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/ Feed Crops and New Inert Ingredients

EPA ICR No. 0597.10 OMB Control No. 2070-0024

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 the 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.

There are basically three types of tolerance actions:

() Permanent tolerance (or an exemption from the requirement for a permanent tolerance) for residues which would result from a pesticide use registered under FIFRA. These tolerances can be established for raw and processed foods and they can address both active and inert ingredients in pesticides. The vast majority of these actions are taken in response to petitions, but the Agency may also initiate such actions.

(1) Temporary tolerance (or an exemption from the requirement for a temporary tolerance) to permit the sale of commodities containing residues resulting from authorized experimental use of an unregistered pesticide. In the absence of such a tolerance or exemption, all such commodities must be destroyed. In submitting an application for Experimental Use Permit (EUP), the applicant may also request that the Agency establish a tolerance or an exemption from the tolerance requirement. This ICR does not cover EUP related tolerance information collection activities, which are covered by the ICR entitled, *Application for Experimental Use Permit (EUP) to Ship and Use a Pesticide for Experimental Purposes Only* (OMB Control #2070-0040, EPA ICR No. 0276).

() Time-limited tolerance (or an exemption there from) to permit the sale of commodities

containing residues resulting from a pesticide whose use was authorized under Section 18 of FIFRA. Under FIFRA §18, EPA may allow States to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. The Food Quality Protection Act of 1996 (FQPA), which amended the two primary statutes regulating pesticides, i.e., FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), requires EPA to establish tolerances to cover all pesticide residues in food, even residues resulting from emergency uses (see Attachment B). Although the Agency initiates these tolerance actions, these actions are taken in response to petitions for the Agency to issue an action under FIFRA §18. This ICR does not cover information collection related to FIFRA §18 tolerance activities, which is collected under the ICR entitled, *Application and Summary Report for an Emergency Exemption for Pesticides* (OMB Control #2070-0032, EPA ICR No.0596).

This ICR only applies to the information collection activities associated with the submission of a petition for a tolerance action. While EPA is authorized to set pesticide tolerances, the Food and Drug Administration (FDA) is responsible for their enforcement. Food or feed 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 the Federal Food, Drug and Cosmetic Act (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 C).

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 receipt 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 revoke 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:

() special protection for infants and children;

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

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

() Consideration of endocrine disruptor effects.

The collection of information covered by this ICR is needed to ensure that the statutory requirements related to tolerances can be met by the public 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 harm 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.

EPA does not require tolerance petitioners to submit any additional information under this ICR in order for the Agency to determine that there is a reasonable certainty that no harm will result from aggregate exposure. However, 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 D).[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. Agency residue chemists and toxicologists review all

[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.

the applicable data. As a result of these reviews, EPA is able to make the statutory determination 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

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, 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

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) Notice announcing this proposed information collection activity and providing a 60-day public comment period (74 FR 8537; February 25, 2009). One public comment was received by email regarding difficulty in accessing an Agency contact by email (see Attachment E). Since the public comment did not provide information related to the burden estimates, no adjustments were made to the ICR based on this comment.

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, as required under 5 CFR 1320.8(d)(1), with stakeholders who actively interact with the Agency through the use of this collection instrument. EPA staff contacted the following relevant stakeholders and asked them for their assessment of the regulatory burden estimates expressed by the Agency in this ICR:

John Abbott
CropLife
john.abbott@syngenta.com

Daniel Kunkel, Ph.D.
IR-4 Program, Rutgers University
732-932-9575

Greg Watson
Syngenta Regulatory Affairs
336-632-2993

Dr. Kunkel of Interregional Project Number 4 (IR-4) responded that the management hours to "prepare petition" have increased from 42 to 55 over the previous ICR. The 13 hour increase has been reflected in this ICR. This increase is due to the additional time that IR-4 spends collecting from each tolerance petitioner the label amendment required to be submitted with the registration package to qualify for registration fee waivers. See section 6(a) "Estimating Respondent Burden" for details.

No other responses have been received.

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 PRA guideline that records be retained for no more than three years.

OMB's 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)). Petitioners have the option to electronically submit underlying study data required by the Agency in support of the tolerance petition process. Under this option, petitioners need only submit 2 two paper copies if they submit the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc. As EPA staff has become familiar with the electronic submission process and the technology, OPP believes this option is allowing the Agency to operate efficiently in the regulation of pesticides through electronic delivery, review, interchange capability and archiving of data supporting the petitions. Under this option, the time normally required for OPP to complete its review of the data should be shortened, thereby allowing faster regulatory decision-making.

The Agency believes that petitioners have become familiar with the electronic submission process and the technology, and that they are able to prepare their data submissions

in less time. The OPP expects petitioners to spend less time and money on preparing copies and using the hybrid paper-electronic submission option, and that they are benefiting from the efficiencies that EPA expects to experience during data reviews.

At this time of this renewal, OPP is not offering a fully electronic submission option. It is, however, beginning the process of defining requirements for electronic submission of studies as well as other elements of applications and petitions. This includes efforts to develop information technology approaches to adequately protect FIFRA Confidential Business Information submitted over the Internet. In the interim, please see EPA's Electronic Submission Interim Guidance documents (Attachment F).

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 code for the most frequent type of respondent is:

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

(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 time 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. The petition must be submitted in triplicate. The petitioner must also show that the pesticide is already registered for the related food or feed use, or that an application for the registration of a pesticide for the related food or feed use has been submitted pursuant to FIFRA section 3 (see Attachment H).

(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 may involve: • conducting additional toxicological or residue chemistry studies • developing analytical methods • *If review is conducted by IR-4, label amendments and PRIA incentives review is conducted
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 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 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. These actions are usually initiated for minor crop uses for which the petitioner is unwilling to seek a tolerance or for residues on commodities which are not grown in the United States and therefore for which there is no U.S. registrant, such as import tolerances. In such cases, the EPA can reduce the burden and cost to small entities by adjusting the range of data requirements to be commensurate with the extent of pesticide use. The Agency also uses this type of regulatory flexibility to set tolerances for residues on commodities which are not grown in the United States.

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 103 tolerance petitions will be submitted to the Agency each year for the next three years. The Agency estimates that 64 of the 103 tolerance petitions will be submitted directly by petitioners, and 39 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 (2006, 2007, and 2008), and is a change from the estimate of the previous ICR of 150 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. There is a 13 hour increase for processing each IR-4 petition 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, renewed under PRIA 2, established registration service fees for pesticide registration actions. (See Attachments I and J.) On March 6, 2008, the President signed a technical correction to PRIA 2 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 tolerance petitions be submitted solely in connection with the registration package, and must include a label amendment request indicating the new use(s), application rates, as well as any precautionary and advisory statements under the proposed tolerance. Thus, IR-4 is conducting more preliminary reviews for the label amendments, which has resulted in a slightly increased burden when compared with the other petitioners. (See Attachment K.)

Assuming that the Agency will receive an average of 103 tolerance petitions each year for the next 3 years, the Agency estimates that the overall annual paperwork burden for all petitioners will be 178,285 hours. This estimate is 80,615 hours less than the previous estimate, resulting from a reduction in the estimated number of tolerance petitions that the Agency anticipates receiving in the next three years.

Since 1995, the Agency has allowed for the use of a single petition to request a tolerance action(s) for a group of similar crops, or "Crop Groupings," rather than submitting individual petitions on a crop by crop basis. FQPA amendments also allow anyone to submit a petition, where previously only registrants could submit the petition. Currently, the Agency does not have tracking mechanisms in place to disaggregate petitions submitted as crop groupings from those submitted as individual crops or to disaggregate the various groups of petitioners. However, a very informal review of some of the petitions seems to indicate petitioners are taking advantage of at least the crop grouping flexibility where some have sought as many as 15 crops per petition.

In addition, the decrease in the number of petitions can be partially attributed to a fee waiver incentive under PRIA and PRIA II for entities who submit 6 or more food uses under one tolerance petition. Particularly with new chemicals, the Agency has been receiving an increasing number of multiple crop groups of 6 or more uses with the initial application. The burden hours for these types of petitions have not increased over the previous ICR as there has been no change

in the process for activities involved with crop grouping submissions.

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. EPA encouraged petitioners who previously submitted data prior to enactment of the law to supplement their original submissions with additional information to aid the Agency's decision-making process in light of its new statutory mandates. 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.

EPA continues to encourage petitioners to develop new and/or submit any existing 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. Agency residue chemists and toxicologists review all the applicable data.

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 for the previous Tolerance Petition ICR, using information from the regulated community, and underwent several rounds of public scrutiny. 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 2007 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 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. 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 (tolerance petitioners and petitioners who submit through IR-4) and the Agency for this ICR renewal are listed in *AttachmentsL, M, and N* respectively.

Table 1. PETITIONER BURDEN/COST ESTIMATES

ACTIVITIES	HOURS and RATES				COSTS (per petition)
	Mgmt. $138/hr	Tech. $73/hr	Cler. $42/hr	Total Hours	Total Costs
Review FFDCA regulations CFR citation; PRN 97-1	25	48	24	97	$7,962
Conduct Field Trial	252	1,080	25	1,357	$114,666
Prepare Petition	42	30	116	188	$12,858
Read Notice of any petition deficiency	1	1	1	3	$253
Prepare response	2	44	12	58	$3,992
Maintain information	1	8	14	23	$1,310
TOTAL BURDEN	323	1,211	192	1,726	$141,041

Data Source: U.S. Department of Labor, Bureau of Labor Statistics, May, 2007. (See cost worksheet Attachment L).

Table 1. IR-4 BURDEN/COST ESTIMATES PER PETITION

ACTIVITIES	HOURS and RATES	COSTS (per petition)

	Mgmt. $129/hr	Tech. $66/hr	Cler. $36/hr	Total Hours	Total Costs
Review FFDCA regulations CFR citation; PRN 97-1	25	48	24	97	$7,257
Conduct Field Trial	252	1,080	25	1,357	$104,688
Prepare Petition	55	30	116	201	$13,251
Read Notice of any petition deficiency	1	1	1	3	$231
Prepare response	2	44	12	58	$3,594
Maintain information	1	8	14	23	$1,161
TOTAL BURDEN	336	1,211	192	1,739	$130,182

Data Source: U.S. Department of Labor, Bureau of Labor Statistics, May, 2007. (See cost worksheet Attachment M).

For tolerance petitioners, the value of labor per hour for management, technical, and clerical is $138, $73, and $42, respectively. Labor rates are by occupation for the Research and Development in the Physical, Engineering, and Life Sciences industry and are taken from the U.S. Department of Labor, Bureau of Labor Statistics. 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". Using the Agency's burden estimate and fully-loaded labor rates, the Agency estimates petitioner costs to be approximately $141,041 per response. The overall annual cost to petitioners associated with this information collection, based on an estimate of 64 petitions per year, is estimated to be $9,026,624.

For IR-4, the value of labor per hour for management, technical, and clerical is $129, $66, and $36, respectively. Labor rates are by occupation for Management, Scientific, and Technical Consulting Services industry[2] (NAICS 541600). 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. Labor rates are fully loaded and include benefits and overhead as described above. Using the Agency's burden estimate and fully-loaded labor rates, the Agency estimates IR-4 costs to be approximately $$130,182 per response. The overall annual cost to petitioners associated with this information collection, based on an estimate of 39 petitions per year, is estimated to be $5,077,098.

The overall annual cost to respondents associated with this information collection, including petitioners and IR-4, based on an estimate of 39 petitions per year, is estimated to be $14,103,722.

ANNUAL COSTS:

Industry		
Management:	323 hours * $138 per hour * 64 tolerance petitions =	$2,852,736
Technical:	1,211 hours * $73 per hour * 64 tolerance petitions =	$5,657,792
Clerical:	192 hours * $42 per hour * 64 tolerance petitions =	$516,096

[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.

	Industry TOTAL:	$9,026,624
IR-4		
Management:	336 hours * $129 per hour * 39 tolerance petitions =	$1,690,416
Technical:	1,211 hours * $66 per hour * 39 tolerance petitions =	$3,117,114
Clerical:	192 hours * $36 per hour * 39 tolerance petitions =	$269,568
	IR-4 TOTAL:	$5,077,098
	GRAND TOTAL:	$14,103,722

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.

6(c) Estimating Agency Burden and Cost

The Pesticide Registration Improvement Renewal Act (PRIA 2), which became effective on October 1, 2007, requires the program to streamline and create service fees for registration actions (see Attachment O). This statute creates a more predictable evaluation process for affected pesticide decisions, and couples the collection of individual fees with specific decision review periods. PRIA 2 also promotes shorter decision review periods for different types of pesticide applications. PRA burden hour and cost estimates for the PRIA program have been OMB approved under the Pesticide Registration Fee Waivers ICR (OMB Control No. 2070-0167; EPA No. 2147) and are not included in the estimates for this ICR. The program reconfigured internal organizations to meet these new challenges, 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 FIFRA 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 P). In the past, the Agency burden calculations for this ICR reflected only activities for the tolerance petition ICR lead divisions (the Registration Division (RD), the Biopesticides and Pollution Prevention Division (BPPD), and the Antimicrobial Division (AD)). The 2009 renewal has added the appropriate FTE activity data from the Health and Effects Division (HED), the Biological and Economic Analysis Division (BEAD), Special Review and Re-registration Division (SRRD), 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 changes to the internal operations for implementing and administering tolerance petition activities. The major impetus for internal program realignment was to implement the

[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.

requirements of the Food Quality Protection Act of 1996 and the Pesticide Registration Improvement Act of 2003 (PRIA) as reauthorized.

Using this new source of data the estimated number of Agency FTE's dedicated to tolerance petition activities is approximately 3 managerial FTEs as shown in Table 2, 19 technical FTEs as shown in Table 3, and 2 clerical FTEs as shown in Table 4. The aggregated Agency estimated FTE dedicated to tolerance petition activities is 24 and the burden hours are 49,920, assuming 2,080 hours per FTE.

Table 2 – Distribution of Agency Managerial FTEs Supporting Tolerance Petition Activities[3]

AD	BEAD	BPPD	EFED	FEAD	HED	RD	SRRD
<1	<1	<1	<1	<1	<1	1.1	<1
Agency total							3

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 * 3 = 6,240).

Table 3 – Distribution of Agency Technical FTEs Supporting Tolerance Petition Activities[4]

AD	BEAD	BPPD	EFED	FEAD	HED	RD	SRRD
<1	1.2	<1	2.5	<1	3.8	9.6	<1
Agency total							19

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 *19 = 39,520).

Table 4 – Distribution of Agency Clerical FTEs Supporting FIFRA Tolerance Petition Activities[3]

AD	BEAD	BPPD	EFED	FEAD	HED	RD	SRRD
<1	<1	<1	<1	<1	<1	<1	<1
Agency total							2

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 * 2 = 4,160).

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 2007 dollars. The fully loaded hourly mean wage rate estimate for managerial occupations is $103 for an average annual FTE cost of $214,240 ($103 per hour * 2,080 hours). For technical occupations, the fully loaded mean wage rate is $71 for an average annual FTE cost of $147,680. And for clerical occupations, the fully loaded mean wage rate is $41 for an average annual FTE cost of $85,280. (See Worksheet for NAICS 999100 EPA or Federal Government, Attachment N.)

[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.

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 $642,720 (3 FTE * $214,240 per FTE); technical costs are $2,805,920 (19 FTE * $147,680 per FTE); and clerical costs are $170,560 (2 FTE * $85,280 per FTE). Total estimated Agency cost is $3,619,200.

6(d) Bottom Line Burden Hours and Cost

Table 5 - Burden Hour and Cost Summary

	Burden Hours	Cost
Petitioner Burden	178,285	$14,103,722
Agency Burden	49,920	$3,619,200

6(e) Reason for Changes in Burden

Agency

The EPA has significantly lowered processing hours to about two-thirds of the previous ICR due to changes in the anticipated number of tolerance petitions in the next three years. The Agency estimates that an average of 103 tolerance petitions will be received annually. This is a decrease by 47 tolerance petitions annually. The estimate is based on the average number of tolerance petitions received by the Agency in the years FY2006, FY2007, and FY2008. In addition, the Agency is using a new source of data consistent with its time reporting to calculate burden. According to this data source, processing tolerance petitions requires significantly fewer hours than previously understood. The decrease in hours and costs reflects both internal program adjustments and changes in the method used to calculate Agency burden

Petitioners (Respondents)

EPA estimates a net decrease of 80,615 hours annually over the expiring ICR. The decrease is primarily related to EPA's projection that 47 fewer tolerance petitions will received from the pesticide registrant community annually compared to the previous three years (2006, 2007, and 2008), down from 150 submissions to 103. This would result in a corresponding 81,122 hour reduction in estimated annual burden. The change is an adjustment. In addition, EPA estimates that IR-4 petitioners are changing the way in which they compile tolerance petitions for submission to EPA in an effort to capture the new fee waiver incentives under the Pesticide Registration Improvement Renewal Act. This change in IR-4 petition preparation results in an additional 13 hours per response, resulting in a program change increase of 507 hours annually.

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-2008-0927, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. 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 http://www.regulations.gov or by mail addressed to Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. You can also send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Include docket ID No. EPA-HQ-OPP-2008-0927 and OMB control number 2070-0024 in any correspondence but do not submit information under this collection to these addresses.

Attachments List: Supporting Statement (EPA-HQ-OPP-2008-0927)

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-2008-0927 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://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t21t25+149+1++%28%29%20%20AND%20%28%2821%29%20ADJ%20USC%29%3ACITE%20AND%20%28USC%20w%2F10%20%28346a%29%29%3ACITE%20%20%20%20%20%20%20%20%20%20

ATTACHMENT B: **Accomplishments under the Food Quality Protection Act**
http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_accomplishments.htm

ATTACHMENT C: **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 D: **PR Notice 97-1** - *Agency Actions under the Requirements of the Food Quality Protection Act*
http://www.epa.gov/opppmsd1/PR_Notices/pr97-1.html

ATTACHMENT E: **Public Comment (see docket)**

ATTACHMENT F: **Electronic Submission Interim Guidance Documents**
http://www.epa.gov/pesticides/regulating/registering/submissions/

ATTACHMENT G: **7 USC 450i: Competitive, special, and facilities research grants**
http://www.csrees.usda.gov/funding/nri/nri_7usc450i.html

ATTACHMENT H: **FIFRA Section 3 (7 U.S.C 136a) (see page 16):**
http://agriculture.senate.gov/Legislation/Compilations/Fifra/FIFRA.pdf
7 U.S.C. 136a:
http://www4.law.cornell.edu/uscode/7/usc_sec_07_00000136---a000-.html

ATTACHMENT I: **Pesticide Registration Improvement Act (PRIA)**

http://agriculture.senate.gov/Legislation/Compilations/Fifra/FIFRA.pdf#page=97

ATTACHMENT J: **Pesticide Registration Improvement Renewal Act (PRIA 2) Related applications and Their Fees (Primary and Secondary)**
http://www.epa.gov/pesticides/regulating/fees/related-apps.html

ATTACHMENT K: **Registration Service Fees Guidance on IR-4 Exemptions**
http://www.epa.gov/pesticides/fees/questions/guidance_ir-4.htm

ATTACHMENT L: **Worksheets Used to Calculate Pesticide Industry (Tolerance Petitioner)**

Labor Costs

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

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

ATTACHMENT O: **PRIA 2: Fees for Registration Applications**
http://www.epa.gov/pesticides/regulating/fees/

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