

**Supporting Statement for a Request for OMB Review under  
The Paperwork Reduction Act**

**1. IDENTIFICATION OF THE INFORMATION COLLECTION**

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

**Title: TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)**

**EPA ICR No.: 0586.11      OMB Control No.: 2070-0054**

**1(b) Short Characterization**

On June 22, 1982, EPA promulgated the generic section 8(a) Preliminary Assessment Information Rule (PAIR) (40 CFR Part 712, see Attachment C) under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607, see Attachment A). EPA uses PAIR to collect information to identify, assess and manage human health and environmental risks from chemical substances, mixtures and categories. PAIR requires chemical manufacturers and importers to complete a standardized reporting form to help evaluate the potential for adverse human health and environmental effects caused by the manufacture or importation of identified chemical substances, mixtures or categories. Attachment B provides a specific section-by-section listing of each of the requirements under Title 40 of the Code of Federal Regulation related to this ICR.

Chemicals identified by the existing chemical review program, any other EPA office or federal agency, for which a justifiable information need for production, use, or exposure-related data can be satisfied by the use of the PAIR, is a proper subject for a chemical-specific TSCA section 8(a) PAIR rulemaking. Many of the chemical substances, mixtures and categories listed in 40 CFR Part 712 have been recommended by the Interagency Testing Committee (ITC) to EPA for test rule consideration. In most instances, such as in a preliminary risk determination, or in reaching a decision whether testing of a chemical is necessary to satisfy an identified data need, the information that EPA receives from a PAIR report is sufficient to satisfy its information needs.

This information collection activity also covers certain specific chemical testing and reporting requirements under Subpart B of 40 CFR part 766 (see Attachment E) that are very similar to the PAIR requirements. The Agency rarely receives submissions of the information required by 40 CFR 766. EPA received no more than five submissions over the course of the last OMB approval for this particular aspect of the information collection. However, collection of this information is covered under the PAIR ICR because the requirements are similar and because the Paperwork Reduction Act requires that recordkeeping and reporting activities contained in any regulation be approved by OMB even if they involve less than ten respondents or would otherwise not require approval (see 5 CFR 1320.3(c)(4)(i)).

The dibenzo-para-dioxin/dibenzofuran regulations at part 766 require that any person who manufactures, imports, or processes a chemical substance listed at 766.25 tests that

chemical substance and submit appropriate information to EPA according to the schedules described in at 766.35. These chemical substances are subject to testing immediately upon manufacture, import or processing. Persons who manufacture or import a chemical substance listed under 766.25 must report results, using the Dioxin/Furan Report form (EPA Form 7710-51, see Attachment F) of all existing test data that show that chemical substance has been tested for the presence of halogenated dibenzodioxins/halogenated dibenzofurans (HDDs/HDFs), as defined in the regulation, no later than 90 days after the person first manufactures or imports the chemical substance. Additionally, any manufacturer or importer of a chemical substance listed in 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA, in accordance with various provisions of 40 CFR 716, no later than 90 days after the person first manufactures or imports the chemical substance.

## **2. NEED FOR AND USE OF THE COLLECTION**

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

Under TSCA, which covers the production, distribution, and disposal of commercial and industrial chemicals in the United States, EPA's Office of Pollution Prevention and Toxics (OPPT) is charged with the responsibility for assuring that chemicals made available for sale and use in the United States do not pose any unreasonable adverse risks to human health or to the environment. To carry out this mandate, EPA has broad authority to issue regulations designed to gather health/safety and exposure information on, require testing of, and control exposure to chemical substances and mixtures. Drugs, cosmetics, foods, food additives, pesticides, and nuclear materials are exempt from TSCA and are subject to control under other U.S. Government statutes (e.g., foods, food additives, drugs and cosmetics are under the purview of the Federal Food, Drug, and Cosmetic Act (FFDCA)).

TSCA section 8(a) gives EPA the authority to promulgate rules under which manufacturers (which by statute includes importers) and processors of chemical substances must maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates. Examples of information that can be required to be reported under TSCA Section 8(a) include:

- chemical or mixture identity;
- categories of use;
- quantity manufactured or processed;
- by-product description;
- health and environmental effects information;
- number of individuals exposed; and
- method(s) of disposal.

Section 8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules, which are covered under EPA ICR #1198.06; OMB Control #2070-0067) or information can be obtained via the use of "model" or standardized reporting rules. One example of a model TSCA Section 8(a) reporting rule is the "Preliminary Assessment

Information Rule” (or PAIR). Under PAIR, producers and importers of a listed chemical are required to report the following site-specific information on a two page form (described in more detail in Chapter 4 of this ICR):

- Quantity of chemical produced and/or imported;
- Amount of chemical lost to the environment during production or importation;
- Quantity of enclosed, controlled and open releases of the chemical; and
- Per release, the number of workers exposed and the number of hours exposed.

Exemptions for such reporting are as follows:

- Production or importation for the sole purpose of research and development (R&D);
- Production or importation of less than 500 kilograms during the reporting period at single plant site;
- Companies whose total annual sales from all sites owned by the domestic or foreign parent company are below \$30 million for the reporting period and who produced or imported less than 45,400 kilograms of the chemical; and
- Production or importation of the listed chemical solely as an impurity, a non-isolated intermediate, and under certain circumstances as a by-product.

This ICR addresses the information collection activities associated with PAIR, which is promulgated at 40 CFR 712, which establishes procedures for chemical manufacturers and processors to report production, use, and exposure-related information on listed chemical substances. Subpart A establishes requirements that apply to all reporting under PAIR, and Subpart B covers manufacturers’ and processors’ reporting. Processors are not required to report PAIR information under this ICR.

In addition, as described in the previous section, this ICR addresses information collection activities associated with the reporting and recordkeeping requirements contained in 40 CFR 766.

## **2(b) Use/Users of the Data**

EPA uses PAIR data to (1) monitor domestic manufacture and/or importation of chemical substances, mixtures and categories, (2) identify possible routes of human or environmental exposure, (3) support regulations designed to prevent possible adverse health effects and (4) support EPA programs. The information provided by PAIR is needed to complete assessments of chemicals of interest and to assist in the development of regulations to control hazardous chemicals.

All EPA program offices are potential users of the PAIR. The information helps EPA evaluate the potential for adverse human health or environmental effects caused by the manufacture and importation of the identified chemical substance, mixture or category. If EPA does not monitor these parameters, adverse human health or environmental effects may occur without EPA’s knowledge. Without this information, EPA would not be able to evaluate the need for additional testing or further regulatory action.

Other federal agencies, which require data on the human health and environmental effects of a chemical, use PAIR information. States also have access to public portions of PAIR information. Public interest groups use information reported under the public portions of PAIR.

### **3. NON-DUPLICATION, CONSULTATION AND OTHER COLLECTION CRITERIA**

#### **3(a) Non-Duplication**

PAIR reporting data assist EPA in identifying, evaluating and managing the human health and environmental effects of chemical substances, mixtures and categories. EPA has developed procedures that must be met to ensure that the chemicals added to the rule and the information requested on these chemicals does not duplicate other activities or impose a burden on industry that outweighs the need for the data. These procedures are for rule promulgation and implementation:

- (1) A continuing evaluation of the information collection and management activities;
- (2) The management of the collected information;
- (3) A chemical nomination, screening and selection process; and
- (4) Technical assistance for persons subject to the rule.

It is unlikely that the information to be reported is duplicative because (1) EPA estimates that each rule will generate only a few reports, (2) the information required by the PAIR is unique to the manufacturer or importer, and (3) efforts are made to ensure that the information requested is not currently in the possession of EPA or easily obtained by EPA from other public sources. The following databases and sources of information are checked:

- The Chemical Screening Branch's Existing Chemical Assessment Tracking System (CECATS), a database containing information on TSCA section 8(e) and For Your Information (FYI) submissions and Chemical Hazard Information Profiles (CHIPs);
- The Toxic Substances Control Act Test Submissions (TSCATS) database, an on-line index to the compiled, unpublished health and safety studies submitted to EPA;
- The Registry of Toxic Effects of Chemical Substances (RTECS), a file containing chemical toxicity data;
- LEXIS/NEXUS, a data network with a wide range of fields including information published in the *Code of Federal Regulations* (CFR) and BNA's *Environmental Reporter and Chemical Regulation Reporter*;
- The Toxicology Data Network (TOXNET), run by the National Library of Medicine; and
- The Toxic Substances Control Act section 8(b) inventory data (CICIS) and inventory update data (CUS).

Similar searches are conducted for each list of chemical substances, mixtures or categories added to the PAIR.

Some chemicals in PAIR are referred to EPA by other federal agencies. These agencies conduct searches of their own databases for existing chemical information before they refer any chemical to EPA. Referrals are made to EPA only after a decision has been made that an agency's existing chemical information is inadequate to meet its needs.

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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on February 19, 2008 (72 FR 72704, December 21, 2007). EPA received no comments during the comment period.

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

On numerous occasions, EPA has published in the *Federal Register* notices requesting comments on the reporting requirements of TSCA section 8(a) PAIR rules. Industry and environmental groups generally respond to these requests for comment.

The American Chemistry Council (ACC), formerly the Chemical Manufacturers Association (CMA), has responded to several *Federal Register* notices. The ACC is a nonprofit trade association whose members account for more than 90 percent of the total U.S. production capacity for basic industrial chemicals. The ACC encourages EPA to use PAIR and has not strongly objected to any of the information requirements contained in PAIR.

The Natural Resources Defense Council (NRDC) has also responded to *Federal Register* notices. NRDC is a national nonprofit environmental organization dedicated to the protection of human health and the environment. NRDC generally urges EPA to adopt a more detailed set of information requirements.

Also, EPA routinely consults with other federal agencies (e.g., OSHA, CPSC, DOT). These consultations include exchanging information on existing chemicals, and referrals of chemicals to EPA by other federal agencies for information collection when the other agency's own authority or information collection requirements have not met their information needs.

In addition to the public notice and comment period required by the OMB regulations that implement the Paperwork Reduction Act (see Section 3(b) of this Supporting Statement), the OMB regulations, 5 CFR 1320.8(d)(1), also require agencies to consult with potential ICR respondents and data users about specific aspects of an ICR before the agency submits the ICR to OMB for review and approval. In accordance with this regulation, EPA met with the American Chemistry Council and member companies of the Council on February 6, 2008, to obtain feedback on pre-reporting burden estimates that they claim are insufficient. A summary of that meeting is included below as Attachment I. Representatives of potential respondents attending that meeting were the following:

Kathleen Roberts  
American Chemistry Council  
[Kathleen\\_Roberts@americanchemistry.com](mailto:Kathleen_Roberts@americanchemistry.com)

Imogene Treble  
The Dow Chemical Company  
[trebleie@dow.com](mailto:trebleie@dow.com)

Greg McCarney  
3M  
[gjmccarney1@mmm.com](mailto:gjmccarney1@mmm.com)

Fred Marashi  
Chevron Phillips  
[marasf@cpchem.com](mailto:marasf@cpchem.com)

Bill Beers  
OMNOVA  
[bill.beers@omnova.com](mailto:bill.beers@omnova.com)

Pat Nevrincean  
FMC Corporation  
[pat\\_nevrincean@fmc.com](mailto:pat_nevrincean@fmc.com)

### **3(d) Effects of Less Frequent Collection**

Under PAIR, persons are required to report only once for a chemical listed in the PAIR. However, if information received from the initial report indicates human health and environmental risks, then the Agency may require that additional information be submitted at some future date to monitor any changes pertaining to that chemical. As such, the reporting frequency for PAIR cannot be reduced without effectively suspending the information collection requirement.

### **3(e) General Guidelines**

This collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6. Note that when this information collection was last approved by OMB in October 2001, OMB established the following terms of clearance:

“The Agency shall ensure that the approximate annual burden estimates for each PAIR rule are provided in the preamble to each rule. Upon renewal of this ICR, the Agency shall provide a list of the chemicals covered by the final PAIR rules issued by EPA over the next three years.”

As requested, in the preamble to each PAIR rule issued during the last ICR approval period, EPA has provided an annual burden estimate for the rules. The list of chemicals in those final PAIR rules, along with the burden estimate provided for those rules, is found under Attachment H to this supporting statement.

Additionally, in an OMB action notice dated May 5, 2005, approving the most recent renewal of this information collection, OMB stated the following terms of clearance:

“OMB notes that in the supporting statement, EPA states that it will consult with the American Chemistry Council during the approval period on the Agency's description of anticipated activities and related burden estimates.”

The meeting referenced above in Section 3(c) and in Attachment I below addresses those terms of clearance.

### **3(f) Confidentiality**

Submitters may designate information reported under PAIR and Subpart B of 40 CFR 766 as confidential business information (CBI). EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with EPA's confidentiality regulations at 40 CFR Part 2, Subpart B, and TSCA Section 10.

### **3(g) Sensitive Questions**

This information collection does not include questions of a sensitive nature.

## **4. THE RESPONDENTS AND THE INFORMATION COLLECTED**

### **4(a) Respondent NAICS Codes**

PAIR's respondents are manufacturers and importers of chemical substances, mixtures or categories. Respondents affected by this collection are included primarily in the following NAICS codes:

- 3251 Basic Chemical Manufacturing
- 3252 Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments Manufacturing
- 3255 Paint, Coating, and Adhesive Manufacturing
- 3253 Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing
- 3259 Other Chemical Product and Preparation Manufacturing
- 32411 Petroleum Refineries

### **4(b) Information Requested**

#### **i. Data Items**

PAIR requires manufacturers or importers of the listed chemical substances, mixtures or categories to report to EPA information such as the substances' chemical identification, quantity produced or imported, chemical processes, employee exposure, environmental releases, uses and products. Respondents are only required to report information that is known or reasonably ascertainable by them. As described in the previous section, extensive files searches are not required. The PAIR reporting requirements are included in the PAIR form and instructions (EPA Form 7710-35).

## ii. Respondent Activities

A representative respondent would engage in the following activities:

- Conduct an initial review of the rule to determine if their company must report;
- Familiarize themselves with the PAIR reporting form;
- Complete the PAIR reporting form;
- Provide trade name notification;
- Indicate CBI status if so desired; and
- Keep a copy for recordkeeping requirements.

The PAIR generally requires one-time reporting and establishes the reporting period for the listed chemical substances, mixtures or categories. Typically, the reporting period is 30 days from the effective date of the PAIR rule. Effective dates of PAIR rules are typically 30 days after publication of the rule in the *Federal Register*. In other words, the reporting period is typically 60 days from the publication of a final PAIR rule in the *Federal Register*. Therefore, a reporting schedule is not required.

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

### **5(a) Agency Activities**

The activities routinely conducted by EPA related to the rule development, processing, analysis and storage of the information collected under a PAIR rule are as follows:

- Chemical nomination, review and selection;
- Rule development;
- Evaluation of the rule (including impact assessments);
- Industry/public assistance;
- Compliance monitoring; and
- Processing of data received for listed chemicals (includes receipt, dissemination, evaluation, etc.).

### **5(b) Collection Methodology and Management**

The PAIR requires respondents to submit TSCA section 8(a) notices to the Information Management Division, Office of Pollution Prevention and Toxics (OPPT), using EPA Form 7710-35. Information collected under PAIR is logged in and assigned a document control number (DCN), distributed to appropriate EPA personnel for further processing, review, analysis, etc. Likewise, in the unexpected instance that a respondent submitted a Dioxin/Furan Report form (EPA Form 7710-51), the information would be managed in the same way. The information is maintained by EPA's Information Management Division.



### **5(c) Small Entity Flexibility**

In accordance with TSCA section 8(a)(1)(B), PAIR contains a small business exemption. A manufacturer or importer is considered a small business if (1) the firm's total annual sales when combined with those of its parent company (if any) are less than \$30 million for the reporting period and (2) its total production and/or importation of the chemical substances, mixture or category, for the reporting period, does not exceed 100,000 pounds (45,000 kilograms) at an individual site owned and controlled by the firm.

The small manufacturer/importer exemptions apply to PAIR, regardless of which office or agency nominates a chemical. In some instances, the EPA Administrator can remove these exemptions on a chemical-specific basis, provided notice and comment rulemaking is utilized. EPA expects that those offices that have a critical need for reporting from small businesses usually exempt from PAIR reporting will use other mechanisms to gather the data. EPA does not expect to issue a PAIR rule during the next 3 years that would impact such small businesses.

### **5(d) Collection Schedule**

Information collection under PAIR occurs after publication of a *Federal Register* notice establishing the reporting period for the listed chemical substances, mixtures or categories. Respondents are asked to respond once, within 30 days of the effective date of the final PAIR rule (which is usually 30 days after publication of the rule in the *Federal Register*). The Agency has no plans to publish the data collected by PAIR, although non-CBI information may be made available to the public upon request.

## **6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION**

### **6(a) Estimating Respondent Burden**

This section presents the Agency's estimates of the burden associated with the reporting and recordkeeping requirements under the TSCA section 8(a) PAIR. The total annual industry burden for both reporting and recordkeeping is estimated to be 1,568 hours. These estimates are based on the level of PAIR reporting activity expected during the ICR period of FY 2009 through 2011. In conducting any study that will be submitted to EPA under TSCA, the respondent must comply with the Good Laboratory Practice Standards (GLPS) at 40 CFR part 792 (see Attachment G). Since the GLPS represent basic standard practices used by laboratories, any burden and costs related to the GLPS are fully captured in the cost and burden estimates provided below.

The PAIR report is submitted on EPA Form 7710-35, which is two pages long (see Attachment D). The first page asks the respondent to provide basic identifying information, such as the identity of the chemical (CAS number), the physical location of the plant and mailing address of the responding entity. The second page requires the respondent to provide general information on the quantities of the chemical used and number of workers exposed and some additional information on the categories of products (e.g., industrial and consumer) associated

with manufacture or processing of the reported substance.

Much of the information requested under this ICR is routinely collected by manufacturers and processors for the maintenance and upkeep of health and safety information but has not previously been made available to the Agency. This information should be readily available to the firm as it is generated and maintained as part of their normal business practices. In fact, the regulations specifically state that the respondent is not required to conduct an exhaustive search of their files (see 40 CFR 712.7). The EPA has reviewed the average per-report burden estimate in light of the Agency's experience and feedback received from actual submitters. Our average estimate of 29.0 hours per response is consistent with that information.

The methodology used to develop these cost estimates follows principles that have been used in previous ICRs. The methodology and calculations used in this analysis assume the employee responsible for filling out the form has a reasonable level of familiarity with the company and knowledge of the operation at the site. The analysis deals with the marginal costs of complying with this specific request and not the total costs to the company of initial employee training and costs associated with collecting and storing records or of file maintenance that enable a company to comply with a range of other Federal and state environmental, health and safety regulations or accounting requirements that rely on this type of information. The 8(a) PAIR requests are issued infrequently and it is our experience, based on conversations with respondents, that this duty is similar to other duties they perform which require familiarity with EPA, state and other Federal agency requests for chemical information and does not involve additional familiarization or training to comply with information requested under this ICR.

The Agency is not asserting an exact measurement of the burden and costs that all potential respondents will incur while complying with this information collection activity. The Agency's burden and cost estimates are based on averages. Some respondents may indeed require more time to respond the information collection than the Agency's estimated average of 29.0 hours per report; however, the Agency believes some respondents will be able to complete their response activities in less time. The Agency also intends to continue to provide rule-specific estimates of burden and costs, presenting them in the preamble to the PAIR rule. Should the Agency determine in that context that this average estimate is insufficient, it will adjust the ICR accordingly. Upon renewal, EPA will reassess its burden estimate based on the next three-year approval period and make adjustments as appropriate

Based on information provided by EPA's Information Management Division (IMD), an average of 26.00 sites submitted a total of 54.20 reports per year (an average of 2.08 reports per site per year) during the period of FY 2003 through FY 2007. In general, the analysis uses data and methodological assumptions from previous economic analyses of the individual PAIR rules and other government data sources. This analysis also assumes that future annual reporting levels will be similar to the annual reporting levels of the FY 2003 through FY 2007 period. This reporting level is substantially higher than had been projected in earlier ICR-supporting analyses (somewhat less than triple the estimate in the most recent previous ICR renewal analysis). The rate at which new PAIR rule chemicals are added is sporadic and not entirely predictable, but this higher level of projected reporting is consistent with the Agency's recent experience. A detailed description of the methodology used to derive the estimates follows.

### Number of Sites and Reports per Site

The burden hour estimates in this analysis are based on an estimate of the level of PAIR reporting activity during the next three-year ICR approval period (FY 2009 to FY 2011). This, in turn, is related to the number of PAIR chemical reports and reporting sites. This report utilizes data from the fiscal years 2003 to 2007 and annualizes the number of sites reporting and the number of reports submitted to develop estimates of future burden. During the 2003 to 2007 period, an annual average of 26.00 sites (respondents) submitted 54.20 reports (forms), for an average of 2.08 reports per respondent. Some PAIR reports submitted during a given fiscal year may have resulted from chemicals added to the PAIR during the previous year.

Chemicals are added to the PAIR (via Federal Register [FR] notices) based on Interagency Testing Committee reports as published in the FR. The number of chemicals added to the PAIR recently is not used in estimating burden but are provided as background (Source: US EPA, CCD, Greg Schweer, (8(a) chemicals)).

Number of chemicals added to PAIR in recent fiscal years: 2003 – 47; 2004 – none; 2005 – 23; 2006 – 208; 2007 – none.

<b>Sites Reporting and PAIR Reports Submitted FY 2003 through 2007</b>		
Fiscal Year	Sites Reporting	Reports Submitted
2003	20	39
2004	6	7
2005	24	53
2006	3	3
2007	77	169
Totals	130	271
5-year average	26.00	54.20
Ratio Forms/Sites	2.08	
Ratio Sites/Form	0.48	

### Unit Burden Estimates

To estimate the burden and costs to industry respondents, several reporting activities (or burden factors) are analyzed. These burden items include: form familiarization; reporting; trade name notification; CBI substantiation; recordkeeping; and, report submission. Each of these activities requires the skills of various labor categories. The section below details each separate activity and presents the estimated labor hours required by each task, by labor category (secretarial, technical and managerial).

#### 1. Form Familiarization

In the 1981 PAIR economic analysis<sup>1</sup> it was estimated that form familiarization would

1 <sup>?</sup> Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary

require 3 hours of effort from managerial personnel and 4 hours from technical personnel for a total of 7 hours per site. The estimate includes efforts for rule familiarization and to determine if reporting is required. To calculate the burden on a per report basis, the above estimate was multiplied by 0.48, the expected average number of sites per report (i.e., 26.00 sites / 54.20 reports). This results in a per report burden of 3.36 hours.

#### **Per-Report Burden Hours for Form Familiarization**

<b>Activity</b>	<b>Secretarial</b>	<b>Technical</b>	<b>Managerial</b>	<b>Total</b>
Form Familiarization	0.00	1.92	1.44	3.36

#### **2. Report Preparation**

The 1981 PAIR economic analysis estimated that direct reporting activities would require a total of 16 hours of effort per report. This consists of the burden related to the completion of the PAIR form. As indicated previously, the respondents are not expected to conduct an exhaustive search of their files. Respondents are only required to report what is known or reasonably ascertainable to them (see 40 CFR 712.7). The relative distribution of reporting burden between managerial, technical and secretarial personnel used in the 1992 PAIR ICR update has been retained and is reflected below.

#### **Per-Report Burden Hours for Report Preparation**

<b>Activity</b>	<b>Secretarial</b>	<b>Technical</b>	<b>Managerial</b>	<b>Total</b>
Reporting	1.25	9.25	5.50	16.00

Given that each site produces an average of 2.08 reports, the per-site burden for report preparation is  $2.08 \times 16$  hours, or 33.28 hours.

#### **3. Trade Name Notification**

Some companies may report their customers' uses as unknown for more than twenty percent of their volume. These companies must list under Item 10 of the PAIR reporting form the market (trade) name(s) under which they distribute the chemical. This reporting is referred to as trade name notification.<sup>2</sup>

All commercial manufacturing, importing and processing sites that distribute any of the chemicals subjected to a PAIR reporting rule under a trade name must take steps to ensure that information about the downstream processors is submitted to EPA. Firms may chose among several options to meet trade name notification requirements, including:

- 1) Submit trade name data to EPA for listing in the Federal Register;

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Assessment Information Rule, Final Report, prepared for the EPA by ICF, Inc., Washington, D.C., 1981.

<sup>2</sup> 40 CFR 712.28 (July 1, 1993).

- 2) Notify all customers of the need to report; or
- 3) Complete the reporting requirements for each customer.

This ICR assumes that companies will adopt the least-costly reporting alternative of providing a trade name list to EPA for inclusion in the Federal Register. However, trade name notification is not relevant if processor reporting is not required. Furthermore, this ICR also assumes that all manufacturers and importers will incur trade name notification costs, but does not address processors due to the lack of data on processor reporting. In the 1994 EPA PAIR ICR,<sup>3</sup> the unit burden of trade name notification was given as 3.2 hours (i.e., 2.2 hours managerial and 1.0 hours secretarial). This unit burden assumption was retained for this analysis.

#### **Per-Report Burden Hours for Trade Name Notification**

<b>Activity</b>	<b>Secretarial</b>	<b>Technical</b>	<b>Managerial</b>	<b>Total</b>
Trade Name Notification	1.00	0.00	2.20	3.20

Given that each site produces an average of 2.08 reports, the trade name notification per-site burden for trade name notification is 2.08 x 3.2 hours, or 6.66 hours.

#### **4. CBI Substantiation**

A company may make claims of confidentiality for any data element contained in its submission. For each CBI (confidential business information) claim, generic information must be supplied for a non-CBI copy of the submission (i.e., a sanitized version must also be submitted). It is assumed that most of the time required for CBI substantiation involves managerial staff discussion of whether or not to make a CBI claim. Furthermore, it is assumed that all firms will review their submissions for CBI content. As used in the previous PAIR ICR, the 1986 alternative CAIR<sup>4</sup> CBI substantiation burden estimates have been used in this analysis with substantial downward adjustments to account for the less rigorous substantiation requirements in PAIR reporting rules. CBI claims for a PAIR report can be made by simply checking the appropriate boxes on the PAIR reporting form. It is assumed that most of the time required for PAIR CBI substantiation involves staff discussion of whether or not to make a CBI claim. As a result, burden estimates used in CAIR has been reduced by one-half in both labor categories to 0.5 hours of secretarial time and 4 hours of managerial time per report.

#### **Per-Substantiation Burden for CBI Substantiation**

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<sup>3</sup> Burden Hour and Cost Estimates for PAIR Section 8(a) Reporting (1994 Update), internal U.S. EPA memorandum from Carol Rawie, Economics, Exposure, and Technology Division to Karen Boswell, Chemical Testing and Information Branch, May 16, 1994.

<sup>4</sup> The alternative Comprehensive Assessment Information Rule (CAIR) estimate was developed to account for CAIR-listed chemicals for which respondents were required to answer only a limited number of questions. A discussion of the alternative CAIR burden and cost estimates is found in Section 6.6 (pp. 67-69) of the Estimated Cost of the Final Comprehensive Assessment Information Rule, Final Report, U.S. EPA/OPPT/EETD, June 1, 1986 (prepared for EPA by Kearney/Centaur).

<b>Activity</b>	<b>Secretarial</b>	<b>Technical</b>	<b>Managerial</b>	<b>Total</b>
Trade Name Notification	0.50	0.00	4.00	4.50

Based on an analysis of CBI claims for reporting to the TSCA Inventory (discussed in the 1986 CAIR economic analysis), only 75 percent of reports are expected to make CBI claims. The burden distributed across all reports is 4.5 hours x 0.75, or 3.38 hours. Multiplying the adjusted report burden and cost by 2.08, in turn, provides the per site burden for CBI substantiations of 7.02 hours.

#### 5. Recordkeeping

Pursuant to TSCA Section 8(a), the manufacturer/importer or processors of the chemical substances identified under PAIR must also maintain records of the information submitted to EPA. In addition, since manufacturer/importer or processors that submit data to EPA must comply with the GLPS in 40 CFR 792, this ICR also generally covers the burden associated with maintaining records as required under the GLPS. These records are used for compliance monitoring and enforcement purposes.

As in the previous ICR, EPA estimates that the recordkeeping burden associated with this ICR involves about an hour of time for both the secretarial and the technical labor category. This burden estimate represents the time necessary for the individuals to identify the information, determine the appropriate location for the record to be kept, and placing the record in such a location. The per-report recordkeeping burden is therefore estimated to be 2 hours.

#### **Per-Report Burden Estimates for Recordkeeping**

<b>Activity</b>	<b>Secretarial</b>	<b>Technical</b>	<b>Managerial</b>	<b>Total</b>
Trade Name Notification	1.00	1.00	0.00	2.00

The per-site burden for recordkeeping is 2.08 reports x 2.0 hours, or 4.16 hours.

#### 6. Report Submission

Report submission consists of three elements: preparation and review of a transmittal letter to accompany the submission of a report, photocopying the report and mailing costs.

As with the previous ICR, EPA estimates that the per report submission will require 0.5 hours of secretarial time and 0.5 hours of managerial time for a total of one hour. The secretarial burden includes the time required to type the transmittal letter, to photocopy the report, and the steps necessary to mail the report package to EPA after management review and approval. The managerial time assumes an involvement in the preparation of the transmittal letter and review of the report package before it is submitted to EPA.

**Per Report Burden Estimates for Report Submission**

Activity	Secretarial	Technical	Managerial	Total
Trade Name Notification	0.50	0.00	0.50	1.00

Given that each site produces an average of 2.08 reports, the per site burden for report submission is 2.08 x 1 hour, or 2.08 hours.

**Total Industry Burden Estimates**

The following table presents the compilation of the annual burden hour estimates for respondents.

<b>Estimated Annual Burden Hours</b> (assuming 54.2 reports and 26 reporting sites per year)			
<b>Burden Item</b>	<b>Hours per Report</b>	<b>Hours per Site</b>	<b>Total Annual Hours</b>
Form familiarization	3.36	7.00	182.11
Reporting	16.00	33.28	867.20
Trade name notification	3.20	6.66	173.44
CBI substantiation	3.38	7.02	182.93
Recordkeeping	2.00	4.16	108.40
Report submission	1.00	2.08	54.20
Totals	29.0	60.20	1,568.28

Note – calculated totals may not agree to reported accuracy due to suppressed digits and/or rounding

In summary, an average of 26.00 respondents would be required to spend an estimated total of 1,568.28 hours each year to respond to PAIR rules during the period of FY 2005 through FY 2008, requiring an average of 60.20 hours per respondent.

**6(b) Estimating Respondent Costs**

This section presents estimates of the cost expected to be incurred as a result of reporting under the TSCA section 8(a) PAIR. The total annual industry cost for both reporting and recordkeeping is estimated to be \$89,593. This estimate is based on the cost of the burden estimate provided in section 6(a) above, and includes other costs associated with this ICR.

Labor costs in this report have been updated using the most recently available, revised wage rates and information on benefits costs. These wage rates are taken from the Bureau of Labor Statistics (BLS) Employer Costs for Employee Compensation Supplemental Tables, December 2006 (released on March 29, 2007), with the information extracted from Table 2, *Private industry workers in manufacturing industries, by occupational group*. This table is available on-line at <http://www.bls.gov/ncs/ect/sp/ecsuptc.pdf> in PDF format, or at <http://www.bls.gov/ncs/ect/sp/ecsuptc.txt> as text. The clerical wages are taken from the BLS data for “office and administrative support.” The technical wages are taken from the BLS data for “professional and related.” The managerial wages are taken from the BLS data for “management,

business and financial.” Labor wage rates and hourly benefit costs taken from those sources have been used to calculate the labor cost to respondents, as shown below. The hourly overhead is calculated as 17 percent of the base wage. This approach is used for consistency with Office of Pollution Prevention and Toxics economics practices, and is based on the analysis in *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, Cody Rice, U.S. EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch, June 10, 2002. This approach, which is now standard practice in this office, produces wage and cost estimates that are somewhat lower than the data and methods used in the most recent previous 8(a) PAIR ICR renewal analysis.

<b>Hourly Labor Costs</b>			
	<b>Clerical</b>	<b>Technical</b>	<b>Managerial</b>
Hourly wage rate	\$16.07	\$32.38	\$39.77
Benefit costs	\$8.20	\$16.77	\$18.83
Overhead	\$2.73	\$5.50	\$6.76
<b>Total hourly cost</b>	<b>\$27.00</b>	<b>\$54.65</b>	<b>\$65.36</b>

These labor costs are multiplied by the estimated burden hours per activity and added to any non-labor costs to develop total unit costs per report. It is estimated that recordkeeping and report submission tasks will require expenditures other than labor. Recordkeeping is estimated to require an additional \$31.63 per report for miscellaneous filing materials while report submission is estimated to require an additional \$19.04 per report for photocopying and mailing expenses. Total non-labor costs per report are estimated to be \$50.67. With an annual estimate of 54.20 reports expected, the total non-labor cost for this ICR is \$2,746 (rounded to the nearest whole dollar). Finally, unit costs per report are multiplied by the number of reports per site per year to arrive at unit costs per site (respondent costs).

### 1. Form Familiarization

The per report cost of form familiarization is:

Managerial labor: 1.44 hours @ \$65.36/hour = \$94.12  
 Technical labor: 1.92 hours @ \$54.65/hour = \$104.93  
 Cost per report = \$199.05

The per site cost of form familiarization is:

Cost per report of \$199.05 x 2.08 reports per site = \$414.02

### 2. Report Preparation

The per report cost for report preparation is:

Managerial labor: 5.5 hours @ \$65.36/hour = \$359.48  
 Technical labor: 9.25 hours @ \$54.65/hour = \$505.51  
 Secretarial labor: 1.25 hours @ \$27.00/hour = \$33.75



Cost per report = \$898.74

The per site cost of report preparation is:

Cost per report of \$898.74 x 2.08 reports per site = \$1,869.38

### 3. Trade Name Notification

The per report cost for trade name notification is:

Managerial labor: 2.20 hours @ \$65.36/hr = \$143.79

Secretarial labor: 1 hour @ \$27.00/hr = \$ 27.00

Cost per report: \$170.79

The per site cost of trade name notification is:

Cost per report of \$170.79 x 2.08 reports per site = \$355.24

### 4. CBI Substantiation

The per report cost for CBI substantiation is:

Managerial labor: 4.0 hours @ \$65.36/hour = \$261.44

Secretarial labor: 0.5 hours @ \$27.00/hour = \$13.50

Cost per report = \$274.94

Adjusted cost per report = \$206.21

(adjustment for 75 percent of reports claiming CBI)

The per site cost of CBI substantiation is:

Cost per report of \$206.21 x 2.08 reports per site = \$428.91

### 5. Recordkeeping

The per report cost for recordkeeping is:

Technical labor: 1.0 hours @ \$54.65/hour = \$54.65

Secretarial labor: 1.0 hours @ \$27.00/hour = \$27.00

Filing materials = \$31.63

Cost per report = \$113.33

The per site cost of recordkeeping is:

Cost per report of \$113.33 x 2.08 reports per site = \$235.73

6. Report Submission

The per report cost of report submission:

Managerial labor: 0.5 hours @ \$65.36/hour = \$32.68

Secretarial labor: 0.5 hours @ \$27.00/hour = \$13.50

Photocopying and mailing<sup>5</sup> = \$19.04

Cost per report = \$65.22

The per site cost of report submission is:

Cost per report of \$65.22 x 2.08 reports per site = \$133.49

The unit cost per report and unit cost per site, including a breakdown of costs by labor category, are summarized in the following table:

<b>Reporting Costs by Labor Category and Reporting Activity in dollars of cost per report</b>					
	Secretarial	Technical	Managerial	Other direct cost	Total cost per report
Form Familiarization		\$104.93	\$94.12		\$199.05
Reporting	\$33.75	\$505.51	\$359.48		\$898.74
Trade Name Notification	\$27.00		\$143.79		\$170.79
CBI Substantiation	\$10.13		\$196.08		\$206.21
Recordkeeping	\$27.00	\$54.65		\$31.63	\$113.28
Report Submission	\$13.50		\$32.68	\$19.04	65.22
Per Report Total	\$111.38	\$665.09	\$826.15	\$50.67	\$1,653.29
Note: Annual Average Reporting Cost per Respondent = \$1653 * 2.08 = \$3,438					

The average respondent is assumed to spend \$1,653 per report, or \$3,438 in total per respondent per year. As noted earlier, EPA estimates an average of 26 reporting sites and 54.2 reports per year. Over all sites, responding to PAIR rules is estimated to cost industry a total of \$89,593 per year during the period of FY 2009 through FY 2011.

**6(c) Estimating Agency Burden and Cost**

The estimated annual cost of the PAIR to the U.S. government is calculated on an annual basis. The FY 2007 cost to EPA of a full-time equivalent employee (FTE), Grade 12, Step 1 in the Baltimore-Washington pay area is \$66,767 (U.S. Office of Personnel Management Internet

<sup>5</sup> ? The figures for filing materials (item 5, \$31.63) and photocopying and mailing (\$19.04) were obtained by inflating the estimates from the previous ICR (\$28.29 and \$17.03, respectively), using the consumer Price Index for urban areas (2003 annual = 184.0; 2007 first half = 205.7).

site at <http://opm.gov>). One FTE is equivalent to 2,080 hours per year. The fully loaded FTE cost is \$106,827. The annual costs per FTE are derived by multiplying the annual pay rate by 1.6 (benefits multiplication factor). The multiplication factor used is recommended in EPA's Office of Policy, Planning, and Evaluation's Instructions for Preparing Information Collection Requests (ICRs), June 1, 1992.

Data processing costs have been updated from 1996 to current dollars using the GDP implicit price deflator from the Bureau of Economic Analysis (BEA). The BEA GDP price index series with a base of 2000 = 100 has the 1006 index at 93.859 and the 2006 index at 116.568, so the adjustment factor from 1996 to 2006 is 1.242 ( $116.568/93.859 = 1.242$ ). Data processing costs for the 1996 PAIR ICR update were estimated to be approximately \$199.56 per report. Adjusting this number to 2003 with the GDP implicit price deflator yields an adjusted data processing cost of \$247.84 per report (i.e.,  $\$199.56 \times 1.242 = \$247.84$ ). Thus, the total annual data processing cost is \$12,442 ( $\$247.84$  per report  $\times$  50.20 annual reports).

This analysis assumes that an annual average of 54.20 reports will be submitted over the three year period of FY 2009 through 2011. Personnel burden and costs associated with industry/public assistance and data processing activities have been adjusted based on that estimate. From the 1989 PAIR ICR update it has been derived that industry/public assistance required approximately 1.5 hours per report. For 54.2 reports, that works out to 81 hours or about 0.04 FTEs. Similarly, the 1989 PAIR ICR update estimated that about 3.75 hours of data processing/system support personnel time would be required per report. For 54.2 reports, that works out to 203 hours or 0.10 FTEs.

The table presented below summarizes the government's activities in developing and administrating the PAIR. The required FTEs per activity are retained from the 1996 PAIR ICR update and from the previous 8(a) PAIR ICR renewal analyses, for all activities except for the recalculation of the two categories of burden discussed in the previous paragraph.

<b>GOVERNMENT BURDEN SUMMARY</b>	
<b>Activity</b>	<b>Annual Burden</b>
Chemical nomination, review and selection	0.25 FTE
Rule development	0.90 FTE
Evaluation of rule	0.05 FTE
Industry/public assistance	0.04 FTE
Compliance monitoring	0.10 FTE
Data Processing and system support personnel	0.10 FTE
<b>Total FTEs</b>	<b>1.44 FTE</b>

It is estimated that the annual cost to the Federal Government will be \$12,442 in data processing costs plus 1.44 FTEs. At an estimated loaded annual salary of \$106,827 per FTE, the total of 1.44 FTEs will cost EPA \$153,831 in fully loaded labor cost (salaries, benefits, and overhead). This brings the total costs to the Federal government to \$166,273 annually (i.e.,  $\$12,442 + \$153,831$ ).

Below is a summary of the costs to the federal government for this information collection.

<b>Government Estimated Annual Burden and Cost Summary</b>	
Total FTEs	1.44
Loaded Cost per FTE	\$106,827
Government Labor Cost	\$153,831
Government Data Processing Cost	\$12,442
Total Annual Government Cost	\$166,273

### **6(c) Bottom Line Burden Hours and Costs: Master Tables**

#### Respondent Burden and Costs

Total respondent annual burden hours = 1,568 hours

Total respondent annual costs = \$89,593

#### Agency Burden and Costs

Agency burden hours: 1.44 FTEs = 2,995 hours

Agency annual costs = \$166,273

### **6(d) Reason for Change in Burden**

This request reflects an increase in the estimated annual burden of 988 hours (from 580 hours to 1,568 hours) from that currently in the OMB inventory. This increase is attributable to an increase in the assumed number of PAIR reports filed annually, from an average of 19.67 per year to 54.2 per year. The more recent average is based on the past five fiscal years (2003-2007) of PAIR reporting data. The annual average number of respondents (reporting sites) is 26.0, and has increased from the previous estimated average of 11.0. There is also a corresponding \$1,746 increase in associated non-labor costs (e.g., photocopying and mailing costs). These changes are adjustments.

### **6(e) Burden Statement**

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0054, is estimated to average 29.0 hours per response. According to the Paperwork Reduction Act, "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. For this collection it 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; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond

to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2007-0670, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. 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-OPPT-2007-0670 and OMB Control No. 2070-0054, to (1) EPA online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

**ATTACHMENTS TO THE SUPPORTING STATEMENT**

Attachment A	Section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607a)
Attachment B	Display Related to OMB Control #2070-0054 - Listings of Related Regulations in 40 CFR 9.1.
Attachment C	Chemical Information Rules – 40 CFR 712
Attachment D	PAIR Reporting Form (EPA Form 7710-35) and Instructions. Available electronically at <a href="http://www.epa.gov/opptintr/chemtest/pubs/pairform.pdf">http://www.epa.gov/opptintr/chemtest/pubs/pairform.pdf</a>
Attachment E	Dibenzo-para-dioxins/dibenzofurans – 40 CFR 766
Attachment F	Dioxin/Furan Report Form (EPA Form 7710-51) and instructions Available electronically at <a href="http://www.epa.gov/opptintr/chemtest/pubs/7710-51.pdf">http://www.epa.gov/opptintr/chemtest/pubs/7710-51.pdf</a>
Attachment G	Good Laboratory Practice Standards – 40 CFR 792
Attachment H	List of Chemicals Covered by Final PAIR Rules, 2004-2007
Attachment I	Consultation Meeting Notes and E-Mails