Procter&Gamble

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May 10, 1996

Ms. Susan Krueger
Regulatory Impacts Branch
Economics, Exposure and Technology Division
Office of Pollution Prevention and Toxics
U.S. EPA
Washington, D.C. 20460

Dear Ms. Krueger:

This provides The Procter & Gamble Company's comments on the recent survey and potential impact of proposed TSCA Inventory Update Rule (IUR) Chemical Use Information (CUI) amendments. Procter & Gamble was requested to participate in this survey as an importer and manufacturer of chemicals regulated by TSCA, submitting past IUR reports. These comments have been separately given to the contractor, ICF (Ms. Anne Fahrig), on 5/6/96, along with effort and cost numbers to be used for impact analysis. We request the comments provided below be entered into any future related rule making record.

Procter & Gamble supports CMA's position on TSCA IUR-CUI, which will be submitted separately to EPA. After participating in the survey and reviewing the draft forms, our position is that benefit to the public under TSCA has not been demonstrated to justify the anticipated exorbitant cost and burden to industry. Procter & Gamble already practices effective product and chemical risk assessment and management before choosing to use chemicals or manufacture products for marketing.

Collection of this data will not help industry better protect workers or the public from exposure or effects of chemicals and products, and is inconsistent with the Paperwork Reduction Act and President Clinton's and EPA's efforts to pursue "common sense" regulations. This proposal is also inconsistent with recent revocation of previous related regulations (CAIR) based on Regulatory Reinvention and reduction of unnecessary regulations.

P&G believes that EPA should use other currently publicly available data to set priorities and manage chemical risk and should not create new regulatory burdens. We also strongly encourage use of a pilot project to test the effort estimate and CBI issues projected via this survey, before wide scale implementation of this or any related data collection requirements.

Contain NO CBI

P&G especially urges that EPA's General Counsel (GC) be asked to specifically review the legal authority for inclusion of exempt non-TSCA uses and its expansive reach of section 8 authority in both the survey and proposed IUR CUI form. Since the court decision in the Corrosion Proof Fittings case would be applied in deciding whether such a mandatory reporting duty is arbitrary, we urge OPPT to get early and close examination of the detailed demands from GC.

Two issues that GC needs to explore are: 1) the arbitrariness of demanding information that would be inaccurate or misleading, and for which alternate sources abound, a decision which poses direct conflicts with the executive order on paperwork and the revised Paperwork Reduction Act; and 2) the inability of a penalty-based enforcement system to deal under TSCA 8(a) authority with overly vague requirements that command estimation for which companies do not have the knowledge and for which customers, not the chemical company, have the data.

Our Company was very involved with the Eckhardt subcommittee debates on section 8's coverage during TSCA legislative development, and the history of section 8 does not support the command and control approach for this mandatory survey of the downstream exposures and uses. We believe GC's close attention to these details is imperative.

Key Comments

1. Data requested in the draft form and discussed in the survey adds no real value for risk assessment and risk management by industry or the agency. Data should only be collected that helps the agency make risk- related determinations.

Use and maximum weight % are not good surrogates for determining exposure or risk. Collecting this data is very costly, could greatly overestimate potential risk, and be misleading to the "public". The gap between the statutory purpose of TSCA and the collection burdens for the proposed amendments to IUR are too wide to have this data collection be sustained. We strongly request OPPT to query the Paperwork Reduction Act experts at the Office of Information and Regulatory Affairs (OIRA) of OMB on this point as we understand that this is also their position.

EPA recognizes that production volume and exposure are not correlated; and that other factors may heavily influence exposure. However, use (via functions and SIC codes) and max. wt. % do not provide the data EPA is looking for to estimate exposure. Exposure estimates depend on a number of factors; concentration in product is just one aspect. Physical form, packaging, and conditions of use (precautions, protective clothing/equipment) play a significant role in assessing exposure.

For example, a chemical used in a dusty granule would have quite different exposure than the same chemical in a solid, capsule, pellet, or liquid form. In the case of the dusty granule, dust control systems and inhalation potential may be the biggest risk concern. In the case of a liquid or cake solid, potential for and control of dermal exposure may be the biggest concern.

Child resistant packaging for consumer products, metered dosing, "pouching" and "encapsulation", closed manufacturing systems, lock out systems, and other exposure controls can minimize potential exposures. Function codes and max. wt. % will not provide the information EPA desires to prioritize risk.

Collecting information as planned may result in the public receiving communications from EPA that a chemical or product type is of concern, while engineering and safety design of dosing, packaging, physical form, and other manufacturing controls have, in reality, eliminated these concerns.

2. The value of collecting this chemical use and worker exposure information does not justify the significant effort and cost to provide this information to EPA.

Based on our review, the additional data elements requested would increase our current paperwork burden by **greater than 3000%** (a one page form for 10 chemicals would change to a three page form for each chemical).

During the last IUR report, our company reported on a total of 184 chemicals, with an average of 20 hours effort per manufactured chemical, and 100 hours per imported chemical reported. The proposed additional reporting burden would result in a significantly greater reporting burden for both manufactured and imported chemicals (orders of magnitude greater), not counting the additional system development costs.

The effort and cost to set up special data systems to record and store this data in case of future EPA audits is estimated at **$200,000+**. This includes the cost of hardware, software, and training, and a minimum of 1500 hours development effort.

Assuming the same 184 chemicals are reported in the next IUR report, the cost burden is estimated to increase **4200%**, as shown in the following table. This is a **very conservative** estimate based on information for 10 SIC/function code combinations per chemical.

Many chemicals will have many more combinations than 10. We believe the range of combinations could be from 2 to 30. This range would result in an increase of effort of **2500-25,000%** for manufactured chemicals (20 hours increases to either 500 or 5000 hours per chemical). Effort would increase from **500 to 5000%** for imported chemicals (100 hours increases to 500 or 5000 hours per chemical).

When the TSCA IUR CUI survey is presented to OIRA for PRA review it is extremely important that the foreign, non-US time burdens also be made very clear to OIRA. Translation, explanation and interpretation will be needed for any non-US participants in the information gathering process. We do not have specific figures, but this burden is geometrically greater than the costs of a US firm using its experienced English-speaking employees to understand the new reporting forms.

Summary of Impact of Proposal

Data	1994 IUR		Future Proposed IUR	
Effort per chemical (based on **10** SIC/function code combinations)				
	Hours	Cost ($)*	Hours	Cost ($)
Manufactured	20	1200	2500+	146,000
Imported	100	5800	2500+	146,000
System Needs	---	---	1500+	200,000+
Cost for total IUR report (based on 10 SIC/function code combination, 184 chemicals)**				
Manufactured	1800	110,400	230,000	13,407,000
Imported	9200	536,300	230,000	13,407,000
Total Hours	11,000	----	461,500	
TOTAL COST ($)***	---	638,200	---	27,014,000

Notes:

* Hrs. per chem. X technical cost (EPA uses $58.29/hr)

** Assumption: 1/2 imported (92 chemicals); 1/2 manufactured (92 chemicals)

*** Total = cost imported + cost manufactured + system cost

3. The data requested is not likely to change substantially over short time periods such as 2 to 4 years. If rule making proceeds, a more limited data set should be collected less frequently.

Market data is fairly stable, so a snapshot of a particular chemical at a point in time could have value in understanding potential for exposure. However, collecting this data every 2-4 years would be a significant effort, without significant benefit. We recommend that several other options be explored:

-Collect data on only 2-3 chemicals per year, on a priority basis (perhaps prioritize by Section 4), or

-Collect some exposure related data on all IUR reportable chemicals on a less frequent basis than every 4 years, since significant changes are not likely to occur more frequently, and EPA will require extensive time to make best use of the data collected, or

-Significantly pare down the data set to be collected to no more than 2 or 3 useful data items for all IUR chemicals, and do this no more frequently than once every 4 years (see OPTION in Attachment 1).

4. If rule making proceeds, we strongly recommend a voluntary pilot project of 2 or 3 chemicals to better assess the costs and benefits of any IUR CUI proposal. EPA's gross underestimate of the effort to respond to this survey supports the need for a pilot study before any final data collection rule is proposed.

Data provided to the contractor represents our best estimate, given a very short amount of time to clarify definitions used in the survey, sketch out several manufacturing and importing scenarios, and calculate effort involved. A pilot study would provide a more realistic understanding of costs and potential benefits, data quality issues, practicalities of managing the immense amounts of data involved, and EPA's capacity to process, manage, and protect the large amount of anticipated CBI information.

The cover letter to the survey estimated a total time of 2.5 hours to fill out the survey, and 0.5 hours to respond to the contractor. Based on the resources that needed to be involved with this issue to provide a reasonable estimate, our company spent a total of at least 30 hours preparing a response to the survey (including clarification of definitions and assumptions to base estimates on), and 1.25 hours with the contractor. This effort does not include time to prepare and review internally these written comments on the survey and proposed IUR form changes.

If the survey itself required 10 times the effort estimated to prepare a response, it is reasonable to assume EPA estimates for collecting the data and justifying CBI could also greatly underestimate the effort. A pilot study would either allay these concerns, or help clarify which data elements were most difficult and time consuming.

5. We recommend that EPA analyze results of the voluntary use and exposure data collections and other public data sources to determine if those sources could meet EPA's needs to understand exposure issues.

Our company participated in a voluntary use and exposure data exercise which collected some overlapping data elements with the proposed IUR CUI. Analysis of the usefulness of this data, and its cost/benefit and impact on prioritization and risk assessment/management should be done before proceeding with IUR CUI proposals.

Other data sources should be reviewed that are readily accessible to EPA, do not require CBI protection, and provide information on processing, exposure issues, and end uses. These sources include: Chemical Economics Handbook, U.S. Dept. of Commerce, Bureau of the Census, International Trade Administration, industry trade journals profiling chemical production volumes and uses in aggregate, various chemical technology encyclopedias and handbooks, and existing EPA data bases.

The Paperwork Reduction Act reviewers at OIRA will be likely to ask, with so very much aggregated chemical data available, how can the OPPT justify the additional new burden-hours in light of PRA and the executive order?

6. "Don't Know" needs to be an acceptable answer for many of the questions. Industry should not be expected to report data which is not currently in its possession or control.

Other TSCA requirements such as 8(d), 8(c), and 8(e), Section 5, and current 8(a) and 8(b), require reporting to EPA of data "in your possession" or which you are knowledgeable about. If TSCA IUR CUI proceeds, it should not create a new standard for data gathering for industry (e.g. fishing for customer SIC codes or function codes). Industry should only be obligated to report data which is in its possession or control. This is a mandatory report that carries penalties. It must allow accurate "don't know" answers from companies and it cannot, under the Paperwork Reduction Act, simply dump the burden of secondary surveying upon the regulated companies.

7. Fewer production volume ranges should be requested to minimize CBI claims.

We propose 3 ranges as an alternative to the proposed 7 ranges as follows (assuming a change in reporting threshold to 25,000 lbs/yr):

25,000 to 250,000

250,000 to 25,000,000

25,000,000 to 2,500,000,000.

As currently stated, we would claim most of our chemical production ranges as CBI. With fewer and broader ranges, these claims would drop significantly. While P&G does not support use and worker exposure reporting, for reasons discussed above, if IUR is broadened to include CUI information, the threshold for additional high effort information should be increased to at least 1 million pounds.

8. Simplify the data set and reduce industry burden by not requesting SIC codes.

Reporting broad categories of use (created without overlap or duplication) would be much simpler than reporting function and/or SIC codes. Reporting on all the combinations of SIC and function codes will create a complex data set with minimal value. Keep the "big picture" in mind to reduce potential impact.

9. Instead of requesting data on all uses, request data on only the top (by either volume or amount of exposure) several uses.

This will also reduce effort for industry, and allow EPA to focus.

10. Repackaging appears to fit better under nonincorporative than incorporative uses.

According to EPA's definitions, incorporative means the chemical is further reacted, or processed into a mixture, either at the reporting site, or at another internal or external site. Nonincorporative was defined as sale of the bulk product "as is" for direct use (e.g. solvent sold as a degreaser). Repackaging would fit the second definition better than the first.

11. As defined, most of industry would have incorporative, not nonincorporative uses.

Even consumer products like antifreeze, which are largely ethylene glycol, take a basic chemical and modify it with processing aids, colorants, stabilizers, and other components to meet consumer performance and safety needs. Therefore, many industry sites would have very few nonincorporative uses. A better way to define this would be to report all internal company incorporative uses, and report all external commercial distribution as nonincorporative uses, since a supplier would not have much data on downstream uses.

Even repackaging, which we see as nonincorporative, downstream could result in incorporative uses, with customers using the repackaged chemical for further formulation or processing.

A confusing aspect of the incorporative/nonincorporative issue is that the nonincorporative section provides mixture ranges, while the definition suggests that only "neat" or "pure" bulk product fits the nonincorporative category (e.g. 100%). This needs to be clarified.

12. The survey and form, as presented, could result in duplication of reporting and confusion in "public" understanding of the data.

It would be arbitrary to have a program that claimed to improve public understanding that consciously allowed duplicative, confusing reports that mislead the public. Chemicals reported in Part 2 (manufactured) could also be reported in both Part 3 (incorporative) and Part 5 (end-use). Over-reporting could result in consumer concern over exposure when such concern is not justified.

In addition, production volume in Part 2 could cover both TSCA and nonTSCA end-use. Currently these numbers are not separated by some companies for IUR reporting due to the difficulty of tracking. Since EPA only has authority to deal with TSCA regulated uses in IUR reporting, Part 5 volumes could be as low as 50% of the Part 2 numbers, based on chemicals with many FDA or FIFRA regulated uses. This may be confusing to those looking to the data to understand potential exposure issues.

13. Definitions for Function Codes and End-Use Categories include many nonTSCA categories (e.g. "sanitizers", "cosmetics and toiletries") which are not subject to IUR reporting.

The agency General Counsel's position after the court decision in the Corrosion Proof Fittings case takes into account what the terms of TSCA allow, and TSCA excludes these statutorily excluded uses. Therefore the survey and data collection should NOT mandate something the law cannot mandate, and the survey should not include any reporting of non-TSCA uses. We urge that GC's views be sought before any movement on this controversial expansion of jurisdiction.

14. Many of the categories in the end use section (Part 5) overlap (e.g. automotive care products and glass/ceramic products; polishes and sanitation and soaps and detergents).

Effort will be wasted trying to determine where a chemical or product "fits" and the resulting data will not provide EPA what is needed to assess exposure or prioritize risk.

15. Eliminate imports from this requirement to streamline the process considerably.

Current data bases are not set up to provide chemical specific data by CAS #. Focusing on manufactured and not imported chemicals could reduce effort for expanded reporting.

Commercial data bases are likely to be set up by brand code or product formulation, not by specific chemical. Any one chemical can be formulated into hundreds of products or submixes used in products. Breaking down formulas of complex mixtures and then aggregating data that needs to be reported takes hundreds of hours. Site reporting tends to be less complex today than reporting of import data, which requires more data processing and manual compilation. Proposed changes to the IUR as reflected in the survey and form would significantly increase effort for both manufactured and imported chemicals to 5-250 X current effort. Eliminating imported chemicals from this expanded reporting would greatly simplify the process.

16. The amount of time spent on CBI issues would vary significantly based on the chemical-whether it was "new" and needed protection of site and chemical identity, or required less protection (e.g. production volume only).

To meet proposed EPA CBI standards (no boilerplate) would require 20+ hours for management and legal for each area needing up front substantiation. For more typical chemicals, 3+ hours to work CBI issues is estimated. These numbers were factored into our survey response.

Most of the data in Parts 3 through 5 would be claimed CBI, yet the survey did not address the effort involved with dealing with the CBI issues for these parts.

17. The actual IUR printed form should be set up so that a specified commonly used font and type size can be easily used to produce printed copies for submittal.

P&G was not able to use previous IUR printed forms with printing via our word processors, because the form spacing and fonts available did not correspond. Preparation of the printed forms required manual typing and substantial rework. Setting up future forms to easily accommodate both electronic and computer generation of printed forms would help companies reduce effort. Printed copies are needed for legal and audit reasons.

18. Assumptions, definitions, and ranges need to be clarified throughout the survey to help industry respond, both at this stage, and to future draft proposed forms.

Effort estimates depend greatly on the assumptions and definitions used, which were not very clear. Substantial time was spent trying to understand EPA's assumptions and definitions. Lack of clarity in the future will lead to confusion in reporting and lower the value of the data collected.

Exposure in particular was a category of concern. EPA considered "exposed" to include workers in the area on a regular basis. Since many industrial systems work on a closed or remote-controlled system basis, control tower operators (near the production area) do not experience what most would consider "exposure".

Maintenance workers, logistics workers unloading trucks, and analytical chemists collecting Quality Control samples could experience more "exposure", but this would occur either infrequently or in very small amounts. Chemical clearance procedures prior to exposure following Responsible Care and OSHA guidelines ensure this exposure is acceptable.

In addition, many typos on the proposed ranges were found throughout the survey. Feedback was provided to the contractor.

Thank you for your consideration of these comments, and feel free to contact me with any questions or clarification as needed.

Sincerely,

Maury Bandurraga

Maury Bandurraga, Ph.D.

Manager, Corporate Regulatory and Government Affairs

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cc: Scott Sherlock, EPA, Anne Fahrig, ICF, Charles Walton, CMA

Attachment 1

OPTION to Simplify TSCA IUR CUI Data Collection

Recommendation: Report on only manufactured chemicals (not imported) with information available for 1 reporting site: (e.g. Chemical A at Site X):

-Production Volume Estimate: (Total = 100%)

% used as a feed stock to form another chemical on site

% processed internally in a mixture on site

% "used" internally "as is" on site

% processed, reacted, or" used" internally at other company sites

% used externally (either processed or reacted or "used")

Other (state what is known)

-List Top Three Categories of Commercial and Consumer End Use from Table Provided

(with clear broad categories (without overlap) related to exposure potential; create categories with stakeholder input)