February 17, 2021

SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST (ICR)

1. Identification of the Information Collection

1(a). Title of the Information Collection

Title: Tolerance Petitions for Pesticides on Food or Feed Crops and New Food Use Inert Ingredients

EPA ICR No. 0597.13 OMB Control No. 2070-0024

Docket ID No. **EPA-HQ-OPP-2015-0715**

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

1(b). Short Characterization/Abstract

The use of pesticides to increase crop production often results in pesticide residues in or on the crop. To protect public health from unsafe pesticide residues, the Environmental Protection agency (EPA) sets limits on the nature and level of residues permitted pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) (See Attachment A). A pesticide may not be used on food or feed crops unless the agency has established a tolerance (maximum residue limit) for the pesticide residues on that crop, or established an exemption from the requirement to have a tolerance.

Under the law, EPA is responsible for ensuring that the maximum residue levels likely to be found in or on food/feed are safe for human consumption through a careful review and evaluation of residue chemistry and toxicology data. In addition, EPA must ensure that adequate enforcement of the tolerance can be achieved through the testing of submitted analytical methods. If the data are adequate for EPA to determine that there is a reasonable certainty that no harm will result from aggregate exposure, the agency will establish the tolerance or grant an exemption from the requirement of a tolerance.

Applicants may petition the EPA for a variety of tolerance actions, the timeframes of which are established by Congress. This ICR describes the processes and burden hours associated with the establishment of new tolerances for pesticides. These approaches can be used to establish tolerances or the explicit exemption from the requirements of a tolerance for a pesticide on raw and processed foods. The vast majority of these actions are taken in response to petitions from registrants (pesticide manufacturers) for the establishment of new tolerances for an existing pesticide ingredient. The agency may also initiate tolerance actions.

Pesticide tolerances are needed in order to support the interstate movement of pesticide-treated foods in commerce. The Food and Drug Administration (FDA) has lead responsibility in the U.S. for tolerance enforcement. Food commodities found to contain pesticide residues in excess of established tolerances are considered adulterated, and are subject to seizure by FDA, and may result in civil penalties.

2. Need For and Use of the Collection

2(a). Need/Authority for the Collection

The tolerances for pesticide residues in food or feed are set primarily under the authority of section 408 of FFDCA, as amended. The agency takes these tolerance actions either on its own initiative pursuant to FFDCA §408(e) or in response to a petition filed pursuant to FFDCA §408(d). The regulations covering tolerances are contained in Title 40 of the Code of Federal Regulations (CFR) Part 180. Actual listings of individual tolerances by chemical are also found in Part 180 (See Attachment B).

Under FFDCA §408(d), any person may file a petition with EPA, proposing the issuance of a regulation establishing, modifying, or revoking (a) a tolerance for a pesticide chemical residue in or on food, or (b) an exemption from the requirement to have a tolerance for such residue. The agency publishes a notice of filing for such petitions in order to provide an opportunity for public comment on the request, and then either issues a final regulation, or a notice denying the petitioner's request. FFDCA §408(d)(4) directs the agency to issue a final regulation establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance, or issue an order denying the petition.

Under FFDCA §408(e), at any time the agency may issue a regulation establishing, modifying, suspending, or revoking (a) a tolerance for a pesticide chemical residue in or on food, or (b) an exemption from the requirement to have a tolerance for such residue. When initiating such actions, FFDCA §408(e)(2) requires the agency to issue a notice of proposed rulemaking to provide an opportunity for public comment.

FQPA requires that tolerances be set at a level to ensure that there is "a reasonable certainty that no harm will result from aggregate exposure." Among other things, FQPA requires EPA to consider a number of factors when setting such tolerances or registering pesticide products, including:

(1) special protection for infants and children;

(2) aggregate exposure and risk from foods and other known sources, such as drinking water and household pesticide use;

(3) consideration of common mechanisms of toxicity (some chemicals have different molecular structures but cause deleterious effects in the same manner); and,

(4) consideration of neurotoxicity, developmental, reproductive and cancer health effects.

The collection of information covered by this ICR is needed to ensure that the statutory requirements related to tolerances can be met by respondents and EPA. Food or feed commodities found to contain residues of a pesticide without or in excess of established tolerances are considered adulterated, and are subject to seizure by FDA, and may result in civil penalties.

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

The FQPA directs the agency to consider aggregate exposures from dietary and non-occupational sources when assessing the risks of a chemical and setting tolerances. In addition to dietary exposure, such sources as drinking water and residential lawn care use need to be considered. EPA must make the statutory determination that the resulting pesticide residues in food or feed will result in a reasonable certainty of no harmful effects of human health from aggregate exposure through dietary, non-occupational, and drinking water routes of exposure before establishing the tolerance. EPA applies the FQPA standard to all tolerances for newly-registered chemicals and food uses.

Section 408 of FFDCA requires petitioners submit "an information summary of the petition and of the data, information and arguments submitted or cited in support of the petition." FQPA requires EPA to consider additional information in order to make the necessary regulatory decisions. To allow for the most efficient processing and review of tolerance petitions, the agency provides a description of the types of information it considers helpful in the appendices to Pesticide Registration (PR) Notice No. 97-1 (See Attachment C).[1] EPA encourages petitioners to submit supplemental information with their petitions to help EPA determine whether there is a reasonable certainty that no harm will result from aggregate exposure.

EPA uses the data to make decisions about the tolerance petitions. The agency's risk managers review, among other things, the regulatory aspects of each petition and coordinate scientific review of the supporting data. The agency residue chemists and toxicologists review all the applicable data and prepare a risk assessment necessary to evaluate if the tolerance can be established. As a result of these reviews, EPA completes the statutory evaluation of the data and, based on the assessment, concludes that the resulting pesticide residues in food or feed will not cause unreasonable adverse dietary effects on human health.

3. Non Duplication, Consultations, and Other Collection Criteria

3(a). Non duplication

[1] PR Notice 97-1 applies to most applicants with registration applications, non-crop-destruct experimental use permit applications, and tolerance or tolerance exemption petitions pending within the Agency. It also applies to most future applicants seeking new or amended pesticide registrations and all actions involving synthetic chemicals, antimicrobial, biochemical and microbial pesticides.

There is no duplication of information because there are no EPA offices or other government agencies that have the data necessary to evaluate tolerance petitions. The requirements for this ICR represent a unique non-redundant information requirement.

To avoid potential overlap between the requirement of developing data in support of a tolerance petition and the development of data required for the registration of a pesticide under FIFRA, the EPA allows the use of data required to support a tolerance petition that are already archived in EPA records for use as part of a FIFRA registration of a pesticide to be used in a like manner and in the same use pattern.

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

EPA published a notice in the Federal Register announcing a 60-day public notice and comment period on the draft ICR on August 17, 2020 (85 FR 50022). EPA received no public comments in response to this notice, which is available in the docket for this ICR and can be accessed at http://www.regulations.gov using the docket identifier EPA-HQ-OPP-2015-0715.

3(c). Consultations

Under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an original or renewal ICR to OMB for review and approval. During the development of this renewal ICR, EPA staff contacted three stakeholders and asked them for their assessment of the regulatory burden estimates expressed by the Agency in this ICR. One stakeholder indicated that EPA's overall burden estimate is similar to theirs, but that they would likely have a greater amount of technical hours. Since the stakeholder agreed that the overall burden hours were similar to theirs, no action by EPA to update the burden estimate is planned. A summary of the consultations has been provided as part of the supporting statement (Attachment N).

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

3(d). Effects of Less Frequent Collection

Not applicable. This activity is conducted only once per "event," so a less frequent collection is not possible.

3(e). General Guidelines

Due to the statutory mandate for the permanent retention of supporting chemistry and toxicological data related to pesticides, the data included in petitions must be maintained for the life of the pesticide. This mandate exceeds the Paperwork Reduction Act of 1995 (PRA) guideline that records be retained for no more than three years.

As of September 1, 2015 registrants have a fully electronic submission option called the Pesticide Submission Portal (the Portal). The Portal uses a secure database to process tolerance

petition requests. However, registrants still have the option of using the previous submission methods- by paper, CD, or DVD. As this option is new to the agency, there is currently not enough data to evaluate it through this ICR. During the next renewal cycle for this ICR we anticipate having burden information for respondents to determine the effects of the Portal on tolerance petition submissions.

By offering this electronic submission option, the agency is keeping with the Executive Order on "Reducing Reporting and Paperwork Burdens" and other related policy and guidance. The agency continues the process of improving options for electronic submission of studies as well as other elements of applications and petitions. This includes efforts to enhance information technology approaches to protect FIFRA Confidential Business Information submitted over the Internet. Please see, “Assembly of Electronic Packages and Discs” (Attachment D).

Electronic submissions: OMB regulations require agencies to provide a statement indicating whether the proposed collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and an explanation of the decision (5 CFR 1320.5(a)(iii)(E)). As discussed previously, OPP now offers a fully electronic submission option.

In the past, registrants would be required to submit three paper copies of study data to EPA; however, registrants now submit one paper copy if they submit the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc. Extensive guidance regarding available electronic submission option is available to registrants via the OPP Internet site at http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications.

During the years covered in this ICR renewal, companies most often use two methods for assembling the e-submission discs for electronic-Submission (or "e-Submissions). In both methods, the files to be submitted along with an XML data file containing information about the files and the submission itself are “zipped” into a single file and placed on a disc (CD/DVD) for submission to the EPA. The first is a newer method introducing the use of a “builder” application. The second, introduced in July 2008, requires the manual editing of the XML file. The XML method of information exchange from industry to EPA is based on a harmonized XML schema used by Canada's PMRA, which OPP has adapted. This harmonization assures industry that a documentation package submitted to one participating regulatory agency can also be submitted to the other participating agency, increasing standardization and decreasing the burden on industry. Additional information about both e-submission methods can be accessed at: http://www2.epa.gov/pesticide-registration/assembly-electronic-packages-and-discs.

EPA encourages electronic submissions for the following regulatory actions:

- New pesticide active ingredients.
- New pesticide products containing already-registered pesticide active ingredients.
- Amendments to registered pesticide products.
- Experimental use permits.
- Petitions for food tolerance.

- Distributor products.
- Endocrine Disruptor Screening Program (EDSP) Orders.

Overall, EPA is investigating opportunities for technological improvements which focus on information collection using fully electronic tools. The ability to electronically submit information required for registration reduces the burden of sending, receiving, and archiving paper submissions, and eliminates the need for multiple data entries across forms. One of OPP's priority areas in developing such electronic tools is related to electronic submission of data and labels. Some of the tools under this initiative are the electronic Confidential Statement of Product Specifications (CSPS) form (to be used in lieu of the Confidential Statement of Formula or CSF) the SmartLabel, and the now functional web-based portal.

The development of the Portal is a critical step in the realization of EPA's long-term vision for secure data exchange between registrants and the agency. Whereas registration applications typically require an ink signature, the Portal uses EPA's Central Data Exchange (CDX) to allow applicants to electronically sign and securely submit the required information**.** The use of CDX is expected to save registrants' and the agency's time and resources by simplifying data submissions, receipt confirmation, information access and reporting.

3(f). Confidentiality

Trade secret or confidential business information (CBI) is frequently submitted to the EPA in this program because submissions usually include the manufacturing process, product formulation, and supporting data. When such information is provided to the agency, the information is protected from disclosure under FIFRA Section 10. CBI data submitted to the EPA is handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual.

3(g). Sensitive Questions

Not applicable. 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 include anyone who files a petition asking the agency to take a specific tolerance action. While any entity can file a petition with the agency, such petitions typically come from those businesses engaged in the manufacturing of pesticides and the Interregional Research Project No.4 (IR-4) (see Attachment G). Thus, the agency only calculates the burden for these two groups.

Although it is impossible to identify all the North American Industrial Classification System (NAICS) codes for all of the potential respondents, the NAICS codes for the most

frequent type of respondent are:

Respondent Category	NAICS code	Examples of potentially affected entities
Pesticide and other agricultural chemical manufacturing	325320	Individuals or entities engaged in activities related to the registration of a pesticide product.
Management, Scientific, and Technical Consulting Services	541600	Establishments primarily engaged in administrative management and general management consulting services.

4(b). Information Requested in this Collection

(i) Data Items, Including Record Keeping Requirements

In addition to a cover letter and fee, a tolerance petition must include the following nine parts:

Chemical identity	The name, chemical identity, and composition of the pesticide chemical. If the pesticide chemical is an ingredient of a pesticide, the complete quantitative formula of the resulting pesticide product should be submitted. The submission of this information does not restrict the application of any tolerance or exemption granted to the specific formula(s) submitted.
Chemical use	The amount, frequency, and timing of application of the pesticide chemical.
Safety reports	Include reports of investigations made with respect to the safety of the pesticide chemical. These reports should include, when necessary, detailed data derived from appropriate animal or other biological experiments in which the methods used and the results obtained are clearly set forth.
Residue test results	The results of tests on the amount of residue remaining, including description of the analytical method used. (See 40 CFR 180.34 for further information about residue tests.)
Residue removal	Practicable methods for removing residue that exceeds any proposed tolerance.
Proposed tolerance	Proposed tolerances for the pesticidal chemical if specific tolerances are being proposed.
Grounds for petition	Reasonable grounds in support of the petition.

Supplemental information	Analysis of factors relevant to the provisions of FQPA
Summary	An informative summary of the petition or application, including a summary of the supporting data, information, accompanying rationales, and a statement providing permission to publish such summary. This summary should indicate how approval of the petition will meet the statutory determination required of "reasonable certainty of no harm."

There are no forms associated with this information collection. The data compiled should be submitted as separate sections, suitably identified. If data have already been submitted with an earlier application, the petitioner may incorporate it by reference in the present petition.

(ii) Respondent Activities

In order for a tolerance to be established for a pesticide product, a respondent (petitioner) must do the following:

Review regulations	Read applicable FFDCA provisions and related tolerance regulations;
Prepare information	Prepare supplemental information to aid agency decision-making concerning a tolerance petition, as encouraged by the agency and outlined in Pesticide Registration Notice 97-1. If necessary, this involves: • conducting additional toxicological or residue chemistry studies • developing analytical methods
Prepare correspondence	Generate petition correspondence, including preparing an informative summary to be published in the Federal Register;
Review agency comment	If applicable, read any agency notice of petition deficiency;
Respond to agency comment	Submit supplemental information or petition, or request that petition be filed as submitted; and
Maintain records	Store, file and maintain the information submitted.

5. The Information Collected - Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

Upon receipt of a tolerance petition, EPA performs the following activities:

Log Receipt	Log petition and associated fee.
Review petition	Screen petition, fee, and supporting data for completeness and acceptability; resolve any deficiencies with petitioner.
Prepare Federal Register notice	Upon acceptance, publish notice of filing in Federal Register.
Review data	Review supporting residue chemistry, toxicology data and other assessments received.
Test analytical methods	Test proposed analytical methods in EPA laboratories, if they are new or modified.
Integrate review	Integrate data reviews and determine adequacy; resolve any deficiencies with petitioner, make registration decision.
Prepare decision document	Prepare exposure and risk assessments on requested tolerance, prepare decision document, Federal Register Notice with rule establishing the tolerance(s) or exemption(s).
Maintain records	Record all actions and decisions in official records.

5(b). Collection Methodology and Management

Specific studies submitted as part of a petition are catalogued and archived as they are received. When the agency review is complete, the remaining portions of the petition record, including correspondence subsequent to filing and all reviews, notices, and other materials created by EPA in the course of its review, are catalogued and archived. All petition materials are retained permanently.

5(c). Small Entity Flexibility

At times, small entities seek a tolerance or an exemption from the requirement of a tolerance for pesticide residues resulting from registered uses. Tolerances are PRIA actions with fees established by Congress with the provision of fee waivers and fee exemptions in certain circumstances. The EPA's website is a resource for the public on fees and the process for seeking a waiver or exemption of fees: http://www2.epa.gov/pria-fees/pria-fee-waivers-small-businesses.

5(d). Collection Schedule

Not applicable. This is not a scheduled collection. A petition is required only once for each raw or processed commodity on which the pesticide is used.

6. Estimating the Burden and Cost of the Collection

6(a). Estimating Respondent Burden

The current ICR renewal estimates that an average of 165 tolerance petitions will be submitted to the Agency each year for the next three years. The Agency estimates that an average of 139 of the 165 tolerance petitions will be submitted directly by registrants, and 26 will be submitted by IR-4. This estimate is based on the average number of tolerance petitions received by the Agency in the past three years (2012, 2013, and 2014), and is an increase from the estimate in the previous ICR of 28 tolerance petitions.

The Agency estimates that the average paperwork burden associated with the submission of a single tolerance petition is 1,726 hours for petitioners and 1,739 hours for those submitted through IR-4. The additional 13 hours required to process each IR-4 petition is due to a fee waiver incentive to submit label amendments with the registration package and the tolerance petitions. The Pesticide Registration Improvement Act (PRIA) of 2003, last renewed under PRIA 3, established registration service fees for pesticide registration actions. (See Attachments G and H.) On March 6, 2008, the President signed a technical correction to PRIA to exempt fees for certain registration applications associated with IR-4 tolerance petitions. This correction became effective retroactively on October 1, 2007. To qualify for the IR-4 provisions for this fee exemption, EPA requires that the registration application is solely associated with a tolerance petition submitted in connection with IR-4, and the action must be considered to be in the public interest. A document that describes the process is attached and more information can be accessed at the following link: http://www2.epa.gov/pria-fees/guidance-ir-4-exemptions. In addition, under PRIA 3, the agency must determine that the exemption is in the public interest. In February 2013, the agency issued the policy document entitled "Factors for IR-4 Public Interest Finding" (Attachment K) which lists the criteria under which an application will be presumed to be in the public interest.

Assuming that the Agency will receive an average of 165 tolerance petitions each year for the next 3 years, the Agency estimates that the overall annual paperwork burden for all petitioners will be 285,128 hours. This estimate is 48,328 hours more than the previous estimate, resulting from an increase in the estimated number of tolerance petitions that the Agency anticipates receiving in the next three years.

Section 408 of FFDCA requires petitioners submit an information summary of the petition and of the data, information and arguments submitted or cited in support of the petition. FQPA requires EPA to consider additional information in order to make the necessary regulatory decisions. To allow for the most efficient processing and review of tolerance petitions, the Agency provided a description of the types of information that EPA considers helpful in the appendices to Pesticide Registration (PR) Notice No. 97-1.

Two types of respondent burden are considered in this analysis: administrative burden and technical burden. The respondents' administrative burden is defined as the time spent to prepare and submit a petition to the Agency. This burden includes the time spent working with the Agency throughout the petition process, gathering data and supplemental information (such as safety reports, residue test data, residue removal data), drafting the grounds for the petition,

reviewing and submitting the petition. Technical burden includes the labor needed to actually derive the test data which involves designing the test, performing it, compiling test data and summarizing the results. Only burden related to the documentation of the test results, complying with good laboratory standards in conducting the tests, and storing testing information in files are included in the technical burden estimates for this ICR.

The Agency's estimate of petitioner burden was largely developed from the previous Tolerance Petition ICR, using information from the regulated community. The information was supplemented with additional feedback from IR-4 and other tolerance petitioners. The estimate also draws from the expertise of the Agency's lead divisions for the tolerance petition review process (AD, BPPD, and RD), and their understanding of changing programmatic requirements that may affect tolerance petitioners' burden. The Agency will consider information received through public comment to further refine estimates of petitioner burden.

6(b) Estimating Respondent Cost

Consistent with recent ICR renewals, OPP has used labor cost estimates from Agency economists with respect to wages, benefits and overhead for all labor categories for affected industries. The goal is to continue to use a transparent, consistent methodology and current, publicly-available data, to provide more accurate estimates and allow easy replication of the estimates.

Methodology: The methodology uses data on each sector and labor type for an *Unloaded wage rate* (hourly wage rate), and calculates the *Loaded wage rate* (unloaded wage rate + benefits), and the *Fully loaded wage rate* (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This renewal uses 2015 base data.

Unloaded Wage Rate: Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm.

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

Loaded Wage Rate: Unless stated otherwise, all benefits represent 46.3% 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 46.3% 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. A copy of the formula work sheets used to re-estimate the labor rates and to derive the fully loaded rates and overhead costs for all respondents (registrants and IR-4) and the Agency for this ICR renewal are listed in Attachments I, J, and K respectively.

Table 1. PETITIONER BURDEN/COST ESTIMATES PER RESPONSE

ACTIVITIES	HOURS and RATES				COSTS (per petition)
	Mgmt. $167.90 /hr	Tech. $87.34/ hr	Cler. $49.90 /hr	Total Hours	Total Costs
Review FFDCA regulations CFR citation; PRN 97-1	25	48	24	97	$9,587
Conduct Field Trial	252	1,080	25	1,357	$137,886
Prepare Petition	42	30	116	188	$15,460
Read Notice of any petition deficiency	1	1	1	3	$305
Prepare response	2	44	12	58	$4,778
Maintain information	1	8	14	23	$1,565
TOTAL BURDEN	**323**	**1,211**	**192**	**1,726**	**$169,581.24**

Data Source: U.S. Department of Labor, Bureau of Labor Statistics, May, 2014. (See cost worksheet Attachment F).

Table 2. IR-4 BURDEN/COST ESTIMATES PER PETITION PER RESPONSE

ACTIVITIES	HOURS and RATES				COSTS (per petition)
	Mgmt. $150.08 /hr	Tech. $75.75/ hr	Cler. $41.52 /hr	Total Hours	Total Costs
Review FFDCA regulations CFR citation; PRN 97-1	25	48	24	97	$8,384
Conduct Field Trial	252	1,080	25	1,357	$120,668
Prepare Petition	55	30	116	201	$15,343
Read Notice of any petition deficiency	1	1	1	3	$267
Prepare response	2	44	12	58	$4,131
Maintain information	1	8	14	23	$1,337
TOTAL BURDEN	**336**	**1,211**	**192**	**1,739**	**$150,131.97**

Data Source: U.S. Department of Labor, Bureau of Labor Statistics, May, 2014. (See cost worksheet Attachment G).

Labor rates are fully loaded and include benefits and overhead costs applied using procedures outlined in the Agency's 2002 publication "EPA Air Pollution Control Cost Manual". The managerial labor rate is based on the Standard Occupational Code (SOC) for management occupations; the technical labor rate is based on the SOC for life, physical and social science occupations; and the clerical labor rate is based on the SOC for office and administrative support occupations. Data is from the U.S. Department of Labor, Bureau of Labor Statistics.

For tolerance petitioners, the value of labor per hour for management, technical, and clerical is $167.90, $87.34 and $49.90 respectively. Labor rates are by occupation for the Research and Development in the Physical, Engineering, and Life Sciences industry (NAICS 541710). Using the Agency's burden estimate and fully-loaded labor rates, the Agency estimates petitioner costs to be approximately $169,581 per response. The overall annual cost to petitioners associated with this information collection, based on an estimate of 139 petitions per year, is estimated to be $23,571,792.36.

For IR-4, the value of labor per hour for management, technical, and clerical is $150.08, $75.75, and $41.52, respectively. Labor rates are by occupation for Management, Scientific, and Technical Consulting Services industry[2] (NAICS 541600). Using the Agency's burden estimate and fully-loaded labor rates, the Agency estimates IR-4 costs to be approximately $150,131.97 per response. The overall annual cost to petitioners associated with this information collection, based on an estimate of 26 petitions per year, is estimated to be $3,903,431.22.

The overall annual cost to respondents associated with this information collection, including petitioners and IR-4, based on an average total estimate of 165 petitions per year, is estimated to be $27,475,223.58.

ANNUAL COSTS:

Industry		
Management:	323 hours * $167.90 per hour * 139 tolerance petitions =	$7,538,206.30
Technical:	1,211 hours * $87.34 per hour * 139 tolerance petitions =	$14,701,854.86
Clerical:	192 hours * $49.90 per hour * 139 tolerance petitions =	$1,331,731.20
	Industry TOTAL:	$23,571,792.36
IR-4		
Management:	336 hours * $150.08 per hour * 26 tolerance petitions =	$1,311,098.88
Technical:	1,211 hours * $75.75 per hour * 26 tolerance petitions =	$2,385,064.50
Clerical:	192 hours * $41.52 per hour * 26 tolerance petitions =	$207,267.84
	IR-4 TOTAL:	$3,903,431.22
	GRAND TOTAL:	$27,475,223.58

These labor burden estimates represent average time and costs. Some tolerance petitions will require less effort and more complicated petitions will require more. The analysis assumes that one respondent will generate the data for a given petition. If a consortium takes responsibility for the petition, the burden and cost will be distributed across members of the consortium.

[2] IR-4 industry classification based on National Economic Impact, Center for Economic Analysis Michigan State University, May 25, 2007, http://ir4.rutgers.edu/Other/IR4EconomicImpact.pdf.

6(c) Estimating Agency Burden and Cost

The Pesticide Registration Improvement Extension Act (PRIA 3), which became effective on October 1, 2012, reauthorized the Pesticide Registration Improvement Renewal Act of 2007 (PRIA 2) for five more years, until 2017. Both Acts established pesticide registration service fees for registration actions. The category of action, the amount of the pesticide registration service fee, and the corresponding decision review periods by year are prescribed in these statutes. Their goal is to create a more predictable evaluation process for affected pesticide decisions, and couple the collection of individual fees with specific decision review periods. They also promote shorter decision review periods for reduced-risk applications.

PRA burden hour and cost estimates for the PRIA program have been OMB approved under the Pesticide Registration Fees Program ICR (OMB Control No. 2070-0179; EPA No. 2330) and are not included in the estimates for this ICR. This ICR only applies to the information collection activities associated with the submission of a petition for a tolerance action. The program reconfigured internal organizations to meet the challenges under PRIA 2 and 3, which has reduced the PRA burden hours and costs for the petitioners, and increased PRA burden hours and costs on the Agency under this ICR.

For this ICR renewal, the Agency is using data on internal OPP Divisions that provide significant support and analysis for the FFDCA tolerance petition ICR program. This data is taken from the Time and Attendance Information System (TAIS), which archives the Agency's Full Time Equivalents (FTEs) for most OPP program activities (see Attachment J). The Agency burden calculations reflect activities for the tolerance petition ICR lead divisions (the Registration Division (RD), the Biopesticides and Pollution Prevention Division (BPPD), and the Antimicrobial Division (AD)), as well as the appropriate FTE activity data from the Health and Effects Division (HED), the Biological and Economic Analysis Division (BEAD), Pesticide Re-evaluation Division (PRD), Field and External Affairs Division (FEAD) and the Environmental Fate and Effects Division (EFED). This approach reflects that (8) OPP Divisions work together to complete the activities related to OPP tolerance petition reviews[3]. The Agency believes that using data from the TAIS reflects the internal operations for implementing and administering tolerance petition activities.

Using TAIS, the estimated number of Agency FTE's dedicated to tolerance petition activities is approximately 1.572 managerial FTEs as shown in Table 2, 14.256 technical FTEs as shown in Table 3, and 0.432 clerical FTEs as shown in Table 4. The aggregated Agency estimated FTE dedicated to tolerance petition activities is 16.26. The associated Agency burden hours are 33,820.80, assuming 2,080 hours per FTE.

Table 3 – Distribution of Agency Managerial FTEs Supporting Tolerance Petition Activities[3]

AD	BEAD	BPPD	EFED	FEAD	HED	RD	PRD

[3] The Agency burden related to OPP's Information Technology and Resource Management Division (ITRMD) processing activities are not included in the burden estimate because ITRMD provides the preliminary data processing and tracking for many OPP ICR activities including tolerance petitions. These systems are integrated for efficient processing, tracking, and maintaining data but they do not readily lend themselves to a clear burden breakdown by ICR activity.

<1	<1	<1	<1	<1	<1	<1	<1
Agency total							1.572

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 * 1.572 = 3,269.76).

Table 4 – Distribution of Agency Technical FTEs Supporting Tolerance Petition Activities[4]

AD	BEAD	BPPD	EFED	FEAD	HED	RD	PRD
<1	<1	<1	<1	<1	3.444	9.552	<1
Agency total							14.256

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 *14.256 = 29,652.48).

Table 5 – Distribution of Agency Clerical FTEs Supporting FIFRA Tolerance Petition Activities[3]

AD	BEAD	BPPD	EFED	FEAD	HED	RD	PRD
<1	<1	<1	<1	<1	<1	<1	<1
Agency total							0.432

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 * 0.432 = 898).

To determine Agency costs, the Agency used the Bureau of Labor Statistics estimates of labor rates for the North American Industry Classification System (NAICS) code for the Federal Executive Branch (NAICS 999100). The managerial labor rate is based on the Standard Occupational Code (SOC) for management occupations; the technical labor rate is based on the SOC for life, physical and social science occupations; and the clerical labor rate is based on the SOC for office and administrative support occupations. The labor rates are fully loaded and indexed to 2014 dollars. The fully loaded hourly mean wage rate estimate for managerial occupations is $124.09 for an average annual FTE cost of $258,107.20 ($124.09 per hour * 2,080 hours). For technical occupations, the fully loaded mean wage rate is $81.53 for an average annual FTE cost of $169,582.40 ($81.53* 2,080). For clerical occupations, the fully loaded mean wage rate is $46.42 for an average annual FTE cost of $96.553.60 ($46.42* 2,080). (See Worksheet for NAICS 999100 EPA or Federal Government, Attachment H.)

To calculate the Agency's estimated annual cost of tolerance petition activities, the number of FTEs allocated to tolerance petition activities is multiplied by the cost per FTE. This represents the Agency's estimate of its cost that will result from tolerance petition activities for each of the next three years. Annual estimated management costs are $405,744.52 (1.572 FTE * $258,107.20 per FTE); technical costs are $2,417,566.69 (14.256 FTE * $169,582.40 per FTE); and clerical costs are $41,702.52 (0.432 FTE * $96,533.60 per FTE). Total estimated Agency cost is $2,919,844.81.

6(d) Bottom Line Burden Hours and Cost

[4] The FTE burden in SRRD and FEAD for each labor category (managerial, technical and clerical) amounted to significantly less than 1 FTE. The estimate for the Agency FTE for each labor category was rounded up to account for the contribution of FEAD and SRRD to the tolerance petition FTE burden.

Table 6 - Burden Hour and Cost Summary

	Burden Hours	Cost
Petitioner Burden	285,128	$27,475,223.58
Agency Burden	33,820	$2,919,844.81

6(e) Reason for Changes in Burden

Agency

The agency estimates that an average of 165 tolerance petitions will be received annually. This is an average increase of 28 tolerance petitions annually. The estimate is based on the average number of tolerance petitions received by the Agency in the years FY2012, FY2013, and FY2014.

Petitioners (Respondents)

EPA estimates a net increase of 48,328 burden hours annually over the expiring ICR. This increase is a result of an increase from 137 to 165 in the estimated average number of tolerance petitions submitted annually, which resulted in a change to the annual burden hours for respondents from 236,800 in the previous renewal to 285,128 in the current renewal. There is no change in burden per tolerance petition; burden for respondents increased as a result of the estimated increase in the average number of petitions submitted annually. The change is an adjustment.

6(f) Burden Statement

The annual respondent burden for collection of information associated with tolerance petitions is estimated to average 1,726 hours for petitions submitted by industry and 1,739 for petitions submitted by IR-4 participants. 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 purposes 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 which have subsequently changed; 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.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2015-0715, which is available for online viewing at *http://www.regulations.gov* or in person viewing at the EPA Docket Center-Public Reading Room, WJC West Building, in Rm. 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. Submit your

comments, referencing Docket ID No. EPA-HQ- OPP-2015-0715 and OMB Control No. 2070-0024, to (1) both EPA and OMB as follows:

• To EPA online using *http://www.regulations.gov* (our preferred method),) or by mail to: EPA Docket Center, Environmental Protection Agency Docket Center (EPA/DC), Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and

• To OMB by email to: *oira_submission@omb.eop.gov*. Address comments to *OMB Desk Officer for EPA.*

These addresses are for your comments - do not submit the information requested in this ICR to these addresses.

7. Attachments List: Supporting Statement (EPA-HQ-OPP-2015-0715)

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted); accessible electronically through *http://www.Regulations.gov*. On the main page, select **Advanced Search** from the menu bar at the top and select **Docket Search**. Enter the Docket ID Number, EPA-HQ-OPP-2015-0715 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.

ATTACHMENT A: **FFDCA Section 408 (21 U.S.C. Sections 346a)**
http://www.gpo.gov/fdsys/pkg/USCODE-2008-title21/pdf/USCODE-2008-title21-chap9-subchapIV-sec346.pdf

ATTACHMENT B: **40 CFR Part 180** - *Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food*
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html

ATTACHMENT C: **PR Notice 97-1** - *Agency Actions under the Requirements of the Food Quality Protection Act*
http://www2.epa.gov/pesticide-registration/prn-97-1-agency-actions-under-requirements-food-quality-protection-act

ATTACHMENT D: **Assembly of Electronic Packages and Discs**
http://www2.epa.gov/pesticide-registration/assembly-electronic-packages-and-discs

ATTACHMENT E: **Registration Service Fees Guidance on IR-4 Exemptions**
http://www2.epa.gov/pria-fees/guidance-ir-4-exemptions.

ATTACHMENT F: **Worksheets Used to Calculate Pesticide Industry (Tolerance Petitioner) Labor Costs**

ATTACHMENT G: **Work Sheets used to Calculate IR-4 Labor Costs**

ATTACHMENT H: **Worksheets Used to Calculate EPA and Federal Government Labor Costs**

ATTACHMENT I: **Pesticide Registration Improvement Extension Act (PRIA 3) of 2012**
http://www2.epa.gov/pria-fees/fy-201617-fee-schedule-registration-applications

ATTACHMENT J: **Time and Attendance Information System (TAIS) Plan Program Accomplishment (PPA) Codes Used to Calculate EPA and Federal Government Burden Hours**

ATTACHMENT K: **Factors for IR-4 Public Interest Finding**
http://www2.epa.gov/pria-fees/factors-ir-4-public-interest-finding

ATTACHMENT L: **Setting Tolerances for Pesticide Residues in Food**
http://www2.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods

ATTACHMENT M: **Display Related to OMB Control Numbers**

ATTACHMENT N: **Summary of Consultations**