

**1 SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST (ICR)**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Title of the Information Collection

Title: Compliance Requirement for Child-Resistant Packaging

OMB No. 2070-0052; EPA No. 0616.13

Docket ID No. EPA-HQ-OPP-2016-0630

1(b). Short Characterization/Abstract

This information collection program is designed to provide the Environmental Protection Agency (EPA, or the Agency) with assurances that the packaging of pesticide products sold and distributed to the general public in the United States meets standards set forth by the Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Registrants must certify to the Agency that the pesticide packaging or device regulated by this Act meets these standards.

EPA is currently developing a new ICR that will consolidate this and several other approved ICRs. The consolidated ICR will include any updates to the information collection activities covered by this ICR. The renewal of this ICR will ensure there is no lapse in approval of this ICR while the new, consolidated ICR is under development. When the consolidated ICR is approved, EPA plans to discontinue this ICR.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

Section 25(c)(3) of FIFRA (Attachment A) authorizes EPA to establish standards for packaging of pesticide products and pesticidal devices to protect children and adults from serious illness or injury resulting from accidental ingestion or contact. The law requires that these standards are designed to be consistent with those under the Poison Prevention Packaging Act, administered by the Consumer Product Safety Commission (CPSC). Unless a pesticide product qualifies for an exemption by meeting certain criteria regarding toxicity and use, it must be sold and distributed in child-resistant packaging (CRP). The authority for this information collection is pursuant to Section 25(c)(3) of the FIFRA. Compliance regulations are contained in 40 Code of Federal Regulations (CFR) Part 157, Subpart B (Attachment B).

2(b). Practical Utility/Users of the Data

EPA reviews a registrant's CRP certification to determine if there are human safety/health risk concerns caused by the packaging of a pesticide product not providing the required protections. Exemption requests are reviewed to ascertain if there is a health risk, and if CRP is technically feasible,

practicable, and appropriate.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non duplication

To avoid duplicative testing of packages for pesticidal and non-pesticidal purposes, EPA's CRP regulations reference the CPSC packaging standards and protocol testing procedures. This is the only information collection activity of its kind and the information collected under this activity is collected only once per event (e.g., once per certification of CRP compliance, which occurs when a product subject to CRP requirements is initially registered, and when the registration is amended as a result of any modification in the composition, labeling, or packaging).

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

EPA published a notice in the Federal Register announcing a 60-day public notice and comment period on the draft ICR on August 17, 2020 (85 FR 50022). EPA received no public comments in response to this notice, which is available in the docket for this ICR and can be accessed at <http://www.regulations.gov> using the docket identifier EPA-HQ-OPP-2016-0630.

3(c). Consultations

In addition to the public notice that EPA published in the Federal Register concerning this ICR, the Agency consulted, as required under 5 CFR 1320.8(d)(1), with representative stakeholders who interact with the Agency through the use of this collection instrument. EPA staff contacted three relevant stakeholders and received responses from all three. The Agency asked for their assessment of the regulatory burden and cost estimates contained in this ICR, the clarity of instructions for respondents, the method and frequency of collection, etc. The responses essentially agreed that the burden and cost estimates are reasonable, although one stated that wage rates used to estimate cost are higher when using a regulatory consultant. All three expressed satisfaction with the collection methodology, including the current electronic options for submitting information. One entity suggested that EPA should rely more on cited package test data previously reviewed and accepted. The Agency does attempt to use our records in this manner, but in some cases a different product in the same CRP may necessitate further information in order to be accepted. In these cases, EPA will explain the rationale and need to the registrant. The most significant suggestion for improvement of the ICR and collection program is in two of the responses, which state that there are inconsistencies among Agency sources of instructions or guidance on CRP certification. These two entities suggested that these sources should be updated and clarified. The other consulted entity responded that the instructions are clear. EPA has recently revised the guidance on our CRP website and plans further updates and improvements. The Agency will also consider issuing a new Pesticide Registration Notice to provide current guidance. The questions asked and full responses from the three entities consulted are in the Record of Consultation Questions and Responses (Attachment C).

In addition to the consultation process discussed above, the Agency also discusses specific packaging issues (for example, determining what can reasonably be required or expected in terms of

technical and/or economic feasibility) with the CPSC and the packaging industry itself. These consultations occur on an informal "as needed" basis during the process of evaluating a certification of the use of CRP or an exemption request. In the past, when any sort of problem (technical, administrative, or other) arose, or there were suggestions for improvement in the program, the respondent is given ample opportunity to inform the Agency and vice versa. This communication between both parties may take place either in a telephone conversation or in a meeting setting, but not by a prescribed schedule.

In addition, EPA is currently developing a new ICR that will consolidate this and several other approved ICRs. The consolidated ICR will include any updates to the information collection activities covered by this ICR.

3(d). Effects of Less Frequent Collection

The information collection occurs once for each product-package combination subject by law to the CRP provisions. In the absence of this information collection activity, the burden of proof would be shifted from the registrant to the EPA. Based on enforcement case precedents involving CRP, EPA would need to have specific evidence to make the product-package case. Consequently, on the basis of the time and cost involved, EPA would find it difficult to fulfill its statutory responsibilities to ensure that pesticides are equipped with protective packages adequate to protect children from accidental illness or injury.

3(e). General Guidelines

Recordkeeping: The only PRA-imposed guideline in 5 CFR 1320.6 that is exceeded in this collection is the recordkeeping retention period. Registrants or applicants of pesticides for which CRP is required must retain the required records for as long as the registration is valid, as specified under 40 CFR 157.36. Registrations are valid unless or until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration due to an adverse finding by EPA. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA-imposed guideline indicating that data, other than health, medical, or tax records need not be retained for more than three years may often be exceeded in this program.

Electronic submissions: CRP certification submissions can now be made electronically through the Pesticide Submission Portal (PSP). Information and links to submit can be found at <https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>. Many respondents that have used the PSP to submit CRP certifications prefer it over older but still available electronic or paper methods.

As an alternative to using the PSP, the Agency notes that [Pesticide Registration Notice 97-9](#) (Attachment D), entitled "*Electronic Submission of Child-resistant Packaging Test Data for All Pesticides and Child-resistant Testing of Prefilled, Nonrefillable Insecticide Bait Stations Not Designed or Intended to be Opened or Activated in a Manner That Exposes the Contents to Human Contact*" contains detailed instructions for submitting CRP test data in electronic format. In addition, when the agency does require test data to be submitted in support of a CRP certification, registrants typically use labs to generate the data and those labs are familiar with the formatting requirements. There is no form

associated with this information collection.

Information: The Agency solicits packaging manufacturers to voluntarily submit samples of CRPs that have passed CRP testing, identify the packaging, its manufacturer, and list the package's classification according to the ASTM International Standard D3475, "*Standard Classification of Child-Resistant Packages*." The Agency will compile and update the information on an ongoing basis on its CRP Website (www.epa.gov/oppr001/crp/). The Website includes descriptions and photographs of the package, with each package classified according to the ASTM International D3475 Standard.

The CRP Website provides a service to CRP manufacturers and pesticide registrants by displaying the various types of CRP in the marketplace which, in turn, should facilitate compliance with the CRP regulations. An Agency request for, and the public's submission of, these packaging samples is not a collection of information for the purposes of the OMB Paperwork Reduction Act regulations. OMB's regulations define "information" such that it excludes "samples of products or of any other physical objects" (*see* 5 CFR 1320.3(h)(2)). Therefore, EPA is not required to estimate the burden associated with submitting these packaging samples.

3(f). Confidentiality

Although submission of confidential information is not required as a part of this information collection confidential data have been submitted voluntarily as supporting material for an exemption request from CRP compliance requirements.

When any trade secret or Confidential Business Information (CBI) is provided to EPA, such information is protected from disclosure under section 10 of FIFRA. Data submitted to EPA is handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Manual. This manual contains instructions relative to all contact with confidential documents, including responsibilities of EPA employees, physical security measures, CBI copying and destruction procedures, transfer of CBI materials within the EPA, to contractors or other government offices, computer security, CBI typing procedures (documents to be typed internally or on contract), and division internal procedures. The manual dictates that all CBI must be marked or flagged as such, only authorized EPA personnel may be permitted access to CBI, and CBI must be kept in secure (double locked) areas. Additionally, all sensitive information stored as paper documents or on electronic media that need to be disposed of should be cleared by a Document Control Officer and placed in the Office of Prevention, Pesticides and Toxic Substances paper shredder.

3(g). Sensitive Questions

No information of a sensitive or private nature is requested in this information collection activity.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a). Respondents/NAICS Codes

Respondents to this information collection activity represent entities involved in manufacturing of pesticide chemicals, wholesale merchandising of pesticide products, or pest management activities.

The North American Industrial Classification System (NAICS) codes for respondents under this ICR include 325320 (Pesticide and other Agricultural Chemical Manufacturing), 424690 (Other Chemical and Allied Products Merchant Wholesalers), and 561710 (Exterminating and Pest Control Services). EPA recognizes that while this list may not be comprehensive, it represents a broad spectrum of large and small entities who are engaged in manufacturing pesticide chemicals, wholesale merchandising of pesticide products, or pest management activities and who submit CRP applications.

4(b). Information Requested

Most pesticide products are not subject to CRP requirements. For any product not subject to CRP requirements, registrants have no paperwork burden associated with Part 157 or this ICR. Products that are automatically exempt from (or not subject to) CRP requirements are any of the following:

- classified for restricted use
- in large package sizes
- not for residential use
- with low toxicity

The limits of what constitutes large package size and low toxicity are specified in 40 CFR 157. Meeting any of the first three of the above criteria effectively eliminates sales of a product to the general public. These products are intended for commercial use even if used in residential areas (i.e., exterminator-use insecticides and professional lawn care products). Products with specified low toxicity do not warrant CRP.

The applicant or registrant of a pesticide product that is subject to CRP requirements must certify to the Agency that the packaging for the product meets the standards of 40 CFR 157.32, or, in rarely applicable cases, request an exemption from the requirement. In order to meet the standards of Part 157.32, the package must have been tested following the required testing protocols, and the results must confirm the acceptability of the package. Child resistant effectiveness (CRE) and senior adult use effectiveness (SAUE) testing are required, in addition to testing for compatibility and durability. In many cases, submission of a certification statement, accompanied by specific basic information, is all that is required. If access to the actual raw testing data is necessary for EPA to reach sound conclusions, the Agency may also require submission of the CRP testing data and final report.

The EPA notes that for products subject to CRP requirements, CRP certification is required when a product is initially registered, and when the registration is amended as a result of any modification in the composition, labeling, or packaging. In addition, certification must be submitted to the EPA if the Agency determines, in accordance with 40 CFR 157.24(a)(1)(ii), 2(ii), or (b)(4), that a currently registered product is required to be packaged in child-resistant packaging, and the certification was not previously submitted.

For pesticide products subject to CRP requirements, there are three types of responses to this collection, only one of which is necessary for approval of each pesticide product as CRP compliant, as a condition of registration:

- (1) Certification without testing data
- (2) Certification with testing data
- (3) Request for exemption

In addition, there are recordkeeping requirements.

(i) *Data items, including reporting and recordkeeping requirements*

(1) Certification without data

Before an applicant or registrant can certify that a product's packaging meets CRP requirements, the appropriate testing must have been conducted and they must be in possession of the testing final report that indicates compliance. Registrants typically use independent laboratories to conduct the testing and prepare the final report, which includes the raw data, unless the testing and report is available from another source. Unless the Agency requests the test data, the registrant is not required to submit it.

CRP certification submitted to EPA must include the following:

- statement certifying that the packaging that is being used for the product meets the standards of 40 CFR 157.32
- name and EPA registration number of the product
- registrant's name and address
- date
- name, title and signature of the company officer making the certification

Requested, but not required, with the certification are:

- description of the packaging used
- summary of CRE and SAUE study results
- ASTM International Standard D3475, "*Standard Classification of Child-Resistant Packages*," designation

(2) Certification with data

If the EPA determines a need to review the actual raw testing data in order to reach sound conclusions on whether the standards of Part 157.32 have been met, the Agency may also require submission of the CRE/SAUE testing data and report.

When EPA requests test data to support CRP certification, the registrant must submit:

- certification statement and all other information listed above, under (1) Certification without data, and
- CRE/SAUE testing final report; or, if the same data have previously been deemed acceptable by the Agency, that data may be cited

CRP data is treated like other data submitted to the EPA. It is assigned a Master Record Identification Number (MRID) upon submission to the Agency. An applicant for CRP certification seeking to rely on previously reviewed CRP may only do so in accordance with the data compensation provisions of FIFRA section 3(c)(1)(F) and the procedures to ensure the protection of data submitters' rights codified in 40 CFR 152, subpart E. While the EPA does not maintain a list of packages/closures for which data has been reviewed and accepted, the Agency believes there are sufficient avenues for applicants to find the information, if needed. Once a registration is issued, applicants who wish to identify whether data had been submitted for a particular pesticide product including product specific

packaging could access the information submitted to the Agency in support of the registration for the product at the National Pesticide Information Retrieval System (NPIRS), available online at <http://state.ceris.purdue.edu/>. Applicants may also obtain a copy of any data compliance materials through the Freedom of Information Act, as provided in § 152.119 and consistent with EPA’s information regulations at 40 CFR part 2. Finally, individual CRP suppliers may also have current information regarding whether CRP data has been submitted for a specific package they supply.

(3) Request for exemption

Registrants may assert that an exemption from the CRP requirement is warranted because CRP is not technically feasible, practicable, or appropriate. Each request for an exemption is unique, and the documentation necessary to support an exemption is unique.

A request for exemption submitted to EPA must include the following:

- request for exemption
- name and address and telephone number of the requestor
- name and EPA registration number of the product
- description of the package and the sizes
- documentation supporting the request for exemption, including:
 - statement explaining why CRP is not technically feasible, practicable, or appropriate for this product
 - the length of time for which the exemption is requested

Recordkeeping: In accordance with 40 CFR 157.36, registrants must retain information supporting CRP certification for as long as the registration of a pesticide product is in effect. Information for which records are required includes all that the registrant must submit for certification with data, above. While EPA will consider information from a supplier’s website, it is the registrant’s responsibility, and not the supplier’s, to retain any required information for the lifetime of the registration.

(ii) *Respondent Activities*

In order to comply with the CRP regulations, registrants must engage in the following activities:

Table 4.1: RESPONDENT ACTIVITIES

Read instructions	Review requirements of FIFRA section 25 (c)(3) and 40 CFR Part 157, including its reference to 16 CFR 1700.15(b) and 16 CFR 1700.20.
Plan activities	Determine whether applicable test data have previously been deemed acceptable by the Agency and that data may be cited, or CRE/SAUE testing must be conducted.
Create information / Gather Data	Compile necessary test data regarding CRP compliance or exemption from requirements. If the package will be in CRP, respondent must conduct CRE/SAUE testing or cite appropriate MRIDs.

Review data for reliability and appropriateness	Review performance testing data to ensure that it will support CRP certification and identify the ASTM International Standard D3475, “Standard Classification of Child-Resistant Packages,” for the package.
Prepare and submit certification	Prepare and submit a certification package, or request for exemption, including all required and requested information and data listed in section 4(b)(i), above.
Store, file, and maintain data	Maintain record of the CRE/SAUE data and all other information used or sent to EPA to certify CRP compliance or justify an exemption from CRP.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a). Agency Activities

Upon receipt of a CRP certification submission, EPA performs the following activities:

Table 5.2: AGENCY ACTIVITIES

Review correspondence	Review CRP certification submission for completeness. Incomplete/incorrect certifications are returned to registrants;
Evaluate certification and data (if applicable); advise registrant	Evaluate the submitted certification statement and request data if there is any concern. If applicable, evaluate data submitted. Determine whether the registrant has met the CRP requirements, or decide whether or not to grant an exemption. Advise registrant of decision;
Store, file, and maintain data	All CRP data submitted to the Agency are referenced by an MRID number in the registration file jacket for the pesticide product. The Agency maintains a record of all CRP certifications in each product’s record.

5(b). Collection Methodology and Management

There is no form associated with this information collection. Respondents to this ICR submit CRP certifications and exemption requests as part of their larger package for registration of a pesticide product. For CRP certifications with test data, EPA requests that responses are submitted electronically to expedite data analysis. See [Pesticide Registration Notice 97-9](#) (Attachment D) for guidance on electronic format and submission of CRP test data. Electronic CRP submissions may be made through the Pesticide Submissions Portal. Information and links to submit can be found at <https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>. The Agency has no objection to submission of the CRP information on CD ROM as part of the registration package, or as a paper submission.

EPA only collects the test data in support of a CRP certification when there are human safety/health risk concerns not sufficiently addressed by the certification alone, or where the Agency needs further clarification. EPA requires that registrants maintain CRP test data in support of their

certifications of the child-resistance of the product's packaging or devices. At the time of CRP certification, we are requesting that the registrant identify the type of packaging used. This additional information may enable the Agency to contact all pesticide registrants using a particular type of CRP should a generic problem with the CRP become evident (e.g., trigger sprayers that are no longer considered CRP compliant). It will also facilitate the review of CRP exemption requests because the Agency can ascertain how similar pesticide formulations are packaged.

The generic database system continually tracks all registration actions from the registration-pending stage through to full registration and until a product is canceled. A generic database maintains information on both currently registered products and previously registered products, thereby acting as a registration action historical file. Additionally, the CRP compliance certification hard copy correspondence letters are filed in the pesticide product registration jacket.

5(c). Small Entity Flexibility

The incorporation of alternative methods to verify that the package meets the requirements of 40 CFR 157.32 have allowed manufacturers to use data bridging, available child-resistant protocol test data, and supporting documentation without spending the time and money to develop the data on the exact package configuration. The burden and cost to industry also is minimized by: the reference of the CPSC effectiveness standards and protocol test procedures that preclude duplicative testing for pesticidal and non-pesticidal purposes, and also allow for the use of CRP developed for non-pesticidal purposes; the use of packaging manufacturer's data rather than product-specific data; discretion and innovation with regard to product packaging compatibility and package selection; and the automatic exemptions without any submission from the registrant or approval by EPA.

5(d). Collection Schedule

CRP certification occurs only for a new product registration or when a registrant notifies EPA by application of their intention to change packaging, enter the residential market, or otherwise become subject to CRP regulations. Therefore, for each registered pesticide product, this is generally a one-time submission unless the labeled product use or the package design changes.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating Respondent Burden

In calculating the respondent burden, EPA estimates that registrants will submit an average of 31 responses annually to the Agency during the three-year period that this ICR is effective. EPA estimates that the average burden associated with this information collection activity is approximately 114 hours per response (3,535 total burden hours / 31 responses). This estimate is based on the average time across all three response types. Registrant submissions under this ICR fall into one of three categories. There are "CRP certifications with data," which require the registrant to submit the CRP study data along with their certifications of CRP compliance. Additionally, there are "CRP certifications without data," wherein the registrant submits only the required certification, and keeps a record of the test data but does not submit it to the Agency. Lastly, there are "CRP exemption requests," which are formal requests for the Agency to grant an exemption from the requirement for CRP. Exemption requests may be granted

for a period of time if the EPA finds that CRP is not practicable, appropriate or technically feasible for the product. The Agency does not receive exemption requests often. The number of responses expected for each response type is based on the average number of each type of CRP submission received annually by the EPA for the fiscal years (FY) 2013, FY2014 and FY2015 (Table 6.3).

Table 6.3: AVERAGE ANNUAL NUMBER OF RESPONSES BY TYPE OF RESPONSE

Type of Response	Number of Responses	Percent of Total
CRP certification with data	17	55%
CRP certification without data	13	42%
CRP exemption requested	1	3%
Total	31	100%

Source: Registrant responses received by EPA in Fiscal Year (FY) 2013, 2014 and 2015.

Table 6.4 shows the estimated respondent burden hours by type of response and the type of labor involved.

Table 6.4: ESTIMATED RESPONDENT BURDEN HOURS BY RESPONSE TYPE

Type of Response	No. of Responses	Managerial Burden		Technical Burden		Clerical Burden		Total Burden
		Hours Per Response	Total	Hours Per Response	Total	Hours Per Response	Total	
CRP certification with data	17	13	221	75	1,275	30	510	2,006
CRP certification without data	13	13	169	75	975	29	377	1,352
CRP Exemption Requested	1	0	0	6	6	2	2	8
TOTAL	31		390		2,256		889	3,366

6(b). Estimating Respondent Costs

This section presents how the respondent cost of paperwork activities is estimated. The Agency determines the type of labor needed for each kind of submission, the amount of time (burden hours) for each type of labor, and then identifies the wage rate for the types of labor needed. Wage rates are used to estimate the cost for each type of response, based on the number of burden hours it takes to complete one response. The resulting estimated cost per response is multiplied by the number of responses to get the annual respondent cost for each type of response.

To calculate the respondent burden costs, consistent with recent ICRs, OPP is using labor cost estimates based on Bureau of Labor Statistics (BLS) data with respect to wages, benefits and overhead for all labor categories for affected industries and EPA employees. This approach uses a transparent and consistent methodology employing publicly-available data to provide more accurate estimates and allow easy replication of the calculations.

Table 6.5: METHODOLOGY FOR CALCULATING FULLY LOADED WAGE RATES

Methodology	The methodology uses data on each sector and labor type for an Unloaded wage rate (hourly wage rate), and calculates the Loaded wage rate (unloaded wage rate + benefits), and the Fully loaded wage rate (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This ICR uses 2015 Bureau of Labor Statistics (BLS) data.
Unloaded Wage Rate	Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm .
Sectors	The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm).
Loaded Wage Rate	Unless stated otherwise, all benefits represent 46% of unloaded wage rates, based on benefits for all civilian nonfarm workers, from http://www.bls.gov/news.release/ecec.t01.htm . However, if other sectors are listed for which 46% is not applicable, the applicable percentage will be stated.
Fully Loaded Wage Rate	We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs.

To derive the labor rates for this ICR, the Agency estimated the wages (Attachment E) for the managerial, technical and clerical labor categories using the methodology cited above. The respondent costs for managerial, technical and clerical wage rates are estimated at \$126.56, \$71.69 and \$42.97 per hour, respectively. These labor rates are fully loaded and include benefits and overhead costs.

Tables 6.6-6.8 present respondent burden hours and costs, by collection activity, for the three types of responses. The burden hours are broken down among the various collection activities and the types of labor needed to complete the CRP submission package. The estimated paperwork cost per respondent to comply with CRP requirements, averaged across the three response types, is approximately \$8,042 per response (\$249,292 total cost/ 31 responses). The average burden hours per response is about 114. There are no capital expenditures associated with this information collection activity.

CRP Certifications with Data: To calculate the burden and costs associated with CRP certifications with and without data, the burden and cost of paperwork activities involved in test data generation or “gathering data” must be estimated. To do this, 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 solicited feedback from three companies that contract with registrants to conduct the required testing. These companies provided data on the cost of their standard Child Resistant Effectiveness (CRE) and Senior Adult Use Effectiveness (SAUE) testing, including the cost of preparing the final test report for registrants. These estimates were averaged to get an expected cost for both CRE and SAUE testing as is presented in Table 6.6.

Table 6.6: CHILD RESISTANT EFFECTIVENESS (CRE) & SENIOR ADULT USE EFFECTIVENESS (SAUE) TESTING COST ESTIMATES

	CRE	SAUE
Firm A	\$ 15,000	\$ 15,000
Firm B	\$ 11,500	\$ 18,000
Firm C	\$ 3,430	\$ 5,300
Average Cost of Testing	\$ 9,977	\$ 12,767

Source: Test cost estimates were provided to EPA by three independent laboratories.

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

Figure 1 illustrates the method for calculating the paperwork burden of data generation.

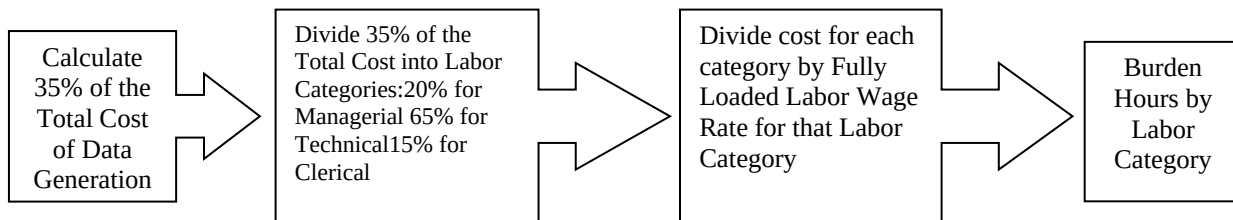


Figure 1: Method for Calculating Paperwork Burden from Test Costs

Similar to the DCI ICR (OMB Control No. 2070-0107), this approach generally assumes and incorporates the following core considerations:

- (1) Registrants generate all of the CRP data as specified in 40 CFR 157.32
- (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 Table 6.5. above.

Using this methodology, Tables 6.5, 6.6 and 6.7 below list the estimates of the paperwork burden associated with conducting CRE and SAUE studies, which are the basis for CRP certification.

Table 6.7: BREAKDOWN OF DATA GENERATION COSTS BY RESPONDENT LABOR HOURS

Type of Data to be Generated	Data Cost ¹	Paperwork Cost ²	Managerial Hours	Technical Hours	Clerical Hours
CRE	\$9,977	\$3,492	6	32	12
SAUE	\$12,767	\$4,468	7	41	16
TOTAL	\$22,743	\$ 7,960	13	72	28

1. See table 6.6
2. 35% of data cost.

As is shown in Table 6.8, respondents submitting a CRP certification with data require an estimated average of 13 hours of managerial time, 75 hours of technical time, and 30 hours of clerical time on paperwork activities per response. The burden includes preparing the certification statement as well as gathering and preparing the basic information to complete the certification package. However, the majority of the burden is for the paperwork associated with conducting the CRE/SAUE testing to generate and gather the test data. Table 6.8 breaks down the managerial, technical, and clerical burden hours estimated for each of the applicable collection activities.

Table 6.8: CRP CERTIFICATION WITH DATA, ESTIMATED RESPONDENT BURDEN

COLLECTION ACTIVITIES	Burden Hours			TOTAL	
	Managerial \$126.56/hr.	Technical, \$71.69/hr.	Clerical, \$42.97/hr.	Burden Hours	Cost
Read instructions	0	0.25	0	0.25	\$17.92
Plan activities	0	0.5	0	0.5	\$35.84
Gather CRP certification information	0	0.25	0	0.25	\$17.92
Generate & gather CRE/SAUE study data & prepare final report	13	72	28	113	\$8,010.14
Process, compile, and complete certification package	0	1.5	0.5	2	\$129.02
Review submission	0	0.5	0.5	1	\$57.33
Submit, file, or maintain CRP certification package and CRE/SAUE study final report with data	0	0	1	1	\$42.97
TOTAL	13	75	30	118	\$8,311.16

Annual Burden: 118 Hours per Response x 17 Responses = 2,006 Burden Hours

Annual Cost: \$8,311.16 per Response x 17 responses = \$141,290

CRP Certifications without Data: Respondents submitting a CRP certification without data require an estimated average of 13 hours of managerial time, 75 hours of technical time, and 29 hours of clerical time on paperwork activities per response. Respondents who submit CRP certifications without data must either have had the studies conducted or cite previously generated data. In either case, the CRE/SAUE study results are the basis for their certification of CRP compliance, and they must keep records of the study data and final report. The Agency does not have records of how many studies are conducted by the respondent vs. cited. For cited studies conducted for another firm, it is expected that registrants pay for data compensation in order to acquire and cite the data. For these reasons, the EPA assumes that registrants submitting certifications without data bear nearly the same paperwork burden as those submitting certifications with data, whether they had the study conducted or not. For this reason, this calculation of burden is likely an overestimate since the full paperwork burden of data generation is being applied to every certification response to give a conservative, upper bound estimate of burden hours and costs. The estimated burden per response for certifications without data is 117 hours, which is one hour less than for certifications with data. It is estimated that clerical staff spends one hour more to process, compile, complete, submit and file a certification package with data than they do for a certification without data.

Table 6.9: CRP CERTIFICATION WITHOUT DATA, ESTIMATED RESPONDENT BURDEN AND COST

COLLECTION ACTIVITIES	Burden Hours			TOTAL	
	Managerial 1 \$126.56/hr.	Technical, \$71.69/hr.	Clerical, \$42.97/hr.	Burden Hours	Cost
Read instructions	0	0.25	0	0.25	\$17.92
Plan activities	0	0.5	0	0.5	\$35.84
Gather CRP certification information	0	0.25	0	0.25	\$17.92
Generate or obtain CRE/SAUE study data & final report	13	72	28	113	\$8,010.14
Process, compile, and complete certification package	0	1.5	0	1.5	\$107.53
Review submission	0	0.5	0.5	1	\$57.33
Submit CRP certification package; file or maintain package and CRE/SAUE study final report with data	0	0	0.5	0.5	\$21.49
TOTAL	13	75	29	117	\$8,268.18

Annual Burden: 117 Hours per Response x 13 Responses = 1,521 Burden Hours

Annual Cost: \$8,268.18 per Response x 13 responses = \$107,486

CRP Exemption Requests: Respondents that formally request an exemption on technical grounds require 6 technical hours and 2 clerical hours to research and prepare their submission indicating why CRP is not technically feasible, practicable, or appropriate (Table 6.10).

Table 6.10: CRP EXEMPTION REQUEST, ESTIMATED RESPONDENT BURDEN AND COST

COLLECTION ACTIVITIES	Burden Hours		TOTAL	
	Technical, \$71.69/hr.	Clerical, \$42.97/hr.	Burden Hours	Cost
Read instructions	0.25	0	0.25	\$17.92
Plan activities	0.5	0	0.5	\$35.84
Create information including electronic format of data	0.25	0	0.25	\$17.92
Gather Data to support Exemption	2.5	0	2.5	\$179.22
Process, compile, and complete written compliance document	2	0.5	2.5	\$164.87
Review submission	0.5	0.5	1	\$57.33
Store, submit, file, or maintain data	0	1	1	\$42.97
TOTAL	6	2	8	\$516.08

Annual Burden: 8 Hours per Response x 1 Response = 8 Burden Hours

Annual Cost: \$516.08 per Response x 1 response = \$516.08

The table below summarizes the annual respondent burden hours and cost for this ICR.

Table 6.11: ESTIMATED TOTAL ANNUAL RESPONDENT BURDEN AND COSTS

Type of Response	Total Annual Burden Hours	Total Annual Cost
CRP certification with data	2,006	\$141,290
CRP certification without data	1,521	\$107,486
CRP exemption request	8	\$516
Total	3,535	\$249,292

Average Burden per Response: 3,535 Total Annual Burden Hours ÷ 31 Responses Annually = 114 Hours per Response

Average Cost per Response: \$249,292 Total Annual Cost ÷ 31 Responses Annually = \$8,042 per Response

Table 6.11 presents estimated total annual respondent burden and costs by response type. The average respondent burden across all types is estimated at approximately 114 hours per response, with a total annual burden of 3,535 hours. The total annual cost to respondents of this information collection is estimated to be \$249,292, with an average cost of \$8,042 per response.

6(c). Estimating Agency Burden and Cost

This section shows how the Agency's paperwork burden hours and costs associated with the information collection are calculated for this ICR. Table 6.12 shows the estimated Agency hours per response for each type of response, broken down by labor type and the activities needed to complete the response. Table 6.13 provides the estimated annual burden for each type of response based on the

average burden per response, and the number of responses received annually.

Table 6.12: AVERAGE AGENCY BURDEN ESTIMATES PER RESPONSE, BY ACTIVITY, RESPONSE TYPE, AND LABOR TYPE

COLLECTION ACTIVITIES	BURDEN HOURS					
	<i>CRP certification with data</i>		<i>CRP certification without data</i>		<i>CRP exemption request</i>	
	Tech.	Admin.	Tech.	Admin.	Tech.	Admin.
Read correspondence	1	0	1	0	1	0
Execute activities including data review	7	1	0.5	0	39	1
Store, file, or maintain data	0	2	0	0.5	0	2
TOTAL	8	3	1.5	0.5	40	3

Table 6.13: ANNUAL AGENCY BURDEN, BY RESPONSE TYPE

Action	No. of Responses	Technical Burden		Administrative Burden		Annual Burden Hours
		Hrs Per Event	Total	Hrs Per Event	Total	
CRP certification with data	17	8	136	3	51	187
CRP certification without data	13	1.5	19.5	0.5	6.5	26
CRP exemption request	1	40	40	3	3	43
TOTAL	31		196		61	256

Average Agency Burden per Response: 256 Total Annual Burden Hours ÷ 31 Responses Annually = 8.26 Hours per Response

Table 6.13 gives an overview of the Agency hours needed by type of labor for CRP certifications and exemption requests. CRP certifications with data require the Agency to review not only the basic certification package, but also the actual CRE/SAUE study data, write up reports and engage with the respondents regarding questions and/or clarifications. CRP certifications without data require the Agency to verify that the test data being cited or summarized is appropriate for the product and complete. The Agency must research exemption requests to verify the registrant's claim that while they might seem to be subject to CRP certification, in reality CRP is not technically feasible, practicable, or appropriate.

The tables above give a breakdown for the time it takes to review CRP certification submissions by collection activity and the type of response. This information is used in the table below to estimate the cost of CRP certification submissions to the Agency based on the time needed for the type of response and each type of labor, and the respective fully loaded wage rates (calculated from BLS using the methodology in Table 6.5 for each labor type).

Table 6.14: AGENCY COST ESTIMATES, BY RESPONSE TYPE

	CRP certification with data		CRP certification without data		Exemption Request	
	Tech. \$/hr	Admin \$/hr	Tech. \$/hr	Admin \$/hr	Tech. \$/hr	Admin \$/hr
	\$81.37	\$46.41	\$81.37	\$46.41	\$81.37	\$46.41
Hours per response, by labor type	8	3	1.5	0.5	40	3
Cost per response, by labor type	\$651	\$139	\$122	\$23	\$3,255	\$139
Annual number of responses	17		13		1	
Cost per response, by response type	\$790		\$145		\$3,394	
TOTAL ANNUAL COST	\$13,433		\$1,888		\$3,394	

Average Agency Cost per Response: $\$13,433 + \$1,888 + \$3,394 = \$18,716$ Total Annual Cost;
 $\$18,716 \div 31$ Responses Annually = \$603.71 per Response

Table 6.14 presents Agency burden and costs by response type. The total annual cost of this ICR to the Agency is estimated to be \$18,716, with an average cost of \$603.71 per response. The average Agency burden per CRP response across all types is estimated at approximately 8.26 hours, with a total annual burden of 256 hours (Table 6.13).

6(d). Bottom Line Burden Hours and Cost

Table 6.15: ESTIMATED TOTAL ANNUAL BURDEN AND COST

Respondent Burden	Total Burden Hours	Total Cost (\$)
CRP certification with data	2006	\$141,290
CRP certification without data	1521	\$107,486
CRP Exemption Request	8	\$516
TOTAL Respondent Burden and Cost	3,535	\$249,292
Agency Burden	Total Burden Hours	Total Cost (\$)
CRP certification with data	187	\$13,433
CRP certification without data	26	\$1,888
CRP Exemption Request	43	\$3,394
TOTAL Agency Burden and Cost	256	\$18,716

6(e). Reasons for Change in Burden

The estimated total annual respondent burden decreased by 1,972 hours from 5,507 hours for the previous ICR approval to 3,535 hours for this request due to a decrease in the number of responses submitted annually, and an increase in the estimated average burden hours per response. There has been

an improvement in the way responses submitted are being categorized by type, tracked, and recorded, resulting in a large decrease in the estimated number of responses per year, from 685 to 31. EPA revised the number of certifications expected annually to reflect the average annual number actually received by the Agency for the fiscal years (FY) 2013, 2014 and 2015.

The reduction in burden from the decrease in the number of responses submitted annually is partially offset by an increase in the estimated average burden hours per response, from 8.04 hours to 114 hours per submission. This large increase is due to including in this ICR request the paperwork burden associated with conducting the CRE/SAUE tests, recording the data, and preparing the final report (data generation burden), to be consistent with other similar ICRs within the Agency. The large paperwork burden associated with data generation is also applied to all certifications without data, resulting in a likely overestimate of total respondent burden.

There is a major decrease in the Agency burden relative to the prior approved version of the ICR, from 19,812 to 256 hours. The decrease in Agency burden is due to the same decrease in the number of responses annually as for respondents, combined with a decrease in the Agency's estimated average burden per response, from 28.9 to 8.3 hours.

6(f). Burden Statement

The total annual respondent burden for the collection of information contained in this ICR is estimated to be 3,535 hours. The average "respondent" burden for the Compliance Requirement for the CRP regulations is estimated to be 114 hours per submission necessary to support a CRP certification or exemption request, including time for: reading relevant federal legislation and regulations; paperwork associated with conducting performance testing on closures and/or devices; reviewing test data; preparing submission or CRP certification; and recordkeeping regarding the CRP certification or submission.

"Burden" is defined in 5 CFR 1320.3(b). The Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to the PRA unless it displays a currently valid OMB control number. OMB control numbers for certain regulations in Title 40, after initial display in the Federal Register, are listed in 40 CFR part 9.1 (Attachment F) and may appear on the information collection instrument as applicable, i.e., form or instructions, and in the Federal Register.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2016-0630, which is available for online viewing at www.regulations.gov, or in person viewing at the EPA Docket Center-Public Reading Room, EPA West Building, in Rm. S-3334, 1301 Constitution Avenue, NW, Washington, DC. This docket facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The docket telephone number is (202) 566-1744. You may submit comments regarding 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.

Comments may be submitted to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T,

1200 Pennsylvania Ave., NW, Washington, DC 20460, and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

7. ATTACHMENTS TO THE SUPPORTING STATEMENT

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted); accessible electronically through <http://www.Regulations.gov>. On the main page, select **Advanced Search** from the menu bar at the top and select **Docket Search**. Enter the Docket ID Number, EPA-HQ-OPP-2016-0630 in the **Docket ID** field. Click on the **Submit button**. From the results page, you will be able to link to the docket view or directly open select documents found in the docket.

Attachment A: Section 25 (c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – also available at <http://www.gpo.gov/fdsys/pkg/USCODE-2012-title7/pdf/USCODE-2012-title7-chap6-subchapII-sec136w.pdf>

Attachment B: 40 CFR Part 157 - PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES – also available at <http://www.gpo.gov/fdsys/pkg/CFR-2003-title40-vol21/pdf/CFR-2003-title40-vol21-part157.pdf>

Attachment C: Record of Consultation Questions and Responses

Attachment D: Pesticide Registration Notice 97-9 - *Electronic Submission of Child-resistant Packaging Test Data for All Pesticides and Child-resistant Testing of Prefilled, Nonrefillable Insecticide Bait Stations Not Designed or Intended to be Opened or Activated in a Manner That Exposes the Contents to Human Contact* – available at http://www.epa.gov/PR_Notices/pr97-9.html

Attachment E: Worksheet for Estimating OPP ICR Wage Rates for Industry and EPA Labor Costs

Attachment F: Display Related to OMB Control #2070-0052 - Listings of Related Regulations in 40 CFR 9.1