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

## 1. <u>IDENTIFICATION OF THE INFORMATION COLLECTION</u>

## 1(a). Title of the Information Collection

Compliance Requirement for Child-Resistant Packaging

OMB No. 2070-0052; EPA No. 0616.11

## 1(b). Short Characterization/Abstract

This information collection program is designed to provide the Environmental Protection Agency (EPA) 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 packaging or device meets these standards. There are no forms associated with this information collection activity.

## 2. NEED FOR AND USE OF THE COLLECTION

## 2(a). Need/Authority for the Collection

Section 25(c)(3) of FIFRA 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 (see Attachment A). 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, if the product meets certain criteria regarding toxicity and use, it must be sold and distributed in child-resistant packaging. 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 (Attachment B).

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

EPA reviews a registrant's child-resistant packaging (CRP) certification to determine if there are human safety/health risk concerns. 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).

# 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 (78 FR 59014; September 25, 2013). EPA received no public comment in response to this notice, which is available in the docket for this ICR and can be accessed at <a href="http://www.regulations.gov">http://www.regulations.gov</a> using the docket identifier EPA-HQ-OPP-2013-0493.

## **3(c).** Consultations

In addition to the public notice that EPA published in the Federal Register concerning the renewal of this ICR, the Agency consulted with stakeholders who actively interact with the Agency through the use of this collection instrument, as required under 5 CFR 1320.8(d)(1). Three companies were selected to respond to questions about the information collection and the accuracy of the burden estimates. A record of the consultations (Attachment C) is available in the docket for this ICR.

With regard to duplication of data collected, one company indicated that their sources of CRP information are the catalog and publications of their packaging suppliers and noted that they obtain their CRP information from either the packaging supplier or the supplier's website. The EPA notes that, in responding to this information collection, applicants and registrants may submit material and literature, including citations to web pages, from a supplier, provided the information meets the requirements in 40 CFR 157 subpart B. While information might be available from a supplier, the agency would not know that the particular products are used to package registered pesticides unless the respondent informs the agency. If access to actual raw data is necessary for EPA to reach sound conclusions, citations to supplier materials, by themselves, will not be deemed adequate to satisfy agency data requirements. In addition, 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. 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.

One company suggested that EPA maintain a list of packages/closures for which data has been reviewed and accepted so that registrants know whether data is required when certifications are submitted for these packages/closures. EPA does not maintain a separate list of packages/closures for which data has been reviewed and accepted. The agency does provide a list of child resistant packages on its website, as well as a list of CRP manufacturers (<a href="http://www.epa.gov/opprd001/crp/">http://www.epa.gov/opprd001/crp/</a>). Packages are designated as child-resistant solely on the basis of the manufacturers' claims. EPA has not reviewed the manufacturers' test data on CRP as a prerequisite for inclusion in the list. The appearance of a package in this publication is not intended in any manner to denote approval, certification, or endorsement of the package by the EPA.

However, even if EPA maintained a list such as the company proposes, it would not be sufficient to enable a registrant or applicant to claim that a package or pesticide product is CRP compliant without citing previously submitted data. An approval of a pesticide product as CRP

compliant is based on CRP data submitted by applicants and registrants in support of registration. CRP data is treated like other data submitted to the agency. CRP data 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 agency 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 and its 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.

With regard to frequency of submission of CRP information, one company noted that they submit certification statements for each registration that the container design and closures meet the CRP requirements when the product is distributed and sold. Further, the company reasoned that unless there is good cause such as a change in the formulation or a change in the packaging, they believe additional or new certifications for packaging are unnecessary. The agency generally agrees with the company. EPA notes that CRP certification may be required (if the toxicity criteria in 40 CFR 157.22 is met) when a product is registered or if the registration is amended as a result of any modification in the composition, labeling, or packaging. In addition, certification must be submitted to the agency 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.

Regarding whether the directions for submissions are clear, one company indicated that directions for the certification statement were adequate and the Application for Pesticide Amendment (EPA Form 8570-1) is adequate and offers the registrant more flexibility than a new form. EPA notes that there is no form associated with this information collection and that the burden for EPA Form 8570-1 is covered under a separate ICR (OMB Control No. 2070-0060). Another company suggested that it would be helpful to have a clearer process for determining if a product is subject to CRP, for example a decision-tree. EPA believes that the toxicity criteria for when a product must be sold and distributed in child-resistant packaging are adequately identified in the regulations at 40 CFR 157.22. The toxicity criteria, as well as information about how to submit CRP information, can be found on EPA's website at http://www.epa.gov/opprd001/crp/. Registrants and applicants may also contact the agency for additional information if they are unsure whether their product meets the toxicity criteria, or if they need assistance with assembling the submission materials. Two companies suggested that it would be helpful to have an example of the electronic template when submitting test data. The Agency notes that Pesticide Registration Notice 97-9, 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 Purpose" contains detailed instructions for submitting CRP 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 formating requirements.

Regarding whether electronic submission is available, one company suggested that, while submitting data via CD is fine, internet submission would be preferable. Electronic submission is already available for some regulatory actions (see <a href="http://www.epa.gov/opp0001/regulating/registering/submissions/">http://www.epa.gov/opp00001/regulating/registering/submissions/</a>). EPA acknowledges, however, that additional opportunities for electronic submission would be more efficient for registrants and the agency. While not available for this renewal, EPA will continue to explore ways to increase availability of electronic submissions and will amend this ICR to create electronic forms as possible.

With regard to EPA's burden estimate, two stakeholders provided no comment on EPA's estimate of the respondent burden hours. One company indicated that the split between technical and clerical time in the respondent burden may be different than EPA's estimate. In particular, the company commented that 2 hours of technical time and no clerical time are needed to submit CRP certification without data rather than EPA's estimation of 1 hr of technical time and 0.5 hrs of clerical time. In addition, the company commented that only 6 hours of technical time and no clerical time are required to submit CRP certification with data rather than EPA's estimate of 8 hrs of technical time and 3 hours of clerical time.

The Agency notes that that its estimates are aggregated averages; some stakeholders may take more time to respond to the information collection, and others less. In addition, EPA expects that there may be variability among respondents with regard to how activities undertaken to respond to this information collection are distributed between technical and clerical staff. As a result of the company's comments, EPA will increase the agency's burden estimate for technical time for CRP certifications without data to 1.5 hrs, leaving the clerical burden at 0.5 hrs, for a total of 2hrs. This new estimate of total burden is consistent with the company's estimate of 2 hrs to submit CRP certification without data, while accounting for variability among respondents of how response time is distributed between technical and clerical staff. EPA is not reducing its burden estimate for CRP with data, but will keep the conservative estimate of 8hrs of technical time and 3 hrs of clerical time.

EPA consults with the CPSC on general packaging issues, products under joint jurisdiction (e.g. bleaches and pine oil products), and the regulatory aspect of implementing consumer (child) safety measures in a way that keeps them consistent with those under the Poison Prevention Packaging Act.

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 exemption requests and certifying to the use of CRP. 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 necessarily by a prescribed schedule.

## 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

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 records required under 40 CFR 157.36 for as long as the registration is valid.

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.

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 (<a href="www.epa.gov/opprd001/crp/">www.epa.gov/opprd001/crp/</a>). 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, there has been at least one instance where 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, CBI for destruction must 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

Pesticide registrants subject to the regulations are required to certify to the Agency that the packaging for the pesticide product meets the standards of 40 CFR 157, or request an exemption to the requirement.

(i) Data items, including record keeping requirements

The respondent certification letter must exercise one of the following information options in this section or in section (i)(a) to comply with 40 CFR Part 157:

Certify to CRP by letter to Agency	The name, and EPA registration number of the product to which the certification applies, the Certification statement, the registrant's name and address, the date, and the name, title and signature of the company officer making the certification. The Certification statement must contain a statement that the pesticide product complies with 40 CFR 157.32. A description of the packaging used and the ASTM International Standard D3475, "Standard Classification of Child-Resistant Packages," designation is requested (not required).				
Product does not meet Toxicity Criteria	Submit toxicity data that indicate a specific product's minimal toxicity, or reformulate to a less toxic product and assert that the CRP regulations do not apply. Less than 2 percent of pesticide registrants choose this option for complying with the CRP program.				
Product is not for Residential Use	Revise product labeling so that CRP regulations do not apply, i.e., specifying non-residential use areas, or eliminate residential use. The registrant is required to send EPA a copy of the revised labeling. Less than 2 percent of pesticide registrants use this option.				

The majority of pesticide registrants choose to certify that their pesticide product packaging meets the effectiveness, compatibility, and durability standards at 40 CFR 157.32. Registrants who certify are required to maintain data to corroborate the certification for the duration of the pesticide's registration as required by 40 CFR 157.36. EPA may also request registrants who certify to submit additional data because of human safety/health risk concerns. If data is needed, EPA requests that registrants submit data electronically to expedite data analysis. Pesticide Regulation (PR) Notice 97-9 describes the benefits and requirements of electronic data submission (see Attachment D).

#### (i)(a) Exemptions from CRP

Currently, registrants have several options by which they may be exempted from CRP requirements. These options include:

- (1) Package the product in a large size so that CRP regulations do not apply. Exercising this option effectively eliminates sales to the general public. It is based on the concept that certain bulk size pesticide packages are intended for commercial use even in residential areas (i.e., exterminator-use insecticides and contract lawn care products). These package sizes are specified in 40 CFR 157.24 (a)(2). The pesticide registrant is not required to seek a formal exemption for this option, and less than 3 percent of registrants use this option. However, CRP may be required for products packaged in a size exceeding those outlined in exemption criteria at 40 CFR 157.24(a)(2) if it is determined by the EPA that the product is distributed or sold to the general public. As such, EPA expects that some of these registrants will no longer meet the criteria for the exemption.
- (2) Registrants may also assert that an exemption to CRP is warranted because the hazards indicated by the toxicity criteria are not indicative of risk to humans, or that CRP is not

technically feasible, practicable, or appropriate. Each request for an exemption is unique, and the data necessary to support an exemption are unique. Less than 3 percent of pesticide registrants choose this option with the CRP program.

# (ii) Respondent Activities

In order to comply with the CRP regulations, registrants must engage in the following 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	Decide under which option to comply with CRP compliance requirements or whether an exemption will be requested;
Create information	Compile necessary data regarding compliance or exemption from CRP requirements;
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 statement.	Draft a certification statement citing compliance with CRP requirements and include a description of the package, or explain why the product is not subject to CRP, or request an exemption from CRP compliance requirements and compile/cite any supporting data as necessary. Submit information to EPA.
Store, file, and maintain data	Maintain any data and information sent to EPA to certify CRP compliance, support a determination as to why product is not subject to CRP, 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 certification letter, EPA performs the following activities:

Review correspondence	Review correspondence for completeness. Incomplete/incorrect certifications are returned to registrants;
Evaluate data and advise registrant	Evaluate data submitted and determine whether the registrant has met the CRP requirements, has sufficiently substantiated reasons for not being subject to CRP (e.g. reformulate to a less toxic product) 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 its generic database.
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# 5(b). Collection Methodology and Management

Respondents to this ICR submit the information as part of their larger package for registration of a pesticide product. At the time of this renewal, OPP is not offering a fully electronic submission option for pesticide registration packages. The Agency is, however, beginning the process of defining requirements for electronic submission of studies as well as other elements of applications and petitions. The Agency has no objection to submission of the CRP information on CD ROM as part of the registration package.

For CRP certifications with data, EPA requests that responses are submitted electronically to expedite data analysis. See Attachment D for guidance on electronic data submission. CRP certifications with data are the most burdensome of the four response types under this ICR.

EPA only collects data in support of a CRP certification when there are human safety/health risk concerns. EPA requires that registrants maintain 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 data is a part of their recordkeeping requirements (under 40 CFR 157.36). This additional piece of data 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). 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 extrapolation schemes, available child-resistant protocol test data, and supporting documentation without spending the time and money to develop the data on their exact package. 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 granting of the size exemptions without requiring

an application from the registrant or approval by EPA.

EPA also estimated the impact of this ICR on small entities by calculating the annual company burden as a percentage of average annual revenue (see Attachment F). EPA estimated the number of small entities that participate under this ICR using information on company revenue and employment from Dun and Bradstreet database reported for the year 2010. EPA estimated that there are 456 (26.3% of 1733) large firms and 1277 (73.7 % of 1733) small firms that are potential respondents to this ICR (see Attachment F). Child Resistant Packaging applications were submitted to the Agency by 49 parent firms between 2006 and 2009. EPA determined that 27 of the companies which submitted CRP during that period were large and 21 were small (see Attachment F for the list of small entities), based on information from the Dun and Bradstreet 2010 database. EPA was unable to size one company.

The table below presents the total and average revenue and employment for small companies, large companies, and all companies combined. As shown below in Section 6, the burden cost per CRP submission is estimated to be approximately \$448 (Table 2, section 6). Assuming that CRP submissions are evenly distributed across small and large companies, an average firm would submit approximately 14 CRP applications per year, assuming 50 companies are responsible for the 685 (see Table 1, section 6) CRP submissions in a given year. This would result in an average annual company burden of \$6,272, or 0.03% of small firm's annual revenue, on average.

	Total Number of Firms	Total Revenue (\$)	Total Employee Size	Average Revenue <sup>1</sup> (\$)	Average Employment <sup>1</sup>				
Small Firms	21	414,668,000	1,737	23,037,111	73				
Large Firms	27	27 312,730,280,167 598,975	598,975	12,028,087,699	23,031				
All Firms	48	313,144,948,167	600,712	7,116,930,640	13,639				
<sup>1</sup> Only based o	<sup>1</sup> Only based on firms that report sales on D&B.								

## 5(d). Collection Schedule

CRP certification is usually conducted only 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 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 685 responses to this information collection activity annually during this renewal ICR. The number of responses is based on the number of products in FY2010, FY2011, and FY2012 with Child-Resistant Packaging (CRP) requirements. During this three year period, approximately 486 CRP applications were submitted annually. The expected decrease from 1,165, estimated during the

previous ICR renewal, to 486 is largely associated with the implementation of the EPA's Registration Review program, which was mandated by the Food Quality Protection Act and requires the Agency to periodically reevaluate pesticides to make sure that as changes occur, products in the marketplace can still be used safely. The registration reviews completed under the program during FY2010-2012 did not result in an expected increase in the number products requiring CRP for that period. The EPA is using the higher number of 685 rather than 486 because the agency is expecting an increase in CRP applications for certain products containing pesticide chemicals that will no longer be under exclusive use data protection. Registrants with products using these chemicals will be required to provide their own CRP test data, which will have to be reviewed for human safety/health risk concerns.

EPA estimates that the average burden associated with this information collection activity is approximately 8.04 hours per response. This estimate is based on an average response time across *all* response types (i.e. CRP certifications, CRP certifications with data, CRP exemption explanation based on large package size, and CRP exemption explanation based on a lack of toxicity, packaging issues, eliminating residential use, lower product toxicity). The number of respondents expected for each of the various response types is based on the number of each type of CRP submission received annually.

EPA's estimates of respondent burden do not include any burden at management levels. Responses to this information collection activity are generally handled without management time by the technical personnel such as the regulatory affairs person and packaging personnel, with some clerical support. Averaged across the four CRP types, each CRP action requires an estimated 5.87 hours of technical time and 2.17 hours of clerical time, which is broken down as follows (see Table 2):

- 0.78 technical hours to ascertain whether the product is subject to the CRP regulations (meets toxicity criteria, residential use) and to decide whether to submit a CRP certification, data, be exempt from regulations due to large size or other criteria;
- 2.35 technical hours to create/prepare the information;
- 2.15 technical hours to review submission for accuracy and appropriateness (process, compile, complete document);
- 1.63 clerical hours to format submission and prepare information;
- 0.59 technical hours to review and sign the appropriate documents; and,
- 0.54 clerical hours to mail the submission, file the respondent copy and CRP documentation

Type of Response	Number of Responses	Percent of Total
CRP certification without data	212	31
CRP certification with data	453	66
Exempt – large package size	12	2
Exempt – lack of toxicity, packaging, no residential use,	8	1
lower product toxicity		

<sup>&</sup>lt;sup>1</sup> Based on Table 1, the avg. technical burden across all response types is approx. 5.87 hrs. per response  $(4,018 \div 685)$  and the avg. clerical burden across all response types is approx. 2.17 hrs. per response  $(1,489 \div 685)$ . For the purposes of estimating respondent burden and cost (*see* Table 2), EPA assumes that the average burden is 8.04 hrs. per response (5.87 technical hrs.) + 2.17 clerical hrs.).

Total 685 100

The burden estimates by response type are summarized in Table 1 below. Respondents submitting CRP certifications without data require 1.5 hours of technical labor time in order to determine whether the product is subject to the CRP regulations (meets toxicity criteria, residential use), identify the type of CRP used, and prepare the CRP certification. An additional 30 minutes clerical time is required to complete the CRP certification submission to the Agency and file the supporting CRP information.

Respondents submitting CRP certifications with data require 8 hours of technical labor time in order to determine the product is subject to the CRP regulations (meets toxicity criteria, residential use); identify the type of CRP used; prepare the CRP certification; gather the supporting CRP data; and 3 hours of clerical time to prepare the CRP data package, complete the CRP certification submission to the Agency, and file the supporting CRP data.

Respondents that are exempt from CRP requirements based on large package size require 1 hour of technical time and no clerical time because the CRP regulations require little action on the part of the respondent. Respondents that are exempt from CRP requirements for the reasons described in Section 4(b) of this ICR (lack of toxicity, packaging, no residential use, lower product toxicity) require 8 technical hours and 3 clerical hours to prepare their submission indicating why CRP is not required and/or CRP is not possible.

The total estimated respondent burden to comply with this information collection activity is 5,507 burden hours/year.

Table 1. RESPONDENT BURDEN BY RESPONSE TYPE

Type of Response	No. of	Technical B	urden	Clerical Bu	rden	Total Burden
	Responses	Hours Per Response	Total	Hours Per Response	Total	
CRP certification without data	212	1.5	318	0.5	106	424
CRP certification with data	453	8	3624	3	1359	4,983
Exempt from CRP due to large package size	12	1	12	0	0	12
Exempt from CRP due to lack of toxicity, packaging, no residential use, lower product toxicity	8	8	64	3	24	88
TOTAL	685	NA	4,018	NA	1,489	5,507

ANNUAL RESPONDENT BURDEN = 4,018 (technical burden) + 1,489 (clerical burden) = 5,507 hrs

# TOTAL HRS/RESPONDENT ACTION = 5,507/685 = 8.04 hrs

Costs associated with this burden are estimated in the next section.

## 6(b). Estimating Respondent Costs

Consistent with recent ICR renewals, OPP is using labor cost estimates from Agency economists with respect to wages, benefits and overhead for all labor categories for affected industries, state government, 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.

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 the Agency's staffing costs.

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 <a href="http://www.bls.gov/oes/current/oes\_nat.htm">http://www.bls.gov/oes/current/oes\_nat.htm</a>.

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 <a href="http://www.bls.gov/oes/current/oes-stru.htm">http://www.bls.gov/oes/current/oes-stru.htm</a>).

Loaded Wage Rate: Unless stated otherwise, all benefits represent 44% of unloaded wage rates, based on benefits for all civilian non-farm workers, from <a href="http://www.bls.gov/news.release/ecec.t01.htm">http://www.bls.gov/news.release/ecec.t01.htm</a>. However, if other sectors are listed for which 44% 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. Attachment E contains worksheets providing the breakout of these costs. Costs are indexed to 2012 data.

To derive the labor rates for this ICR, Agency economists estimated the wages for the management, technical, and clerical labor categories using the methodology cited above. The respondent costs for this renewal for technical and clerical rates are estimated at \$62.58 and \$37.33 per hour, respectively. These labor rates are fully loaded and include benefits and overhead costs.

Table 2 presents respondent burden hours and costs by collection activity averaged across all four CRP response types. For example, the total per-response technical burden hours is 5.87 hrs, which is obtained by dividing the total technical burden hours (5,057 in Table 1) across all four CRP response types by the total number of responses (685). The total clerical burden hours

per response is similarly computed. These are then broken down among the various collection activities in Table 2 according to the same proportions used in the previous ICR renewal, using input from industry consultation. The total average cost of the estimated burden per respondent to comply with CRP requirements is approximately \$448.20 per response. Using the Agency's burden estimate and the fully-loaded labor rates, the Agency estimates total respondent costs to be approximately \$306,880 per year. There are no capital expenditures associated with this information collection activity.

Table 2. RESPONDENT BURDEN/COST ESTIMATES PER RESPONSE

	Burden	Hours	TO	TAL
COLLECTION ACTIVITIES	Technical, \$65.58 /hr.	Clerical, \$37.33/hr.	Burden Hours	Cost
Read instructions	0.35	0.00	0.35	\$22.02
Plan activities	0.43	0.00	0.43	\$26.92
Create information including electronic format of data	2.35	0.00	2.35	\$146.82
Process, compile, and complete written compliance				
document	2.15	1.63	3.78	\$195.45
Review submission	0.59	0.00	0.59	\$36.70
Store, submit, file, or maintain data	0.00	0.54	0.54	\$20.29
TOTAL	5.87	2.17	8.04	\$448.20

Totals may not sum due to rounding.

Table 3 presents the total annual respondent burden and cost.

Table 3. TOTAL ANNUAL RESPONDENT BURDEN/COST

Per Submission I	Estimates	Total Submissions	Annual Totals		
Burden (hrs)	Costs (\$)	Expected each year	Burden (hrs)	Cost (\$)	
8.04	448	685	5,507	306,880	

Totals may not sum due to rounding

Annual Burden: 8.04 Hours per Response x 685 Responses = 5,507 Burden Hours

Annual Cost: \$448 per Response x 685 responses = \$306,880

### 6(c). Estimating Agency Burden and Cost

The Agency burden and costs are shown in Table 4. The Agency burden hours for the entire CRP process will increase from 14.8 hours to 28.9 hours per response. Although there has been a decrease in the total number of CRP submissions to the Agency, there has been a net shift from less-burdensome to more-burdensome type responses (e.g., increased percentage of registrants electing to certify to the CRP requirements with data). As a result, there is an overall increase in the average Agency burden per response.

Table 4. ANNUAL AGENCY BURDEN BY RESPONSE TYPE

Action	No. of	Technic	al Burden	Clerica	al Burden	Aggregate	
	Respondents	Hrs Total Per		Hrs Total Per		Burden	
		Event		Event			
CRP certification without data	212	2.3	488	1	212	700	
CRP certification with data	453	40	18,120	1	453	18,573	

Exempt from CRP due to large package size (registrant meets size requirement, no action needed)	12	0	0	0	0	0
Exempt from CRP due to lack of toxicity, packaging, no residential use, lower product toxicity	8	66.5	532	0.9	7	539
TOTAL	685	n/a	19,140	n/a	672	19,812

ANNUAL AGENCY BURDEN = 19,140 (technical burden) + 672 (clerical burden) = 19,812

TOTAL HRS/AGENCY ACTION = 19,812/685 = 28.9 hrs

Table 5 presents Agency burden hours and costs by collection activity averaged across all CRP response types. The average Agency burden per CRP response is estimated at approximately 28.9 hours at a cost of \$2,230.87 per response.

Table 5. AVERAGE AGENCY BURDEN/COST ESTIMATES PER RESPONSE

	BUI	BURDEN HOURS						TOTAL		
COLLECTION ACTIVITIES	Mgmt. \$/hr		Tech. \$/hr		h. \$/hr   Clerical \$/hr		Burden Hours	Costs		
	\$	120.60	\$	78.24	\$	44.61				
Read correspondence		0		1.6		0	1.6	\$126.08		
Execute activities including data review and certifications for large size										
non-liquid pool chemicals		0		26.4		0	26.4	\$2,064.64		
Store, file, or maintain data		0		0		0.9	0.9	\$40.15		
TOTAL		0		28.0		0.9	28.9	\$2,230.87		

Table 6 presents the total annual agency burden and cost.

Table 6. TOTAL ANNUAL AGENCY BURDEN/COST

Per Submission Estimates		Total Submissions	Totals	
Burden (hrs)	Costs (\$)	Expected each year	Burden (hrs)	Cost (\$)
28.9	\$2,230	685	19,812	1,528,145

Totals may not sum due to rounding

Annual Burden = 28.9 hours per response x 685 responses = 19,812

Annual Cost = \$2,230 per response x 685 responses = \$1,528,145

# 6(d). Bottom Line Burden Hours and Cost Table

	Hours	Costs
Respondent Burden/Cost Estimates	5,507	\$306,880
Agency Burden/Cost Estimates	19,812	\$1,528,145

# 6(e). Reasons for Change in Burden

The estimated total respondent burden is expected to increase by 614 hours from 4,893 for the previous ICR renewal hours to 5,507 hours for this renewal. The increase in burden is a result of a number of factors. First, the estimated average burden hours per response increased from 4.20 hours to 8.04 hours per submission. The average burden per response is an average over all response types. Based on comments received during consultations with stakeholders, EPA increased the burden estimate per response for CRP certifications that do not require data. Second, there has been a change in the distribution of responses among the four response types. The number of responses annually is expected to decrease from 1,165 in the last ICR approval to 685. Although the estimated number of responses for the current ICR renewal is expected to be significantly less than the last ICR approval, there is a net shift from less-burdensome (CRP certifications without data) to more-burdensome (CRP certifications with data) type responses. This increase is partially due to the expiration of the exclusive use period for certain pesticide chemicals; registrants with products using these chemicals will be required to provide their own CRP test data, which will have to be reviewed for human safety/health risk concerns.

### 6(f). Burden Statement

The total annual respondent burden for the collection of information contained in this ICR is estimated to be 5,507 hours. The average "respondent" (certifier) burden for the Compliance Requirement for the CRP regulations is estimated to be 8.04 hours per submission of data necessary to support a claim that product is not subject to CRP, should be exempt from CRP, or CRP certification, including time for: reading relevant federal legislation and regulations; 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 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-2013-0493, which is available for online viewing at <a href="www.regulations.gov">www.regulations.gov</a>, 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 EPA electronically through <a href="http://www.regulations.gov">http://www.regulations.gov</a> or by mail addressed to Director, Collection Strategies Division, U.S. Environmental Protection

Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include Docket ID No. EPA-HQ-OPP-2013-0493 and OMB control number 2070-0052 in any correspondence.

### 7. <u>ATTACHMENTS</u>

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted); accessible electronically through <a href="http://www.Regulations.gov">http://www.Regulations.gov</a>. 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-2013-0493 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 <a href="http://www.gpo.gov/fdsys/pkg/USCODE-2012-title7-chap6-subchapII-sec136w.pdf">http://www.gpo.gov/fdsys/pkg/USCODE-2012-title7-chap6-subchapII-sec136w.pdf</a>

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

**Attachment C: Record of Consultations** 

**Attachment D: Pesticide Registration Notice 97-9** - Electronic Submission of Childresistant 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 <a href="http://www.epa.gov/PR\_Notices/pr97-9.html">http://www.epa.gov/PR\_Notices/pr97-9.html</a>

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

Attachment F: Calculations Regarding Small Entities that Participate in this ICR

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