Information Collection Worksheet (ICW) – Supplemental Information

October 17, 2007

The following information is being provided to explain the requested increase presented in the Information Collection Worksheet (ICW) to the burden hours that are approved by OMB. This document provides a summary of the existing ICR approved by OMB, the currently approved burden hours, and the covered reporting activities in Part 1 below. These activities are not being changed by this ICW, the ICW only changes the burden estimate. More detailed information about the existing ICR and approved activities can be found in the Supporting Statement for the ICR[1]. In Part 2, this document then explains why we need to increase the approved burden hours through the ICW.

1. BACKGROUND (Existing ICR)

1. What Information Collection Request (ICR) is impacted?

Title: Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies
OMB Control No.: 2070-0004
EPA ICR No.: 0575.10

2. What is the current status of this ICR?

This ICR is currently approved through July 31, 2009. The annual public reporting burden for this collection of information is estimated to average 19 hours per response, with an estimated 36 total potential respondents in any year with 1 response per respondent. Other potential respondents only have to read the rule to determine if they are subject to reporting in that rule by determining whether or not they manufacture or import the listed chemical substance. The total annual reporting burden approved for this ICR is 1,278 hours.

3. What does the currently approved ICR cover?

This ICR covers the information collection activities associated with rulemakings issued under section 8(d) of the Toxic Substances Control Act (TSCA). The requirements and procedures for submitting lists and copies of unpublished health and safety studies under TSCA §8(d) are promulgated in 40 CFR part 716. The requirements apply to the specific chemical substances and mixtures that are listed in 40 CFR part 716, which is periodically amended to add chemical substances or mixtures. The listed chemical substances and mixtures include chemicals recommended for testing under section 4 by the Interagency Testing Committee (ITC) and other chemical substances that EPA (particularly the Office of Pollution Prevention and Toxics (OPPT)), or other federal agencies, identify as chemicals to assess for health or environmental effects.

[1] To view a copy of the existing supporting statement, go to http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPPT-2005-0019.

The TSCA §8(d) Health and Safety Data Reporting Rule (40 CFR 716) requires manufacturers and (if specified) processors to submit lists and copies of health and safety studies relating to the health and/or environmental effects of the chemical substances and mixtures listed in 40 CFR part 716. To comply with the reporting requirements of the rule, the respondents (manufacturers and processors) must search their files to identify any health and safety studies in their possession, copy and process the relevant studies, make lists of studies that are currently in progress, and review the studies for confidential business information. All studies submitted to EPA will be verified and the contents of the submissions recorded and inspected for the inclusion of confidential business information. Photocopies of the documents will then be prepared and distributed, based on the associated chemical identity, to program offices at EPA and/or to other federal agencies for scientific analysis. A coding form will be completed to capture certain descriptive information such as identity, document control number, confidentiality indicator, document title, document date, receipt date and chemical identity. The document will be converted to microfiche and stored for archival purposes.

EPA will use the studies to support its investigation of the risks posed by listed chemicals and, in particular, to support its decisions on whether to require industry to test chemicals under TSCA §4.

4. What is the Authority/Need for this collection activity?

TSCA section 8(d), 15 U.S.C. 2607(d), requires EPA to promulgate rules requiring persons who manufacture, process or distribute, or propose to manufacture, process or distribute chemical substances and mixtures, to submit to EPA lists and copies of health and safety studies in their possession. OPPT reviews these studies to determine the kinds of testing needed to fill the information gaps in known effects of the listed chemicals, to make decisions during the risk assessment process, and for considering control actions. Other federal agencies use the studies when they are assessing a listed chemical substance for health or environmental effects.

5. Do these activities duplicate any other collections?

No. In drafting a TSCA section 8(d) rule, EPA considers all available information, i.e. published and unpublished literature, databases, and all data available from EPA programs and offices and other federal entities. If existing data are sufficient for assessment or control purposes, EPA will not require TSCA section 8(d) reporting. However, if that information is not sufficient, or is obtained in a way that makes EPA doubt its validity, then the Agency must require the submission of non-published health and safety studies.

The health and safety studies to be submitted under the TSCA section 8(d) rule are not available from any other source. The TSCA section 8(d) rule requires the listing and submission of studies that are conducted in-house by industry or by industry contractors and not published in the scientific literature. Under the revisions to the Model Rule promulgated in September 1986, respondents do not have to list or submit any studies that have been published in the scientific literature, or submitted previously to OPPT on a non-confidential basis. Studies that have previously been submitted on a non-confidential basis to other EPA offices or programs need only be listed.

6. What information is being requested (Data Elements)?

Respondents are required to submit copies of the unpublished health and safety studies in their possession for the listed substances or mixtures. They must also submit lists of reportable studies that they initiate or, about which they know, for each of the listed substances or listed mixtures.

All submitted studies must be accompanied by a cover letter that contains the following data (40 CFR 716.30):

- Name, job title, address, and telephone numbers of the submitting official.
- Name and address of the manufacturing or processing establishment on whose behalf the submission was made.
- Identify any impurity or additive known to have been present in the substance or listed mixtures as studied, unless so noted in the study.
- Identify that the study is being submitted under Part 716.

Respondents may voluntarily choose to develop and submit robust summaries of the full toxicological study reports in conjunction with the submitted full study reports. The robust summaries should contain technical information to adequately describe the study and results, and should be written such that the information provided is sufficient to allow a technically qualified person to evaluate study results without needing to review an entire study report. Typically, a robust summary would include a description of the test substance, methods, results, conclusions, data quality description, and references associated with the full study.

List of studies shall include (40 CFR 716.35): (1) ongoing health and safety studies conducted by or initiated by them; (2) studies they know about but do not have copies of; and, (3) studies that have been sent to another federal agency with no claims of confidentiality.

For ongoing health and safety studies conducted by or initiated for the respondent, the list should include the following data:

- Beginning date of the study and anticipated date of completion;
- Purpose of the study;
- Types of data to be collected; and
- Name and address of the laboratory conducting the study.

For studies known to the respondent but for which they do not possess copies, the list should include the following data:

- Name and address of a person known to them that possess a copy of the study.

For studies previously sent to a federal agency with no claims of confidentiality, the list should include the following data:

- Title of the study;
- Name and address of the person to whom the study was sent; and
- Month and year in which the study was submitted.

7. What Respondent activities are involved?

A representative respondent would engage in the following activities in order to produce the lists of studies and required data requested:

- Conduct an initial review of the rule to determine if its company must report;
- Conduct a corporate review to identify which company sites must be searched to locate the appropriate health and safety studies;
- Search its files at each site to locate the studies;
- Compile and transcribe a list of studies being submitted, studies in progress, and studies known to exist but not known to be in the respondent's possession;
- Photocopy the studies;
- Review the studies and title lists for possible confidential business information;
- After initial study submissions, notify EPA when other studies are initiated; and
- Submit studies completed after the initial reporting period.

8. What method was used to estimate Respondent burden in the ICR?

The methodology used in estimating the burden and costs to industry resulting from the addition of chemicals to the TSCA section 8(d) rule over the next three years is based on EPA's experience with the program over the past 2 ½ decades. In general, the Agency identifies a unit burden associated with each of the respondent activities.

Unless EPA specifies otherwise, the coverage of 8(d) rules is limited to chemical manufacturers and petroleum refineries. Most firms in these industries will not manufacture a listed chemical, but many may still spend some time making that determination and reviewing the rule. Table 1 below (which is Table 1 in the ICR) provides the estimated unit burden:

Table 1. TSCA Section 8(d) Reporting Unit Burden

Collection Activity	Average Burden per Firm
1. Review of Rule	2 hours managerial
2. Site Identification	3 hours managerial
3. Site File Search	7.2 hours technical
4. Study Title Lists	1 hour clerical
5. Photocopy Studies	0.5 hours clerical
6. Robust Summaries	6 hours technical
7. CBI Review	5 hours managerial
8. Post-Reporting Period Submission	1 hour managerial; 0.5 hours clerical
Note: Not all respondents perform all activities.	

Submitting a response typically involves reviewing the rule (2 hours), site identification (3 hours), site file search (7.2 hours), preparing study title lists (1 hour), photocopying studies (0.5 hours), and CBI review (5 hours), for an average burden of approximately 19 hours per respondent. Most respondents will not submit a robust summary or a post-reporting period submission. These unit burden estimates are average values.

9. How did EPA estimate the Respondent universe for the ICR?

As explained in more detail in the ICR, the number of chemicals added to the section 8(d) reporting list has varied from year to year. Based on history for the past ten years and anticipated additions during the three year period covered by the ICR, EPA assumed the addition of a total of 300 chemicals from 2006 to 2009, or an average of 100 chemicals per year.

Assuming that the rate of response to the addition of chemicals to the section 8(d) list under this ICR is proportional to the results for 2004, then 43 percent of the manufacturers, or 34 firms (0.43 * 79 manufacturers) will submit reports each year. The 34 firms are estimated to submit a total of 170 studies annually (34 firms* 5 studies per firm). Two of these respondents (5% of 34 firms) are also assumed to submit a second response (for a newly initiated or ongoing study) after the reporting period ends.

The number of firms or studies described in the ICR are combined with the estimated average unit burden hours and cost from the ICR to present the total burden hours and cost per year. The results are shown in Table 2 (which is Table 4 in the ICR).

Table 2. Annual Respondent Cost and Burden Hour Estimates

Collection Activity	(a) Unit Burden Hours	(b) Unit Cost	(c) Number of Firms	(d) = (a) x (c) Total Burden Hours	(e) = (b) x (c) Total Cost
1. Review of Rule	2 hours	$107.64	79	158	$8,504
2. Site Identification	3 hours	$161.46	34	102	$5,490
3. Site File Search	7.2 hours	$331.78	82	590	$27,206
4. Study Title Lists	1hours	$24.47	34	34	$832
5. Photocopy Studies	0.5 hours	$12.24	34	17	$416
6. Robust Summaries	6 hours	$276.48	34	204	$9,400
7. CBI Review	5 hours	$269.10	34	170	$9,149
8. Post-Reporting Period Submission	1.5 hours	$66.06	2	3	$132
Total				1,278	$61,129
Note: Not all respondents perform all activities.					

2. RATIONALE FOR THE ICW REQUEST

10. Why is EPA requesting an increase in the approved burden for this ICR?

The total approved burden for this ICR is insufficient to cover the next TSCA §8(d) rule that will be adding a chemical category to the list in 40 CFR part 716(c). When EPA last amended and updated the existing ICR, it did not anticipate issuing this particular TSCA §8(d) rule. However, the ITC recently recommended in it's 60th report to EPA that this chemical category be added for TSCA §8(d) reporting. As a result, EPA is preparing to issue this rule shortly.

11. What chemical(s) are being added by the new TSCA §8(d) rule?

Based on the recommendation from the ITC, EPA is adding the category of “lead

and lead compounds" to the TSCA §8(d) reporting list in 40 CFR part 716 so that EPA can obtain unpublished health and safety studies that relate to the lead content of consumer products that are "intended for use by children" as that term is defined at 40 CFR 710.43 (excluding children's metal jewelry), and studies that assess children's exposure to lead from such products (including studies of bioavailability).

In adding "lead and lead compounds" to the TSCA §8(d) reporting list, EPA is adding several chemicals. Table 5 lists twelve specific chemicals or compounds that fall under that general heading, which are listed as examples in the rule. The rule is not intended to be restricted to these twelve example chemicals.

Table 3. Examples of Lead and Lead Compounds by CAS Numbers

Chemical	CAS Number
Lead (Pb)	7339-92-1
Lead acetate ($Pb(OAc)_2$)	301-04-2
Lead carbonate ($PbCO_3$)	598-63-0
Lead chloride ($PbCl_2$)	7758-95-4
Lead chromate ($PbCrO_4$)	7758-97-6
Lead dioxide (PbO_2)	1309-60-0
Lead fluoborate ($Pb(BF_4)_2$)	13814-96-5
Lead phosphate ($Pb_3(PO_4)_2$)	7446-27-7
Lead silicate	53466-66-3
Lead stearate	7428-48-0
Lead sulfate (basic)	63653-42-9
Lead sulfide (PbS)	1314-87-0

12. Who are the respondents?

Respondents potentially affected by this collection activity are those companies that import lead-containing consumer products that are "intended for use by children" as that term is defined at 40 CFR 710.43 (excluding children's metal jewelry). Using the North American Industry Classification System (NAICS) and 2002 Economic Census Data, EPA has identified the following potential respondents:

- NAICS code 339914, Costume jewelry and novelty manufacturing
- NAICS code 339931, Doll and stuffed toy manufacturing
- NAICS code 339932, Game, toy, and children's vehicle manufacturing
- NAICS code 339993, Fastener, button, needle and pin manufacturing
- NAICS code 42392, Toy and hobby goods wholesalers, establishments with product line 12812
- NAICS code 452112, Discount department stores
- NAICS code 45291, Warehouse clubs and supercenters

13. How did EPA estimate the Respondent universe for this new TSCA § 8(d) rule?

The number of firms that will be subject to this rule cannot be estimated directly. In most previous instances, the TSCA 8(d) process has addressed chemicals that are not widely used, and the focus in the analyses of those actions has been on the relatively small number of firms that manufacture those chemicals, as shown in the EPA-maintained Chemical Update System (CUS) database. In this instance, the

chemicals subject to this process (lead and lead compounds) are very widely used. But in this case the requirements of 8(d) are restricted to those companies that import lead or lead compounds in consumer products intended for use by children and those studies that relate to the lead content of consumer products that are intended for use by children or studies that assess children's exposure to lead from such products. The respondent universe was estimated based on census data on NAICS industry categories that are believed to be importers of toys and related children's products that may contain lead. The number of firms and establishments in those NAICS categories are shown in Table 4 below, which is Table 4 in the economic analysis of this rule.

Table 4. Size of the Responding Industries

Industry NAICS Code	Industry Description	Companies	Establishments or sites
339914	Costume jewelry and novelty manufacturing	651	655
339931	Doll and stuffed toy manufacturing	134	137
339932	Game, toy, and children's vehicle manufacturing	733	743
339993	Fastener, button, needle and pin manufacturing	180	185
42392	Toy and hobby goods wholesalers, establishments with product line 12812	1,310	1,389
452112	Discount department stores	39	39*
45291	Warehouse clubs and supercenters	16	16*
	Total	3,063	3,164

* Note that companies in NAICS 452112 and 45291 have many sites, but it is assumed (based on EPA's knowledge of these industries) that any reports relevant to this 8(d) request will be found at a single central administrative facility.

14. How did EPA estimate the the burden and the cost of this new TSCA § 8(d) rule?

EPA used the methods and estimates from the previous ICR analysis that were described earlier in section 1.9, but applied to the particular circumstances of this rule. The ICR estimates were modified to adjust to current wages and to reflect the estimated number of data collection related activities for this particular rule. The number of firms required to review the rule to determine whether they are subject to its reporting requirements is estimated to be about 3,000. About half of that number are expected to be required to search for reports, and about 60 reports are expected to be found. The specific burden and cost estimates for this rule are shown in Table 5 below, which is Table 5 from the economic analysis.

Table 5. Respondent Cost and Burden Hour Estimates

Collection Activity	**(a) Unit Burden Hours**	**(b) Unit Cost**	**(c) Number of Firms or sites per activity**	**(d) = (a) x (c) Total Burden Hours**	**(e) = (b) x (c) Total Cost**
1. Review of Rule	2 hours	$126.66	3,063	6,126	$387,960
2. Site Identification	3 hours	$189.99	1,317	3,951	$250,584
3. Site File Search	3 hours	$161.34	1,361	4,083	$219,584

4. Study Title Lists	1 hour	$26.40	60	60	$1,584
5. Photocopy Studies	0.5 hour	$13.20	60	30	$792
6. Robust Summaries	6 hours	$322.68	6	36	$1,936
7. CBI Review	1 hour	$63.33	60	60	$3,800
8. Post-Reporting Period Submission	1.5 hours	$76.53	1	1.5	$77
Total				14,347	$865,949
Note: Not all respondents perform all activities. Also, the ICR assumed 2.4 sites per company in the calculations of certain burden hours (e.g., Site File Search), whereas the economic analysis for this rule estimated the number of sites per company for each distinct NAICS category (see Table 4 above).					

The number of studies that will be located and submitted to EPA under this action is not known, and an error in EPA's projection could alter the burden and cost estimate. This section of the analysis provides an assessment of the degree to which that burden and cost estimate could be affected by a substantial under-estimation of the number of studies. In Table 6, the cost and burden estimates are revised under the assumption that the number of studies is 600 rather than 60, and that the number of post-reporting period submissions is ten rather than one.

Table 6. Sensitivity Analysis of Respondent Cost and Burden Hour Estimates

Collection Activity	(a) Unit Burden Hours	(b) Unit Cost	(c) Number of Firms or Activities	(d) = (a) x (c) Total Burden Hours	(e) = (b) x (c) Total Cost
1. Review of Rule	2 hours	$126.66	3,063	6,126	$387,960
2. Site Identification	3 hours	$189.99	1,317	3,951	$250,584
3. Site File Search	3 hours	$161.34	1,361	4,083	$219,584
4. Study Title Lists	1 hour	$26.40	600	600	$15,840
5. Photocopy Studies	0.5 hour	$13.20	600	300	$7,920
6. Robust Summaries	6 hours	$322.68	60	360	$19,361
7. CBI Review	1 hour	$63.33	600	600	$37,998
8. Post-Reporting Period Submission	1.5 hours	$76.53	10	1.5	$77
Total				16,021	$939,644
Note: Not all respondents perform all activities. Also, the ICR assumed 2.4 sites per company in the calculations of certain burden hours (e.g., Site File Search), whereas the economic analysis for this rule estimated the number of sites per company for each distinct NAICS category (see Table 4 above).					

This computation suggests that the burden estimate for this TSCA section 8(d) action is relatively insensitive to the estimate of the number of studies. A ten-fold error in that estimate is calculated to lead to an increase of roughly 1,500 burden hours (or less than 12 percent), and an increase of about $74,000 in cost (or less than 10 percent). The burden and cost estimates are largely determined by the estimate of the number of responding firms, and is relatively insensitive to the estimate of the number of studies.