated the burden hours by considering the activities themselves and the average expected amount of time that the activity is anticipated to involve. These estimates consider the Agency's experience with similar data collection activities and direct experience in conducting the tests in EPA Laboratories. The methodology used to calculate cost are identified in Appendix D, section VI*, Is the burden for those not generating data covered?*

3(a)(iv). Common DCI-Related Respondent Activities

For each program DCI (reregistration, registration review, special review, etc.,) each DCI will involve 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:

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. These initial response options are generally available under the pesticide program, and the activities, along with the paperwork burden and costs associated with those

activities, are already addressed under other ICRs. Not all DCI recipients will generate data in response to a DCI. The DCI recipient is assumed to be involved in the four burden activities listed in Table 1. The burden for DCI recipients only will be lower than the burden estimates for the DCI recipients who are also part of 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 burden activities listed in Table 1. 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.[8] 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.). The seven additional consortium burden activities and operating costs are accounted for in Table 1.
Table 1 identifies the paperwork activities that would typically be performed by a DCI recipient. Each recipient group is expressed by the activities of the corresponding categories.

8 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.

Table 1 – Expected DCI Recipient Activities and Categories

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 Activities	
1) Negotiate/establish consortium/task force agreements/select administrator	Paperwork burden associated with operating a consortium
2) Establish/conduct appropriate technical working groups	
3) Participate in consortium discussions	
4) Plan logistics for calls or meetings	
5) Schedule and participate in discussions with Agency	
6) Review Agency assessments, participate in public comment activities	
7) Store, file, or maintain consortium information	

3(a)(v). Variance of the DCI Related Respondent Burden and Cost Estimates

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 program group (e.g., reregistration, registration review, special review etc.,) and the combination of activities (waivers, exemptions, consortium participation, data generation 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, [9] Phase 1 requirements outlined in Case Study #1, Attachment A of that document reflects the activities that all DCI recipients would have to conduct regardless of whether or not they 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.

Data Generators - The paperwork burden and costs for data generators are based in part on the average cost of 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 previously mentioned, 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 Attachment B, 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.

Consortium Participants - Although consortium members encumber burden from consortium activities, the cost savings from avoiding study generation are expected to far exceed the burden of 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

9 See Appendix D.

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 3 for Data Generators. Unlike typical data generators, however, consortiums face additional paperwork burden activities, such as meetings and correspondence to coordinate consortium activities. Industry provided EPA with information to support that approximately 21 consortiums exist and typical consortium activities that result in paperwork burden. Details on consortium activities and the methodology used for calculating total consortium paperwork burden are located in Attachment B, Appendix C.

3(a)(vi). Projected DCIs to be issued

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 Attachment B, Appendix A. EPA expects to issue approximately 221 DCIs annually over the next three years that will require data generation. This estimate for data generators does not include voluntarily submitted data as they are not DCIs (i.e., IC Groups 2, 3, 8 and 9) in Table 2 are excluded from this estimate).

The breakdown of the regulatory decisions for DCIs that EPA expects to make over the next three years (2018-2021) is as follows:

Table 2: Estimated Number of Annual DCIs by IC Group (FY 2018 – 2021)

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	Maintenance DCI[1]	35 – NTIP 0.3 - Efficacy	105 – NTIP 1 - Efficacy
6	Registration Review DCIs	61.3	184
7	Registration Review Resistance Management Plans	79	237
8	Registration Review: Voluntarily Submitted Data (Low Burden Studies)	50	150
9	Registration Review: Voluntarily Submitted Data (High Burden Studies)		
10	Anticipated Residue DCIs: Base Set of Data	0.3	1
11	Anticipated Residue DCIs: Verification of Use Data	0.3	1
12	Anticipated Residue DCIs: Updated Public Source Monitoring Data	0.3	1
13	DCIs for Percent Crop Treated Estimates	0.3	1
Total DCIs*		***221***	***663***
Total Voluntarily Submitted Data		***50.7***	***151***

[1]Includes Non-Target Insect Pollinator (NTIP) and Efficacy Studies

* Counts for IC Groups 2, 3, 8, and 9 are for voluntarily submitted data—i.e., they are not DCIs. Therefore, the total DCI count does not include these estimates. Numbers may not add due to rounding.

The following programs involve reviews of existing registrations that could result in a determination that additional data are necessary for a decision, and which would be sought through the issuance of a DCI under FIFRA §3(c)(2)(B). [10]

3(a)(vii). Reregistration Program

FIFRA §4[11] 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, Reregistration Eligibility Decisions (REDs) were completed by 2006 for food-use pesticide ingredients and 2008 for non-food use pesticide ingredients, the Agency still has several DCIs to issue after FY 2017 to close out the program (e.g., to resolve conservative assumptions that may have been used in the risk assessment pending the development of data).

3(a)(viii). Registration Review Program

FIFRA §3(g)[12] directs EPA to establish by regulation procedures for periodically reviewing pesticide registrations, and to complete each pesticide's registration review no later than every 15 years. 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.[13] EPA's regulation contains provisions to help achieve the goal of reviewing each pesticide every 15 years to assure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. The Pesticide Registration Improvement Act (PRIA)[14], 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 for these reviews to also 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

10 Though rarely used, EPA may conduct a Special Review (40 CFR 154.7) if EPA believes that a 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. However, for this ICR renewal no burden is calculated for this program since the EPA has not conducted a special review for over a decade.
11 7 USC 136a-1
12 7 USC 136a(g)
13 71 FR 45719, August 9, 2006.
14 7 USC 136w-8. For more information about PRIA, go to Pesticide Registration Improvement Extension Act (PRIA 3) of 2012 | US EPA

determinations) required under the Endangered Species Act (ESA)[15], 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)[16] as part of the risk characterization of the pesticide under Registration Review. [17] FFDCA §408(p) mandates the issuance of Orders requiring screening of substances for their potential endocrine disruptor effects. FIFRA §3(c)(2)(B) of FIFRA 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 indicated that it intended to 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.

3(a)(ix). 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 established 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, any additional data must be submitted at least five years after a tolerance is initially established. If PCT data are used, FFDCA affords EPA the

15 16 USC 1531 *et seq*. For information about the ESPP, go to http://www.epa.gov/espp/.
16 21 USC 346a(p).
17 For information about the EDSP, go to https://www.epa.gov/endocrine-disruption

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.

3(a)(x). Maintenance DCIs

Section 3(c) (2) (B) of FIFRA provides a means of obtaining needed additional data "to maintain in effect an existing registration of a pesticide". A need for a data call-in may arise from evolving of scientific understanding and methodologies, changes in the discovery of deficiencies in previously submitted data, or from the new discovery of specific attributes of the pesticide or its ingredients. For example, such data may be needed in support of Agency enforcement cases resulting from consumer complaints about the product, its storage stability, the integrity of its container, or exaggerated advertising claims. A DCI might also be needed to confirm product performance of public health pesticides or a new type of manufacturing process may call into question data submitted for a pesticide registration using older manufacturing technologies no longer used today. These situations may give rise to new concerns such as observed or suspected adverse human health or environmental effects attributed to the use of a pesticide that were not present at the time of the original registration or from unanticipated circumstances such as changes in pathogens of public health concern, new EPA initiatives, or the evolution of scientific test methodologies or manufacturing technologies. This IC category replaces the old IC named "Enforcement and Unanticipated Incident" activities in the currently approved ICR.

3(b). Estimated DCI-Related Annual Respondent Burden and Costs per Company/DCI

The Agency has updated 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 US 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 this ICR renewal are listed in Attachment C. Tables 3 and 4 provide information on the burden and costs faced by DCI recipients, data generators, and consortium participants. Respondent costs are based on managerial, technical and clerical wage rates estimated at $126.56, $71.69, and $42.97 per hour, respectively. These wage rates are based on 2015 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 3 outlines burden and cost to these three groups per company or DCI. For DCI recipients, burden is estimated by company since companies are responsible for responding to the 90-day notice. For data generators, the burden is based on the assumption that only one data package is being submitted by one or more companies for each DCI. 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 Attachment B, Appendix A, B, and C.

Table 3: Estimated DCI-Related Annual Respondent Burden and Costs per Company/DCI*

Activity Category	Clerical		Technical		Manager		Totals	
	Hrs.	$42.97/hr	Hrs.	$71.69/hr	Hrs.	$126.56/ hr	Burden (hrs)	Costs ($)
IC Category – DCI Recipients								
Reporting	0	$0	7	$502	12	$1,519	19	$2,021
Recordkeeping	1	$43	0	$0	0	$0	1	$43
IC Category – Data Generators[1]								
Reregistration Program DCIs								
1) Confirmatory DCIs								
Reporting	835	$35,886	4,070	$291,760	576	$72,852	5,480	$400,498
Recordkeeping	732	$31,443	0	$0	134	$16,920	865	$48,363
2) Product Specific DCIs								
Reporting	127	$5,471	619	$44,348	86	$10,846	832	$60,665
Recordkeeping	111	$4,764	0	$0	22	$2,799	133	$7,563
3) Reregistration: Voluntarily Submitted Low Burden Studies								
Reporting	87	$3,723	422	$30,252	65	$8,185	573	$42,160
Recordkeeping	76	$3,258	0	$0	9	$1,123	85	$4,381
4) Reregistration: Voluntarily Submitted High Burden Studies								
Reporting	479	$20,577	2,334	$167,287	326	$41,317	3,139	$229,181

Recordkeeping	420	$18,028	0	$0	80	$10,156	500	$28,184
Maintenance and Registration Review DCIs								
5) Maintenance DCIs								
Reporting	450	$19,322	2,188	$156,889	320	$40,536	2,958	$216,747
Recordkeeping	393	$16,883	0	$0	61	$7,737	454	$24,621
6) Registration Review DCIs								
Reporting	3,213	$138,095	15,916	$1,141,005	2,544	$321,951	21,673	$1,601,051
Recordkeeping	2,846	$122,326	0	$0	525	$66,462	3,372	$188,787
7) Registration Review Resistance Management Plans								
Reporting	0	$0	30	$2,152	6	$755	36	$2,907
Recordkeeping	0	$0	4	$302	0	$0	4	$302
8) Registration Review: Voluntarily Submitted Low Burden Studies								
Reporting	87	$3,723	422	$30,252	65	$8,185	573	$42,160
Recordkeeping	76	$3,258	0	$0	9	$1,123	85	$4,381
9) Registration Review: Voluntarily Submitted High Burden Studies								
Reporting	479	$20,577	2,334	$167,287	326	$41,317	3,139	$229,181
Recordkeeping	420	$18,028	0	$0	80	$10,156	500	$28,184
Anticipated Residue/Percent Crop Treated DCIs								
10) AR DCIs: Base Set of Data								
Reporting	3	$114	11,898	$852,992	5	$598	11,906	$853,703
Recordkeeping	1	$57	0	$0	0	$0	1	$57
11) AR DCIs: Verification-of-use Data								
Reporting	15	$651	36	$2,590	18	$2,308	70	$5,548
Recordkeeping	2	$81	0	$0	0	$0	2	$81
12) AR DCIs: Updated Public Source Monitoring Data								
Reporting	14	$615	101	$7,216	16	$1,977	131	$9,808
Recordkeeping	2	$77	0	$0	0	$0	2	$77
13) DCIs for Percent Crop Treated Estimates								
Reporting	3	$126	47	$3,403	1	$189	52	$3,718
Recordkeeping	1	$63	0	$0	0	$0	1	$63
IC Category - Consortiums								
Paperwork burden associated with operating a consortium	510	$21,917	800	$57,351	810	$102,511	2,120	$181,779

* 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, B, and C.

3(b)(i). Respondent Bottom line: Total Estimated Burden and Costs

Table 4 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 Attachment 1, Appendices A, B, and C 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 Attachment B, Appendix B provide the same information for data generators by IC group. The 3-year total bottom-line paperwork burden is estimated at 1,877,007 burden hours (or 625,669 hours annually) which equates to $134,671,171 in paperwork burden costs (or $44,890,390 annually).

Table 4: Respondent Bottom line: Costs (3-year Totals)

	Burden Hours			Costs		
	Reporting	Recordkeeping	**Total**	Reporting	Recordkeeping	**Total**
Data Recipients	2,318	122	**2,440**	$246,502	$5,243	**$251,745**
Data Generators						
Reregistration Program DCIs						
Confirmatory DCIs	129,705	20,480	**150,185**	$9,478,451	$1,144,593	**$10,623,044**
Product Specific DCIs	16,910	2,704	**19,613**	$1,233,528	$153,774	**$1,387,302**
Voluntarily Submitted Low Burden Studies	191	28	**219**	$14,053	$1,460	**$15,514**
Voluntarily Submitted High Burden Studies	1,046	167	**1,213**	$76,394	$9,395	**$85,788**
Maintenance and Registration Review DCIs						
Maintenance DCIs	101,377	15,549	**116,925**	$7,427,823	$842,633	**$8,270,456**
Registration Review DCIs	1,329,299	206,794	**1,536,093**	$98,197,781	$11,578,951	**$109,776,732**
Registration Review Resistance Management Plans	2,843	333	**3,176**	$229,651	$23,860	**$253,511**
Registration Review: Voluntarily Submitted Low Burden Studies	28,665	4,234	**32,899**	$2,107,986	$219,064	**$2,327,050**
Registration Review: Voluntarily Submitted High Burden Studies	156,940	24,988	**181,927**	$11,459,042	$1,409,208	**$12,868,250**
Anticipated Residue/Percent Crop Treated DCIs						
AR DCIs: Base Set of Data	3,969	0.4	**3,969**	$284,568	$19	**$284,587**
AR DCIs: Verification-of-use Data	23	0.6	**24**	$1,849	$27	**$1,877**
AR DCIs: Updated Public Source Monitoring Data	44	0.6	**44**	$3,269	$26	**$3,295**
DCIs for Percent Crop Treated Estimates	17	0.5	**18**	$1,239	$21	**$1,260**
DCI Data Generator Total	***1,584,185***	***245,862***	***1,830,047***	***$116,858,160***	***$13,743,903***	***$130,602,062***
	Operating Activities Burden Hours			Operating Activities Cost		
Consortium Members	-	-	44,520	-	-	$3,817,364
Total Burden	***1,586,503***	***245,984***	***1,877,007***	***$117,104,661***	***$13,749,146***	***$134,671,171***

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 Appendices A, B, and C.

4. PRACTICAL UTILITY/USERS OF THE DATA

EPA uses the information collected under this ICR to carry out its statutory responsibilities under FIFRA §§ 4, 3(g), 6(b), and FFDCA §408. The data collected allows EPA to consider the data or information in making a registration decision and assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment. The data and information collected under this ICR are used by Agency scientists to assess and characterize pesticide risks, and to determine whether the pesticide continues to meet the standards established by federal law.

Through a rigorous scientific and public process, EPA specifies the kinds of data and information necessary to make the regulatory judgments required under FIFRA and FFDCA. Some of these judgments include, but are not limited to:

- Determine if a pesticide can be registered or remain registered because it does not cause an unreasonable adverse effect on human health or the environment.
- Determine if a pesticide has the potential to interact with the endocrine system, and meeting the safety standard of FFDCA §408.
- Determine if a pesticide might harm a listed species, under the Endangered Species Act, or its designated critical habitat.
- Determine if pesticide residues in food or feed will result in a reasonable certainty of no harm to human health from aggregate exposure through dietary, non-occupational, and drinking water routes of exposure.
- EPA must also consider the cumulative effects of pesticides that share a “common mechanism of toxicity,” consider special sensitivities of infants and children
- EPA evaluates the data submitted by registrants to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance. If the submitted residue data demonstrates that the residue levels are above the levels relied on for establishing the tolerance, EPA will take appropriate action to modify or revoke the tolerance.
- Inherent in EPA’s review of most of the programs is an evaluation of the risks posed by the pesticide, which may also result in risk mitigation considerations.

The availability of data and information about the pesticide is essential to perform quality and accurate risk assessment that impact Agency decisions, which may result in a more or less restrictive pesticide use. The lack of data will mean that there would be a higher degree of uncertainty and the potential for effects or exposures cannot be accurately characterized, often requiring the use of conservative assumptions in lieu of the data. Use of conservative assumptions may result in overestimates of potential effects or exposures or limit the flexibility the registrants and Agency have when complying with other mandates, e.g., ESA. Limited flexibility can result in use restrictions that could have otherwise been avoided. If new data or information show that the risk is increased, then additional mitigation may be needed to address potential risks of concern. However, if the new data or information show that the risk

is less than previously assumed, then the registrants may be able to expand uses or the Agency may be able to reduce restrictions previously imposed.

The issuance of a DCI may also help registrants in asserting their rights with regard to the exclusive use or data compensation provisions under FIFRA §3(c)(1)(F); as well as facilitating collaborative efforts to generate data when such opportunities are available.

In general, the practical utility of the data that might be collected through a DCI has been determined to be necessary in order to answer specific questions about the safety of the pesticide product before the Agency can register it. Although the issuance of a particular DCI is based on the circumstances presented by the individual pesticide chemical, EPA has established data requirements based on the pesticide type and intended use patterns, while maintaining flexibility to address individual circumstances when appropriate.

Under any of the programs covered by this ICR, a particular request for data may serve a specific purpose, either in terms of its function or use in the assessment that supports the Agency's regulatory judgments about the risks and benefits of the pesticide under FIFRA §§ 3, 4 and 5, and to determine the safety of pesticide chemical residues under FFDCA §408.

4(a). General Purpose Categories

The data that EPA may collect under a DCI may be grouped into four general purpose categories: confirmatory data, chemical-specific data, product-specific data, and voluntary data.

Confirmatory Data. In making a regulatory decision related to a registration under review, additional data or information are sometimes necessary to confirm assumptions used in the risk assessments, the Agency's findings or conclusions about a pesticide.

Chemical-Specific Data. In making a regulatory decision related to a registration under review, additional data or information are sometimes necessary to determine whether the registration can continue in effect without change, or if modifications to the registration will be necessary to reduce risks of concern. Such data needs are determined by a chemical or active ingredient level and are used for making all decisions regarding that chemical or active ingredient.

Product-Specific Data. After the existing data supporting a pesticide on a chemical or active ingredient basis are evaluated, and a regulatory determination is made, EPA's focus turns to the information and data required to make regulatory decisions at the product-specific level. For every end-use product (that is, every product that contains an active ingredient), registrants are required to submit certain data specific to the product as formulated and sold (including, but not limited to, acute toxicity, product chemistry studies, and product-specific labeling). In certain instances, the Agency requires the registrant to submit a Confidential Statement of Formula. For example, registrants are required to submit a Confidential Statement of Formula (EPA Form 8570-4)[18] to comply with registration-related requirements under FIFRA §3, when a registrant seeks to add uses for a currently-registered pesticide, or

18 The paperwork burden for the submission of Form 8570-4 is covered under OMB Control No. 2070-0060, identified under EPA ICR. No. 0277, and entitled "*Application for New/Amended Pesticide Registration*."

when the registrant changes a registered pesticide's formulation. Thus, information and data are essential to making the final regulatory decision regarding the particulars of a specific product.

Voluntary Data. Historically, registrants (and other interested parties) have voluntarily submitted data to EPA that was not specifically required and/or requested, but nonetheless data or information that the registrant wanted EPA to consider in making its decisions. A small percentage of FIFRA registrants will always submit voluntary data to support a new and/or alternative scientific approach for meeting a data requirement that is needed to obtain or retain a pesticide registration. On occasion, EPA has suggested that certain data or information be voluntarily submitted to the Agency. However, the Agency does not anticipate large volumes of voluntary data to be submitted for the current statutorily mandated programs. In response to an Industry recommendation, the Agency has revised the estimates for voluntary submissions to one submission per chemical case (or 50 submissions per year), with the expected range of potential annual burden from voluntary submissions from 32,899 to 181,927 burden hours.

4(b). EPA Use of Data in the Assessments

In general, EPA may use a DCI to request, or the registrant may voluntarily submit, the data from several categories and study types, which reflect how the requirements in 40 CFR part 158 are organized. The studies required under 40 CFR part 158 provide the scientific basis for characterizing the potential risks associated with pesticide exposure.

EPA provided OPP staff with guidance to assist them in focusing on the information most relevant to the assessment.[19] EPA's goal is to ensure there is sufficient information to reliably support registration decisions that are protective of public health and the environment while avoiding the generation and evaluation of data that does not materially influence the scientific certainty of a regulatory decision. It is important only to require data that adequately inform regulatory decision making and thereby avoid unnecessary use of time and resources, data generation costs, and animal testing. This guidance is consistent with OPP's strategic direction of using "Integrated Approaches to Testing and Assessment" [20] which promotes a hypothesis based, systematic, integrative use of exposure and hazard information for assessing pesticide risk. OPP's strategic direction is consistent with the 2007 and 2009 National Research Council reports, Toxicity Testing in the 21st Century: A Vision and a Strategy and Science and Decisions: Advancing Risk Assessment.

In keeping with applicable EPA guidance, the data collected through a DCI may be used by EPA in the following ways.

Data about Product Performance – Requirements to develop data on product performance provide a mechanism to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy

19 See EPA document entitled "Guiding Principles for Data Requirements" (May 31, 2013).
20 See FIFRA Science Advisory Panel Consultation May24-26, 2011 at http://yosemite.epa.gov/sab/sabproduct.nsf/373C1DB0E0591296852579F2005BECB3/$File/OPP+SAP+document-May2011.pdf

data in the public health areas, including disinfectants used to control microorganisms infectious to humans in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats, and skunks) and invertebrates (ticks, mosquitoes, etc.) that may directly or indirectly transmit diseases to humans.

Data from Studies that Determine Hazard to Humans and Domestic Animals – Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic, and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

Acute Studies – Determination of acute oral, dermal, and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farm worker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also:

- provide information used in establishing the appropriate dose levels in subchronic and other studies;
- provide initial information on the mode of toxic action(s) of a substance;
- determine the need for child-resistant packaging; and
- determine the need to restrict the use of the pesticide to trained applicators or in other ways to minimize human and environmental hazards.

Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes, and skin.

Subchronic Studies – Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (e.g., carcinogenicity).

Chronic Studies – Chronic toxicity (usually conducted by feeding the test substance to the test species) studies are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects that have a long latency period or are cumulative should be detected. The purpose of long-term carcinogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

Data from Studies that Determine Hazard to Nontarget Organisms – The information required to assess hazards to nontarget organisms are derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system that progresses from the basic laboratory tests

to the applied field tests. The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause harmful effects and to determine whether further testing is required. A purpose common to all data requirements is to help determine the need for (and appropriate wording for) precautionary label statements to minimize the potential harm to nontarget organisms.

Acute and Subacute Studies – The short-term acute and subacute laboratory studies provide basic toxicity information that serves as a starting point for the hazard assessment. These data are used to:

- establish acute toxicity levels of the active ingredient to the test organisms;
- compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential effects on fish, wildlife, plants, and other nontarget organisms; and
- indicate whether further laboratory and/or field studies are needed.

Chronic and Field Studies – Additional studies (i.e., avian, fish, and invertebrate reproduction; life cycle studies; and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to:

- estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and
- determine if additional field or laboratory data are necessary to evaluate further hazards.

Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for harmful effects is high.

Data on Occupational and Residential Exposure may be required to assess hazard to farm workers or exposure for pesticide applicators and users.

- **Post-Application Exposure Studies -** Data required to assess hazard to farm employees resulting from reentry into areas treated with pesticides are derived from studies on toxicity, residue dissipation, and human exposure. Data may also be required to assess residential exposure. Monitoring data generated during exposure studies are used to determine how much pesticide people may be exposed to after application and to establish how long workers must wait before reentering a treated area.

- **Applicator/User Exposure Studies** -EPA requires applicator/user exposure data for all pesticides to evaluate the potential risks to people applying the pesticide, i.e., those who may be exposed to higher concentrations of the pesticide through handling, including mixing or applying.

Pesticide Spray Drift Evaluation – Data required to evaluate pesticide spray drift are derived from studies on the range of droplet sizes and spray drift field evaluations. These data contribute to the development of the overall exposure estimate. Along with data on toxicity for humans, fish, and wildlife, or plants, data on spray drift are used to assess the potential exposure of these organisms to pesticides. A purpose common to all these tests is to provide data to help determine the need (and appropriate wording) for precautionary labeling to minimize the potential harm to nontarget organisms.

Environmental Fate – EPA uses the data generated by environmental fate studies to:

- assess the presence of widely distributed and persistent pesticides in the environment that may result in loss of usable land, surface water, ground water, and wildlife resources;
- assess the potential environmental exposure of other nontarget organisms, such as fish, wildlife, and plants, to pesticides; and
- help estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.
    - o

Residue Chemistry – EPA uses residue chemistry data to estimate the exposure of the general population to pesticide residues in food or materials preserved with pesticides and for setting and enforcing tolerances for pesticide residues in food or feed. The Agency can estimate the amount and nature of residues likely to be present in food or animal feed because of a proposed pesticide usage by evaluating information on:

- The chemical identity and composition of the pesticide product;
- the amounts, frequency, and time of pesticide application; and
- test results on the amount of residues remaining on or in the treated food, feed or material preserved with the pesticide.

5. PRA CRITERIA, GUIDELINES, AND REQUIREMENTS

5(a). Small Entity Flexibility

Currently, pesticide registrants may be divided into two groups. Approximately 10 percent of the total: manufacture or import chemical active ingredients intended for use as pesticides, sell these active ingredients to other firms for formulation into pesticide products, and/or make the end products themselves. The second, and by far the larger, group of registrants purchase the active ingredients in their pesticide products from members of the first group, and combine them with pesticide inert ingredients or sometimes simply repackage them to make their end-use products.

This second group is primarily comprised of small businesses. When small businesses use a registered source of the active ingredient to formulate their products, they generally are exempt from generating health and safety data for pesticide active ingredients ("generic data"). Consequently, they usually need only respond to a DCI for active ingredient data by claiming the "generic data exemption" and do not incur any other information burden associated with the data call-in.

5(b). Non-Duplication

This information collection is specific to the needs of the federal pesticide laws negating the need for similar data by other federal agencies or any other office within EPA. Prior to requesting any information, the Agency must review existing records for the availability of the information that it is considering requesting. The Agency maintains files on all pesticide chemicals, which includes all correspondence and information/data submitted. Before any DCI is issued, these files are referenced to determine whether the necessary data are already on hand, thereby eliminating duplicative data requests. For example, a majority of the percent-crop-treated information can currently be obtained internally, thus, DCIs will only be issued when more data is necessary. The data for anticipated residues, on the other hand, are unique to the requirements of FIFRA, and, therefore, must be submitted to the Agency.

In addition, EPA facilitates a variety of public comment periods for all the review programs covered by this ICR, the result of which may modify the data that is included in a specific DCI if warranted by information provided by registrants or the public.

OPP also encourages cost-sharing agreements among manufacturers of specific pesticide chemicals in order to minimize the potential duplication of laboratory tests, minimize animal testing, and reduce the costs of developing the data. All DCI notices explain the statutory provisions for cost-sharing agreements under FIFRA, as well as the various response opportunities, which include the citation to or submission of other scientifically relevant data that they believe satisfies the DCI.

5(c). Use of Existing Forms

The forms associated with the DCI activities covered by this ICR are already approved under OMB Control No. 2070-0060 and are also used for other information collection activities that are not covered by this ICR. Specifically, the following Forms are used in the context of DCI activities.[21]

Confidential Statement of Formula, (EPA Form 8570-4).

- Formulator's Exemption Statement, (EPA Form 8570-27).
- Certification of Compliance with Data Gap Procedures (EPA Form 8570-28).
- Certification of Attempt to Enter into an Agreement with Registrants for Development of Data (EPA Form 8570-32).
- Certification with Respect to Citation of Data (in Pesticide Registration (PR) Notice 98-5) (EPA Form 8570-34).
- Data Matrix (also in PR Notice 98-5) (EPA Form 8570-35).
- Summary of the Physical/Chemical Properties (EPA Form 8570-36).
- Self-Certification Statement for the Physical/Chemical Properties (EPA Form 8570-37).

The following Forms were previously approved for use under this ICR, and are automatically generated by EPA's computer databases and are pre-populated with information that is specific to each individual registrant or recipient of the specific DCI for a given pesticide. To reduce respondent burden, EPA will continue to generate the pre-populated, registrant-specific forms through the Agency's computer system when preparing to issue Data Call-In notices.

21 See Attachment A.

- Requirements Status and Registrant's Response (EPA Form 6300-3).
- Data Call-In Response Form (EPA Form 6300-4).

5(d). Use of Technology to Facilitate Collection Activities

In September 2015, OPP debuted a new electronic system for pesticide applications, the Pesticide Submission Portal. In February 2016, EPA began to accept DCI response packages through the PSP. EPA will continue to accept paper, CD and DVD applications but encourages applicants to take advantage of this new, more efficient option. For registrants currently submitting CDs or DVDs using the e-Dossier downloadable tool or their own builder tools using EPA's XML guidance, they may use the portal and forego the courier costs to send to EPA. For electronic submissions, applicants do not need to submit multiple copies of any pieces of their application, the requirement for multiple copies of data and five copies draft labeling only applies to paper submissions. Additional benefits of using the Portal include a status indicator that allows registrants to track the movement of their submissions and automatically generated MRID numbers. Guidance for electronic submission through the Pesticide Portal is available to applicants at https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications.

The Agency's pesticide program, along with the pesticide industry, recognizes the advantages in terms of accuracy, speed, cost and personnel from electronic data transfer technologies. In addition, OPP continues to consult with industry associations and other federal agencies and is participating in an Agency-wide workgroup to develop electronic reporting standards intended to facilitate the submission and use of information about pesticides.

5(e). Collection Schedule

There is not a collection schedule per se. DCIs are issued when the need is identified. The time frame in which the respondents must then submit the requested material is specifically established for each DCI based on the individual circumstances surrounding the particular DCI and applicable review. However, as discussed in Section 3(b) *Programs Involving DCIs*, a variety of FIFRA programs require EPA to conduct periodic reviews to ensure the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. These review processes generate the bulk of the DCI determinations. For a variety of reasons, most manufacturers wait to generate new data and/or submit new/existing data until EPA issues the DCI. One of the most important reasons for this is that EPA's issuance of a DCI is a public statement that the data are needed, and will be relied on, thus "triggering" the data compensation provisions of FIFRA §3(g)(1)(B).

As part of the consultation and public participation process, EPA generally works with respondents to ensure that sufficient time is built into the individual DCIs to allow for respondents to gather and submit the requested information. However, the timing of AR/PCT-related DCIs and respondent data submissions is somewhat different.

AR DCIs will generally be issued whenever ARs data is relied upon, either to establish new tolerances or to reassess existing tolerances. Registrants have five years before data must generally be submitted in support of the ARs used. Data must also be periodically reviewed

when PCT estimates are relied upon, but in most cases the Agency will be able to collect internally or generate this data. EPA will issue PCT DCIs in cases where the Agency is unable to obtain the information on its own. In these cases, the registrant must submit data within five years of the use of PCT estimates. Additional time is provided for the development of new studies appropriate to the nature of the studies required.

5(f). Effects of Less Frequent Collection

The frequency of collection is on occasion in response to the receipt of a DCI requesting specific information. DCIs are issued on occasion based on the Agency's determination of an identified need for the data for a particular pesticide. As such, a specific DCI is typically issued once per respondent (i.e., pesticide, data, and the respondent combination is unique). Given the on occasion and single frequency of this collection, there isn't an opportunity to consider a less frequent collection.

AR or PCT information is collected one time within the five years preceding the reliance on such data. The AR or PCT information collection is required by FFDCA §§ 408(b)(2)(E)(I) and 408(b)(2)(F) and cannot be collected less frequently.

For each DCI issued, the respondent provides an initial response, and, as determined by the nature of that initial response, may also provide a study status report for multi-year studies, and then submit the final data.

5(g). Confidentiality

Except as provided in FIFRA §10(d)(1)(A), (B) or (C), health and safety data submitted by registrants under FIFRA must be made available by the Agency upon request from anyone not affiliated with a multinational pesticide firm. These exceptions, however, specifically prohibit disclosure of the inert ingredients in a pesticide or of its manufacturing, quality control processes, sales and production data, or trade secrets.

Registrants may claim at the time of submission that specific data are subject to treatment as confidential for reasons other than falling within the exclusions for mandatory release. All data subject to such claims, or falling within FIFRA §10(d)(1)(A), (B), or (C) are handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual. The manual requires that all CBI must be marked or flagged as such, all CBI must be kept in secure (double-locked) areas, and all CBI intended to be destroyed must be cleared by a Document Control Officer and shredded.

5(h). Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity, and this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

5(i). Other General PRA Guidelines

The only PRA guideline that may be exceeded in this collection is the time period for retaining records related to the studies conducted to generate the data that is submitted to EPA. Pursuant to FIFRA §8, EPA recordkeeping requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years will be exceeded in this collection activity.

In addition, pursuant to 5 CFR 1320.5(a)(1)(iii)(C), EPA previously sought and OMB provided approval for the elimination of expiration dates on the forms that may be used as part of the DCI activities covered by this ICR. The justification for doing so included the statutory basis for the collections; the stability of the information collected; the general use of the forms for multiple purposes; and the use of pre-populated or numbered forms. Although these forms are not established under this ICR, EPA notes that it will continue to omit the expiration dates on these forms.

6. STAKEHOLDER INVOLVEMENT

6(a). Consultations

Consultation and/or dialogue between registrants and the Agency concerning data requirements need for particular information and the protocol to be used to conduct the study are frequent and ongoing.

Generally, all programs discussed in this ICR are intrinsically woven into the Agency's public participation review process. Stakeholders and the public have a number of opportunities for input, consultation and involvement throughout the process, including but not limited to issues such as the need for additional data. Significant public comments will be addressed prior to issuing DCIs. Until the DCI is issued, registrants are not required to submit data. This integrated public participation framework provides consistent, predictable opportunities for public and stakeholder involvement through public comment periods at regular intervals to help inform EPA’s regulatory decision-making.

EPA’s formalized public participation process for reregistration and tolerance reassessment recognizes that all pesticides do not present the same degree of risk or complexity of issues, and accordingly describes the ways in which the Agency tailor the public participation process to the uses and risks of each pesticide and to obtain public input as needed while still making timely decisions and meeting statutory deadlines and program goals.[22]

The process for registration review, including public participation, is described in the procedural rule for registration review (see 40 CFR part 155) and is summarized on the

22 69 FR 26819, May 14, 2004

Agency's website at https://www.epa.gov/pesticide-reevaluation/focus-meetings-pesticide-registration-review

EPA intends the Endangered Species Protection Program (ESPP) to be flexible and to modify it as necessary to achieve the goals of protecting listed species and minimizing the impact on pesticide users. When geographically specific use limitations are necessary, they are reflected in Endangered Species Protection Bulletins, which are posted at http://www.epa.gov/oppfead1/endanger/bulletins.htm. ESPP incorporates public participation within existing processes of registration, reregistration, and registration review. The processes for public participation during registration and registration review are described in the above paragraph. In general, there are three major phases of a listed species assessment that provide opportunity for public input; (1) prior to a "may affect" determination by EPA, (2) when identifying potential mitigation if a risk assessment identifies a listed species concern, and (3) prior to issuance of a Biological Opinion to EPA by the Services.

For all programs covered under this ICR, updates are also available to anyone interested by e-mail. For over a decade, EPA has maintained a list server (Listserv) or "mailing group." Interested parties may sign up to receive periodic e-mail notifications announcing the availability of program materials. Also, EPA provides for public comment in notices published in the Federal Register. A list of past publications is available through the appropriate websites.

If appropriate to resolve scientific questions, the Agency may also seek peer review and/or advice from the FIFRA Science Advisory Panel SAP. The FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA, as amended, established a Science Review Board consisting of at least 60 scientists who are available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the Panel.

As part of this ICR renewal process EPA has solicited comment from several individual respondents to seek specific feedback on the proposed burden and costs in this proposal. In December 2013, the Agency held a DCI Response Burden Assessment Workshop with industry stakeholders. As part of the reassessment, OPP consulted 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.[23] Industry feedback provided the basis for the revisions to the burden methodology used in this ICR. See Attachment B

23 On December 12, 2013, The Office Pesticide Programs sponsored a DCI Response Burden Assessment Workshop. Industry participants included, but were not limited to: representatives from BASF, the DOW Chemical Company, the American Chemistry Council Biocides Panel, Steptoe and Johnson, LLP, Technology Sciences Group Inc., Monsanto, and SC Johnson. Meeting materials and Industry comments are part of the docket for the ICR renewal at: EPA-HQ-OPP- 2016-0109.

6(b). Public Notice Required Prior to ICR Submission to OMB

Pursuant to 5 CFR 1320.8(d), EPA published Federal Register (FR) notices 82 FR 39997, August 23, 2017 and 83 FR 3344, January 24, 2018 soliciting comment on this information collection activity and the Agency's intent to renew and request OMB approval of this ICR. The Agency received seven public comments which have been placed in the docket for this action. The Agency will post a response to the public comments received in the docket EPA-HQ-OPP-2016-0109 accessible at http://www.regulations.gov.

7. AGENCY ACTIVITIES & ESTIMATED COSTS

7(a). Agency Activities

The following Agency activities are necessary to conduct a DCI or Order under this ICR:

develop DCI correspondence	prepare the DCI letter identifying all the data needed
answer registrants' questions	respond to any questions the registrant may have regarding the DCI
review data submissions	review data submissions for completeness and appropriateness
record DCI submissions	record submissions in tracking system for internal review
analyze data	conduct scientific reviews of data
store data	index data and store it in Agency files

7(b). Collection Methodology and Management

After initiating a statutorily mandated pesticide review whether a Special Review, closeout of a Reregistration Review, a Registration Review or a AR or PCT Review and determining that additional data are needed, the Agency will issue a DCI when the need for additional data has been identified.

The Pesticide Registration Information System (PRISM) software application developed within OPP integrates the functionality necessary to support the Registration Review and EDSP (Endocrine Disrupter Screening Program)[24] programs. PRISM supports many of the Registration Review and EDSP processes associated with tracking, including DCIs, 408(p) orders s, and data submissions. PRISM serves as a replacement for the equivalent functionality provided by the Office of Pesticide Programs Information Network (OPPIN) application. PRISM was enhanced to accept electronic registration (e-Registration) documents. The e-Submission module of PRISM supports the processing of a number of specific application documents (FIFRA §3 new applications, §3 amendments, experimental use permits, petitions for tolerances, and applications for supplemental distributor products) required for pesticide applications. OPP continues to track Reregistration program information, including DCIs, registrant responses, and reregistration data submissions through OPPIN.

24 As noted earlier in section 3(b)(ii), the information collection activities associated with EDSP are already covered by another ICR.

Also currently, OPPIN lists the bibliography of data submitters for all the DCIs. All correspondence associated with the issuance and response to the DCI is filed in the master registration file or 'registration jacket' of affected products. Failures to comply with DCI requirements are referred to EPA's Office of Enforcement and Compliance Assurance for appropriate follow-up actions.

Although the Agency does not publish the submitted information, public access to the OPPIN bibliography is made through the National Pesticides Information Retrieval System (NPIRS). NPIRS supports searches of the OPPIN database by chemical, subject, submission date, laboratory, guideline number, and document type. The public may request copies of non-confidential studies through FOIA.

7(c). Agency Burden and Costs

While Agency burden activities for processing all DCIs is substantially similar, the Agency burden and cost are commensurate with the amount of data to be analyzed and the specific DCI. A detailed breakout of the Agency burden and cost for the different types of DCIs for the Reregistration, Registration Review, Special Review, AR and PCT programs are in Attachment B, Appendices A, B and C. The Agency labor, and wage rate calculations are in Attachment C.

7(d). Agency Burden and Cost Estimates – Bottom Line Master Chart

Table 5 provides a summary of the 3-year total estimated Agency burden and cost for all DCI programs. Annual Agency burden hours for DCI activities are estimated at 9410 hours at a cost of $751,759.

Table 5. Summary of Agency DCI Paperwork Burden and Cost (3-year totals)

	Burden Hours			**Costs**		
	Reporting	Recordkeeping	Total	Reporting	Recordkeeping	Total
Reregistration Program DCIs	14,339	198	14,537	$1,168,974	$9,190	$1,178,164
Maintenance DCI	7,170	99	7,269	$584,487	$4,595	$589,082
Registration Review DCIs	5,618	737	6,354	$448,228	$34,195	$482,423
Anticipated Residue/Percent Crop Treated DCIs	12	60	72	$697	$4,886	$5,583
Total Agency Burden	***27,138***	***1,094***	***28,232***	***$2,202,386***	***$52,865***	***$2,255,251***

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 vary for each type of DCI. For a review of methods used in these calculations, refer to Appendices B.

8. PRA BURDEN STATEMENT

Under the PRA, an Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. After appearing in the ***Federal Register***, the OMB control numbers for EPA's regulations in

title 40 of the CFR, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable. The burden is defined at 5 CFR 1320.3(b).

The response burden for this ICR is estimated to range between 20 and 8182 hours per response, depending on the particulars associated with the individual DCI. The total annualized burden for this ICR is estimated to be 625,669 hours at a cost of $44,890,390. Mailing costs for DCIs are not included in the estimates since electronic submissions are now accepted, and it is typical practice for registrants to submit data using this method. See http://www.epa.gov/pesticide-registration/e-submission-resource-documents-assembly-electronic-packages-and-discs. In the case that DCI submissions are submitted using certified mail, it is estimated that the cost to submit an individual DCI would be no more than $20

Changes in Burden Estimates: This ICR represents an increase of 362,368 hours (625,669 – 262,301) in the total estimated annualized burden compared with that currently approved by OMB. The burden increase is a cumulative result of the program implementing new methodologies to calculate respondent burden, the inclusion of a new IC group - consortium participants - to more accurately reflect the respondent burden, renaming and recalculating an existing IC group from Enforcement and Unanticipated Incident activities to Maintenance DCIs, and the acceleration of the Registration Review Program. All of these activities have contributed to the significant increase in number of DCIs to be issued (221 versus 45) annually. This change represents a program adjustment.

9. DOCKET INFORMATION

The Agency has established a docket for this ICR under Docket ID No. EPA-HQ-OPP-2016-0109, which is available for online viewing at www.regulations.gov, or in person viewing at [insert updated information].

Comment on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Submit comments to (1) EPA online through http://www.regulations.gov and (2) OMB via email to *oira_submission@omb.eop.gov* and address your comments to the OMB Desk Officer for EPA. Include docket ID No. EPA-HQ-OPP-2016-0109 and OMB control number 2070-0174; in any correspondence but do not submit any DCI or other related information (e.g., forms, reports, etc.) to these addresses.

10. ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPP-2016-0109. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in this section 6(f) of the supporting statement.

Attachment A: Forms that are commonly associated with Data Call-ins are available electronically at: https://www.epa.gov/pesticide-registration/label-review-manual in the forms section.

EPA Form No. 8570-4 - Confidential Statement of Formula

EPA Form No. 8570-27 - Formulator's Exemption Statement

EPA Form No. 8570-28 - Certification of Compliance with Data Gap Procedures

EPA Form No. 8570-32 - Certification of Attempt to Enter into an Agreement with Registrants for Development of Data Form

EPA Form No. 8570-34 - Certification with Respect to Citation of Data Form

EPA Form No. 8570-35 - Data Matrix Form

EPA Form No. 8570-36 - Summary of the Physical/Chemical Properties Form

EPA Form No. 8570-37 - Self-Certification Statement for the Physical/Chemical Properties

The remaining forms are computer generated and uniquely pre-populated and sent directly to individual registrants. The forms below are part of the multipage DCI notice which contain samples of the forms and instructions below. This information has been provided to OMB directly.

EPA Form No. 6300-3 - Requirements Status and Registrant's Response.

EPA Form No. 6300-4 - Data Call-In Response Form.

Attachment B: Office of Pesticide Programs 2014 Revised General Methodology and assumptions Used to Estimate Paperwork Response Burden for Pesticide Data Call-In Recipients, November 2014. This methodology includes the calculations for paperwork burden and costs of data generation activities.

Appendix – ***A*** Estimated Burden Hours and Costs for DCI Recipients
Appendix – B Estimated Burden Hours and Costs for DCI Collection Activities for Data Generators, by IC Group
Appendix – C Estimated Burden Hours and Costs for Consortium Activities
Appendix – D 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, October 2007.
Appendix – E Non-Codified Study Justifications, May 15, 2015.

Attachment C: Work sheets to Calculate Industry and EPA Labor Costs (2015).