

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

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Title and Number of the Information Collection

Title: Compliance Requirement for Child-Resistant Packaging

EPA ICR No. 0616.10

OMB No. 2070-0052

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

In preparing to renew this ICR, EPA published a notice in the Federal Register which provided a 60-day public notice and comment period on the draft ICR (see 75 FR 9594; March 3, 2010). EPA received no public comment 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-2009-0887.

3(c). Consultations

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.

During the preparation of this ICR renewal, EPA staff contacted the following representatives of pesticide registrants by telephone and e-mail and asked them to comment on the burden and cost estimates in the ICR:

1. John F. Wright, Product & Regulatory Associates, LLC, P. O. Box 1683, Voorhees, NJ 08043-9998, Telephone: 856-424-1528, Email: JwrightCH@comcast.net
2. Amy Plato Roberts, Technology Sciences Group, Inc., 712 5th Street, Suite A, Davis, CA 95616, Telephone (530) 757-1432, Email: ARoberts@TSGUSA.COM
3. Karen C. Cunningham, Head, Regulatory Affairs Lifecycle Management, Merial Limited, 3239 Satellite Blvd., Duluth, GA 30096, Telephone: 678-638-3138, Email: karen.cunningham@merial.com
4. Mark Jernigan, Regulatory Affairs Manager, Bio-Lab, Inc., A Chemtura Company, P.O. Box 98, Atlanta, GA, Telephone: 678-502-4149, Email: Mark.Jernigan@chemtura.com

All four of the above respondent representatives provided feedback to a questionnaire about the collection process and the burden estimates used by EPA (see Attachment C). As is the case with pesticide registrant companies, the above respondents vary widely in their experience submitting CRP certifications and/or exemptions. In particular, since CRP exemptions represent approximately only 6% of all CRP certifications, some companies may have little or no experience submitting CRP exemptions. The variability among companies included in this consultation resulted in variable responses with respect to estimates for burden hours for the different types of CRP submissions. One respondent agreed with EPA's burden estimate, and two respondents offered no comment. A fourth respondent, however, believed that the burden estimate for CRP exemptions was too low. Mr. Wright, a representative of a consulting firm whose clients include small entities, proposed that EPA's estimate of the burden hours for processing CRP exemptions was too low. EPA selected Mr. Wright to participate in this consultation in part to address the concern of the Office of Management and Budget (OMB) regarding the impact of this information collection on small entities. Mr. Wright also has experience with submitting CRP exemptions. Hence, EPA considers his comments sufficient to warrant an amendment of the burden estimate for CRP exemptions.

The new burden hours for CRP exemptions are given in Table 1 below. EPA is increasing the burden hours for CRP exemptions for large package size from 0 to 1 hour. Previously, EPA had assumed that no time was required because the CRP regulations for size exemptions require no action on the part of registrants. EPA acknowledges that registrants must read the regulations and plan activities, such as reviewing the pesticide label and marketing options, to support the justification for this exemption. EPA is also increasing the burden hours for CRP exemptions due to lack of toxicity, packaging, or no residential use from 4 to 8 hours. EPA's previous estimate of 4 hours was based on the assumption that registrants would require less time to submit a CRP exemption based on lack of toxicity, packaging, or no residential use than to submit a CRP certification with data. Mr. Wright's comments imply that it requires registrants the same amount of time to complete both of these types of CRP submissions. His comments are consistent with informal consultations OPP staff has had with registrants and applicants seeking clarification with regard to their CRP submissions. EPA believes that such informal consultations are beneficial to both EPA and the applicants. By encouraging communication and exchange of ideas, such discussions can help in the development of clearer expectations of what must be submitted and of industry burden.

With respect to the format for CRP submissions, three of the four respondent representatives indicated that the format might be clearer than it currently is if a structured form were provided. Currently, there are no forms associated with this ICR. EPA believes this provides registrants with the greatest amount of flexibility to meet the requirements of the Information Collection. Guidance for CRP submissions is available on-line (see attachments), or may be obtained by contacting EPA directly.

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 (www.epa.gov/opprd001/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, 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 following North American Industrial Classification System (NAICS) codes account for over 80% of respondents:

<u>NAICS 2-Digit Code</u>	<u>Category</u>	<u>Description</u>
32	Chemical Manufacturing	manufacturers of chemicals used in pesticide products
42	Wholesale Trade	wholesale merchandisers of pesticide products
56	Administrative and Support and Waste Management and Remediation Services	establishments performing routine support activities related to pest management.

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.

Approximately 94 percent 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. Of those registrants who do certify, approximately 27% may also be required 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. Although EPA is working to allow electronic submission of registration packages, they are currently submitted by mail. 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, comprising about 25 percent of all responses and nearly 67 percent of the total estimated burden.

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.

During the last ICR approval process, OMB was concerned about the impact of this information collection on small entities. The ICR was conditionally cleared by OMB with the request that EPA provide the number of small entities that are respondents. In order to respond to this request from OMB, EPA used information on company revenue and employment from the Dun and Bradstreet database. The Dun and Bradstreet database is a comprehensive source of financial information on entities, including firm locations, sales, number of employees, and primary business classifications under North American Industrial Classification System code (NAICS).

To estimate the number of small entities that participate under this ICR, EPA assumed the majority of respondents are individual companies with a NAICS code 325320 (Pesticide and Other Agricultural Chemical Manufacturing). Currently, the number of companies in the Dun and Bradstreet 2010 database using this code is 892. EPA was able to determine the size of 882 of these individual companies. The parent company of the 10 remaining un-sized companies did not report enough sales or employee data to allow a proper analysis based on the SBA size classifications. Of the sized firms, 26.3% (232) are large firms or are subsidiaries of large firms, and 73.7% (650) are small firms or subsidiaries of small firms. Currently, 1733 companies are listed in EPA’s registration tracking database discussed in section 5(b). Assuming that the distribution of large and small firms is independent of NAICS code, EPA estimates 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.

EPA also estimated the impact of this ICR on small entities by calculating the annual company burden as a percentage of average annual revenue. Child Resistant Packaging applications were submitted to the Agency by 49 parent firms between 2006 and 2009. EPA determined that 27 of the submitting companies were large and 21 were small (see Attachment F for the list of small entities), based on information from the Dun and Bradstreet 2009 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 approximately \$224. Assuming that CRP submissions are evenly distributed across small and large companies, an average firm would submit approximately 23 CRP applications per year, assuming 50 companies are responsible for the 1,165 CRP submissions in a given year. This would result in an average annual company burden of \$5,152, or 0.02% of small firm’s annual revenue, on average.

	Total Number of Firms	Total Revenue (\$)	Total Employee Size	Average Revenue¹ (\$)	Average Employment¹
Small Firms	21	414,668,000	1,737	23,037,111	73
Large Firms	27	312,730,280,167	598,975	12,028,087,699	23,031
All Firms	48	313,144,948,167	600,712	7,116,930,640	13,639

¹ 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 labeled product use or 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 1,165 responses to this information collection activity annually during this renewal ICR. The number of responses is based on the number of products in FY2007, FY2008, and FY2009 with Child-Resistant Packaging (CRP) requirements. During this three year period, approximately 703 CRP applications were submitted annually. The expected increase in the number of CRP submissions from 703 to 1,165 is largely associated with the implementation of the EPA's Registration Review program. Through the Registration Review program, which was mandated by the Food Quality Protection Act, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can still be used safely.

EPA estimates that the average burden associated with this information collection activity is approximately 4.2 hours per response.¹ 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 3.0 hours of technical time and 1.2 of hours clerical time, which is broken down as follows:

- 24 technical minutes 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;
- 72 technical minutes to create/prepare the information;
- 66 technical minutes to review submission for accuracy and appropriateness (process, compile, complete document);
- 54 clerical minutes to format submission and prepare information;
- 18 technical minutes to review and sign the appropriate documents; and,

¹ Based on Table 1, the avg. technical burden across all response types is approx. 3.0 hrs. per response (3,496 ÷ 1,165) and the avg. clerical burden across all response types is approx. 1.2 hrs. per response (1,398 ÷ 1,165). For the purposes of estimating respondent burden and cost (*see* Table 2), EPA assumes that the average burden is 4.2 hrs. per response (3.0 technical hrs. + 1.2 clerical hrs.).

- 18 clerical minutes to mail the submission, file the respondent copy and CRP documentation

<u>Type of Response</u>	<u>Number of Responses</u>	<u>Percent of Total</u>
CRP certification without data	798	68
CRP certification with data	296	25
Exempt – large package size	34	3
Exempt – lack of toxicity, packaging, no residential use, lower product toxicity	37	3

Respondents submitting CRP certifications without data require 1 hour 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 one 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. These burden estimates by response type are summarized in Table 1.

The total estimated respondent burden to comply with this information collection activity is 4,893 burden hours/year (4.2 hours per respondent x 1,165 respondents) at a cost of \$261,237. This cost estimate is illustrated in Table 2.

Table 1. ANNUAL RESPONDENT BURDEN BY RESPONSE TYPE

Type of Response	No. of Responses	Technical Burden		Clerical Burden		Aggregate Burden
		Hours Per Event	Total	Hours Per Event	Total	
CRP certification	798	1.0	798	0.5	399	1,197
CRP certification with data	296	8.0	2,368	3.0	888	3,256

Exempt from CRP due to large package size	34	1.0	34	0.0	0	34
Exempt from CRP due to lack of toxicity, packaging, no residential use, lower product toxicity	37	8.0	296	3.0	111	407
TOTAL	1,165	NA	3,496	NA	1,398	4,893

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 http://www.bls.gov/oes/current/oes_nat.htm.

Sectors: The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector’s wage rate table. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm).

Loaded Wage Rate: Unless stated otherwise, all benefits represent 43% of unloaded wage rates, based on benefits for all civilian non-farm workers, from <http://www.bls.gov/news.release/ecec.t01.htm>. However, if other sectors are listed for which 43% is not applicable; the applicable percentage will be stated.

Fully Loaded Wage Rate: We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs. Attachments F and F.1 contain worksheets providing the breakout of these costs. Costs are indexed to 2008 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 managerial, technical and clerical rates are estimated at \$109.82, \$60.39 and \$35.89 per hour, respectively. These labor rates are fully loaded and

include benefits and overhead costs.

Table 2 presents respondent burden hours and cost by collection activity averaged across all four CRP response types. The total average cost of the estimated burden per respondent to comply with CRP requirements is approximately \$224 per response. Using the Agency’s burden estimate and the fully-loaded labor rates, the Agency estimates total applicant costs to be approximately \$261,237 per year. There are no capital expenditures associated with this information collection activity.

Table 2. ANNUAL RESPONDENT BURDEN/COST ESTIMATES

COLLECTION ACTIVITIES	Burden Hours		TOTAL	
	Tech. \$60.39/hr.	Clerical \$35.89/hr.	Burden Hours	Cost
Read instructions	0.18	0.00	0.18	\$10.57
Plan activities	0.22	0.00	0.22	\$13.29
Create information including electronic format of data	1.20	0.00	1.20	\$72.47
Process, compile, and complete written compliance document	1.10	0.90	1.90	\$98.73
Review submission	0.30	0.00	0.40	\$18.12
Store, submit, file, or maintain data	0.00	0.30	0.30	\$10.77
TOTAL	3.00	1.20	4.20	\$223.94

Totals may not sum due to rounding.

ANNUAL BURDEN: 4.2 Hours Per Response x 1,165 Responses = 4,893 Burden Hours

ANNUAL COSTS:

(a) **Technical:** 3.0 hours x \$60.39 x 1,165 responses = \$211,063.05

(b) **Clerical:** 1.2 hours x \$35.89 x 1,165 responses = \$ 50,174.22

Total = \$261,237.27

6(c). Estimating Agency Burden and Cost

The Agency burden hours for the entire CRP process will decrease from 18.9 hours to 14.8 hours per response. There has been an increase in the number of CRP submissions to the Agency. However, the majority of new submissions are for CRP certification without data, which is the least resource intensive activity for EPA. As a result, there is an overall decrease in the average Agency burden per response.

Annual burden to the Agency is estimated at 17,263 burden hours at a cost of \$1,202,339.

Despite the larger increase in applications for CRP Certification without data, the main portion of the burden hours is still expected to result from the evaluation of those CRP Certifications submitted with data related to human safety/health risk concerns, and assessing some of the more complex options for compliance (e.g. requesting an exemption).

Table 3. ANNUAL AGENCY BURDEN BY RESPONSE TYPE

Action	No. of Respondents	Technical Burden		Clerical Burden		Aggregate Burden
		Hrs Per Event	Total	Hrs Per Event	Total	
CRP certification without data	798	2.3	1,835	1.0	798	2,633
CRP certification with data	296	40.0	11,840	1.0	296	12,136
Exempt from CRP due to large package size (registrant meets size requirement, no action needed)	34	0.0	0.0	0.0	0.0	0.0
Exempt from CRP due to lack of toxicity, packaging, no residential use, lower product toxicity	37	66.5	2,461	0.9	33	2,494
TOTAL	1,165	n/a	16,136	n/a	1,127	17,263

AGENCY BURDEN = 16,136 (technical burden) + 1,127 (clerical burden) = 17,263

TOTAL HRS/AGENCY ACTION = 17,263 ÷ 1,165 = 14.8 hrs

Table 4 presents Agency burden hours and costs by collection activity averaged across all CRP response types. The average cost to the agency of receiving a CRP submission is 14.8 hours and \$1,032.

Table 4. ANNUAL AGENCY BURDEN/COST ESTIMATES

COLLECTION ACTIVITIES	BURDEN HOURS (per respondent)			TOTAL	
	Mgmt. \$107.56/hr	Tech. \$71.58/hr	Clerical \$41.21/hr.	Burden Hours	Costs
Read correspondence	0.00	0.8	0.0	0.8	\$57.26
Execute activities including data review and certifications for large size non-liquid pool chemicals	0.00	13.1	0.0	13.1	\$937.70.
Store, file, or maintain data	0.00	0.0	0.9	0.9	\$37.09
TOTAL	0.00	13.9	0.9	14.8	\$1,032.05

Totals may not sum due to rounding.

ANNUAL BURDEN: The average Agency burden per CRP response is estimated at approximately 14.8 hours, costing \$1,032 per response ($\$1,202,339 \div 1,165$).

ANNUAL COSTS:

(a) Technical: 13.9 hours x \$71.58 x 1,165 responses = \$1,159,130.73
 (b) Clerical: 0.9 hours x \$41.21 x 1,165 responses = \$ 43,208.69
 Total = \$1,202,339.42

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

	Hours	Costs
Respondent Burden/Cost Estimates	4,893	\$261,237
Agency Burden/Cost Estimates	17,263	\$1,202,339

6(e). Reasons for Change In Burden

The number of responses has increased from 703 in the last ICR approval to 1,165. The increase in the expected number of responses is driven primarily by the expected influx of CRP submissions associated with the implementation of the Registration Review program. In addition, the exclusive use period for certain pesticide chemicals is expiring. Registrants with products using these chemicals will now be required to provide their own CRP test data, which will have to be reviewed for human safety/health risk concerns.

The average total burden hours per respondent decreased from 4.94 hours to 4.2 hours per submission. While the average burden estimate for CRP exemptions has increased, the burden estimate remained the same for CRP certifications and certifications with data, which together represent 94% of all submissions. Furthermore, the distribution of responses among the four response types has changed, resulting in a significant net shift from more-burdensome to less-burdensome type responses. In particular, EPA expects to receive a larger percentage of CRP certifications without data during this ICR renewal than during the previous ICR. The estimated annual burden under the last ICR approval was 3,473 hours. Under this renewal ICR, the annual burden is estimated to be 4,893 hours. This increase is due to the increase in the expected number of responses. The estimated burden increase represents an adjustment.

6(f). Burden Statement

The total annual respondent burden for the collection of information contained in this

ICR is estimated to be 4,893 hours. The average "respondent" (certifier) burden for the Compliance Requirement for the CRP regulations is estimated to be **4.2 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; prepare submission or CRP certification; and recordkeeping regarding the CRP certification or submission.

As defined by the PRA and 5 CFR 1320.3(b), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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

To facilitate public comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public for this ICR under Docket ID No. EPA-HQ-OPP-2009-0887. All documents in the docket are listed in the docket index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID No. EPA-HQ-OPP-2009-0887 and OMB Control No. 2070-0052 in any correspondence.

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 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-2009-0887 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.epa.gov/opprd001/crp/>

Attachment B: **40 CFR Part 157 - PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES** – also available at http://www.access.gpo.gov/nara/cfr/waisidx_03/40cfr157_03.html

Attachment C: **Record of Consultations Between the U.S. Environmental Protection Agency and Respondents to the Information Collection Request: “Compliance Requirement for Child-Resistant Packaging”**

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*** – also available at http://www.epa.gov/opppmsd1/PR_Notices/pr97-9.html

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

Attachment F: **Classification and List of Small Entities**

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

