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Comments on
TSCA Inventory Update Reporting Modifications: Proposed Rule
EPA-HQ-OPPT-2009-0187
75 Federal Register 49656-49707 (Friday, August 13, 2010)
Submitted October 12, 2010

Summary

The undersigned organizations hereby submit the following comments on EPA's proposed rule to make modifications to its TSCA Inventory Update Reporting rule. We strongly support both the intent and the substance of most of the changes proposed by EPA. While the agency clearly faces certain major constraints in its current legal authority and resource capacity that can only be remedied through substantive legislative reform of TSCA, we believe that the changes proposed by EPA would, within the limits of its current statutory authority, both significantly advance EPA's ability to manage the safety of chemicals in U.S. commerce, and enhance market and public confidence in EPA decisions made based on information it receives from industry.

Robust information is the lifeblood of a sound chemicals management system. Government needs access to comprehensive, reliable information to inform policy, programmatic and regulatory decisions it must make to carry out its mission. The market needs access to such information to inform the myriad decisions made every day by producers, sellers and users of chemicals and products and materials made using chemicals. And researchers, the public and groups that work in the public interest need access if they are to have confidence in,

and be able meaningfully to contribute to, decisions and actions taken by government and the private sector.

EPA's Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) rule is one of the very few means by which the federal government can obtain and provide public access to robust information on the identity, production, processing and use of so-called "industrial chemicals."[1] TSCA Section 8(b) provides EPA with broad authority and a mandate "to compile *and keep current* an inventory of chemical substances manufactured or processed in the United States" (emphasis added), and Section 8(a) establishes EPA's authority to require manufacturers (including importers) and processors of chemical substances to report information "as the Administrator may reasonably require." Unfortunately, the IUR has been severely hobbled as a result of provisions in implementing regulations that have constrained the scope and frequency of reporting of chemical information by industry, and have unduly restricted public access to the collected information.[2]

On August 13, 2010, EPA proposed a number of significant modifications to the IUR rule (75 Federal Register 49656-49707). As detailed in our comments below, we are particularly supportive of the following proposed modifications, although for a number of them, we propose further changes that we consider essential to EPA's ability to fulfill its mandate under TSCA:

- Requiring electronic reporting – essential to improving accuracy, reducing burdens to both EPA and industry, and speeding EPA's provision of public access to chemical information.
- Requiring reporting for any chemical the production or import of which exceeds the reporting threshold in any year of the reporting cycle, rather than only a single year in each cycle, as currently required – essential to effectively capture the substantial year-to-year fluctuation in production/import volumes that in past IUR reporting cycles has yielded a very incomplete account of chemicals actually in commerce at a given time. ***We believe it is also essential that this change in the reporting trigger be applied in the next reporting cycle taking place in 2011***, rather than being postponed until the cycle after the next, as EPA has proposed.
- Eliminating the 300,000 pounds/year/site threshold for reporting processing and use information – essential to providing EPA and the public with critical

[1] The term "industrial chemicals" is used to refer to chemical substances that fall under the jurisdiction of the Toxic Substances Control Act (TSCA). It is not intended to imply that such chemicals are only used in industrial applications; many such chemicals are found in commercial and consumer products.

[2] Environmental Defense Fund. 2009. "Across the Pond: Assessing REACH's First Big Impact on U.S. Companies and Chemicals," prepared by Richard A. Denison, Ph.D., Senior Scientist. (January). (www.edf.org/AcrossThePond) Environmental Defense comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (70 Fed. Reg. 3658, 26 January 2005), Docket ID No. EPA-HQ-OPPT-2004-0106, accessible at www.regulations.gov (search for docket number).

information for evaluating the potential for release of and exposure to chemicals in commerce.

- Eliminating the 25,000 pounds/year/site threshold for reporting under the IUR for certain chemicals for which EPA has cause for concern about their potential hazards, exposures or risks – essential to ensuring that information is available on chemicals that could pose health or environmental concerns at levels of production or import below the threshold that would apply to most chemicals. We believe, however, that the criteria EPA proposes to use to identify such chemicals need to be expanded to include other chemicals known or suspected of possessing significant hazard, exposure potential or both.
- Requiring reporting of production or import volume for each year of the reporting cycle – also essential to effectively capture the substantial year-to-year fluctuation in production/import volumes that was missed in past IUR reporting cycles, thereby skewing the picture of how many and which chemicals are actually in commerce at a given time and at what levels of production or import.
- Requiring reporting of the volumes of a reported chemical used on-site and exported, and indicating whether an imported chemical is physically present at the reporting site – essential to increasing the accuracy and utility of reported production/import volume information.
- Enhancing the scope and utility of the indicators of industrial functions, industrial sectors, and commercial and consumer uses reporters must designate, including requiring those who select "other" to provide a specific description of the function, sector or use category – essential to eliminating the extensive non-reporting or use of an unspecified "other" designation in the last IUR reporting cycle.
- Replacing the "readily obtainable" standard EPA had applied to the reporting of processing and use information with the more common "known or reasonably ascertainable" standard – essential to eliminating what became a major loophole in the last IUR cycle that severely limited the processing and use information EPA received from industry.
- Restricting conditions under which submitters can claim information to be Confidential Business Information (CBI), and where such claims are made, requiring upfront substantiation of the claims – essential to reducing abuses of CBI claims and increasing the amount of submitted information that is publicly accessible.
- Increasing the frequency of reporting from the current 5-year cycle to a shorter cycle – essential to more accurately capturing information on the chemicals actually in commerce at a given time. As the best way to respond to the well-

documented large fluctuations in production, while optimizing both the amount of information reported and the frequency with which it is reported, we support shortening to a 3-year cycle. This modification should be coupled with reporting triggered by an exceedance of the production volume reporting threshold in any year of the cycle, and with an obligation to report annual production volume information for each year of the cycle for any reportable chemical. All three of the following elements in combination are essential to define the reporting cycle.

EPA also requested comment on additional possible modifications, several of which we strongly support:

- Reducing the reporting threshold from the current level of 25,000 pounds/year/site, at least to the previous threshold of 10,000 pounds/year/site or some other level. We support significantly lowering the threshold, and believe EPA should strongly consider lowering the threshold to 1 metric ton (2,200 pounds), thereby harmonizing its reporting system with that of the European Union under its REACH Regulation.
- Enhancing the exposure data that EPA obtains from manufacturers and importers to more closely mirror that received for new chemicals under TSCA Section 5, facilitating EPA's ability to conduct screening-level exposure assessments. We comment further below on the specifics of EPA's proposed option, specifically the issues of requiring such additional reporting for a limited number of chemicals at a time, and of collecting such information using any of several possible mechanisms, one of which would be via the IUR.
- Requiring processors to report exposure-relevant information about their own processing and use of chemicals that are reported under the IUR. While TSCA's Sections 8(a) and 8(b) explicitly provide EPA with authority to require reporting by processors, EPA's IUR rule has never done so and has instead limited reporting to manufacturers and importers. We believe that extending reporting requirements downstream to processors is essential to ensure EPA obtains robust processing and use information, given that manufacturers and importers frequently have only limited access to such information for their chemicals.

General comments

Criticality of robust production, processing and use data to risk-based decision-making: The above changes being proposed and considered by EPA are essential, especially if it is to continue to rely primarily on a risk-based approach to addressing chemical health and

environmental safety. Only if robust, comprehensive information on the identity, production, processing and use of chemicals sufficient to characterize and accurately assess exposure is available, will EPA's decisions – and the market's and the public's confidence in those decisions – be sufficient. Reliance on risk-based decisions is perhaps the most prominent of all of the chemical industry's talking points about chemicals management. So, if the chemical industry is serious about wanting a risk-based system that will actually restore the confidence of its customers as well as the public in regards to the safety of chemicals, it needs to provide robust chemical production, processing and use data. Under TSCA, the only routine means for EPA – and for that matter the entire Federal government – to collect chemical production, processing and use data is the IUR.

Chemical information reporting imposes a cost burden on industry, of course. But industry also stands to benefit from effective government policies and programs that provide the public and market with greater confidence in the safety of chemicals. Some companies subject to the EU's REACH Regulation (under which the first registration deadline is rapidly approaching) seem to be increasingly recognizing that the mandatory information requirements of that regulation can yield benefits that more than offset any cost burdens. Case in point: A new report[3] by the German chemical industry trade association VCI discusses implementation of the Global Product Strategy (GPS) of the International Council of Chemical Associations (ICCA), of which the American Chemistry Council (ACC) is the U.S. representative.

The report touts the efforts of companies like BASF, Dow Chemical, Bayer and Evonik (formerly Degussa) to meet market, government and public demands for more chemical information and evidence of safety. It quotes Dr. Klaus Engel, Chairman of Evonik (which also operates here in the U.S.): "The data requirements under REACH are enormous. While some used to consider this a bother, for GPS it's now a blessing."

Engineered nanomaterials: We note that EPA's proposal makes no mention nor provides provisions specific to an important, critical emerging class of chemicals subject to TSCA: nanomaterials. The Government Accountability Office (GAO) recently recommended that EPA consider revising the IUR to better address nanomaterials.[4] GAO noted in particular the need for periodic reporting as required under the IUR, in contrast to the one-time reporting traditionally required by reporting rules issued under TSCA Section 8(a), which EPA has indicated it will use to address nanomaterials. We understand it is EPA's intent to propose a requirement for periodic reporting when it proposes its nanomaterial-specific Section 8(a) rule,

[3] VCI. (2010). "Product Stewardship: Think global – and act global: How the German chemical industry implements Global Products Strategy (GPS)." (January). P. 20. (http://corporate.evonik.com/sites/dc/Downloadcenter/Evonik/Corporate/en/Chemicals/100115_GPS%20ChemieReport%20spezial_GB.pdf.)

[4] Government Accountability Office. 2002. "Nanotechnology: Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk." (May). Pp. 49-50. (http://www.gao.gov/new.items/d10549.pdf.)

to occur either under that rule or as a further modification to the IUR. We therefore defer further comment on this important issue in the present context, while emphasizing how essential it is that EPA promptly provide a means to ensure robust, periodic reporting of nanomaterials in commerce.

Environmental Defense Fund (EDF) analyses provided and referenced in these comments: In the course of developing these comments, EDF conducted two analyses, summarized here and provided in more detail in Appendices A and B, that are germane to multiple aspects of the proposed rule. The first is EDF's analysis of the degree of fluctuation observed in the chemicals and production volumes reported between the 2002 and 2006 IUR reporting cycles (Appendix A). The second is some findings from EDF's review of the Economic Analysis for the proposed rule (Appendix B).

Fluctuations Analysis: Fluctuations that occur in the composition and reported production volumes for chemicals on the IUR witnessed between the 2002 and 2006 reporting cycles expose the inadequacy of the current reporting requirements. EPA is not able to obtain information using single-year reporting in a 4 or 5-year reporting cycle with a reporting threshold of 25,000 pounds/year to state within any confidence which chemicals are actually in commerce above the reporting threshold or in what quantities, because available evidence indicates that year-to-year fluctuation is substantial and information on chemical production in the intervening years is completely unavailable.

EDF's analyses of data reported in the last two cycles found the following dramatic indicators of the extent of fluctuation:

- "Disappearances:" About 32% of the organic chemicals reported on the 2002 IUR do not appear at all on the 2006 inventory. This includes more than 400 organic high production volume (HPV) chemicals that had been reported being produced in aggregate above one million pounds/year, a finding that cannot possibly be explained by the increase in the reporting threshold to 25,000 pounds/year/site.
- "Appearances:" About 26% of the chemicals reported on the 2006 IUR do not appear on the 2002 IUR, including more than 200 organic and 300 inorganic HPV chemicals.
- For chemicals reported on both the 2002 and 2006 IURs:
    - The aggregate production volume range (e.g., 1 to 10 million pounds) published by EPA changed for about 30% of chemicals, with the range increasing in 2006 relative to 2002 for 17% of the chemicals and the range decreasing for 13%.
    - Of the chemicals that showed an increase from 2002 to 2006 in the production volume range, 16% were inorganic and 84% were organic.

- Of the chemicals that showed a decrease from 2002 to 2006 in the production volume range, 2% were inorganic and 98% were organic. The lower percentage of inorganic chemicals decreasing compared to the percentage increasing from 2002 to 2006 is explained by the fact that, while some inorganics were reported on the 2002 IUR, they were first required to be reported only in 2006.
- For 10% of the chemicals, the reporting range changed by more than one range (6% increased by two or more ranges, while 4% decreased by two or more ranges)

Appendix A provides further detail on these analyses.

Findings of EDF's review of the Economic Analysis: The Economic Analysis prepared for the Proposed IUR Modifications Rule (EPA, 2010), hereinafter referred to as the "2010 Economic Analysis," puts undue weight on the expected social costs and not enough on the considerable expected benefits of the proposed modifications. The Analysis does not attempt to estimate the monetary value of the benefits, and uses outdated information to extrapolate future costs to industry, thus risking considerable margins of error.

Furthermore, the methodology for the analysis likely overestimates the burden and cost to industry in several ways:

- It uses a 1996 industry survey to estimate the burden, failing to account for major changes in the availability and sophistication of Information Technology and in the structure of the regulated community in the intervening 14 years.
- It does not incorporate a sliding scale to estimate efficiencies gained from the first cycle to future reporting cycles.
- It fails to include efficiencies gained from more frequent collection and reporting of information that relate to factors such as reduced staff turnover and retention of rule familiarity and information transferable from one collection or reporting period to the next.
- It likely overestimates costs that would result from reducing the reporting threshold from 25,000 to 10,000 pounds/year/site, because the costs are based on older information that may not sufficiently account for subsequent industry consolidation.

EDF's review of the 2010 Economic Analysis is presented in more detail in Appendix B.

Detailed comments

Our detailed comments below follow the order and the lettering/numbering that EPA used in Units III and V of the August 13 Federal Register notice. Where we do not offer comment on particular aspects of EPA's proposals, those items are omitted in the sequence below.

III. Modifications Affecting All Manufacturers (Including Importers)

B. **Electronic reporting:** EPA is proposing to introduce mandatory electronic reporting to address the major errors and inefficiencies associated with allowance for paper submissions in past IUR cycles.

We strongly support the implementation of the mandatory e-IUR reporting system, which is more than justified by the significant decreases in submission burden and cost for the submitters and the Agency alike. The Economic Analysis for the proposed rule (reference 15 in the Federal Register notice) amply illustrates that electronic reporting will significantly increase the overall efficiency of the IUR. A streamlined process will also allow EPA to make information available more quickly for use by both the Agency and the public.

EDF has had firsthand experience with the problems resulting from the major delays in publication of the 2006 IUR data. For example, we were forced to rely on data from the 2002 IUR to conduct an analysis for a major report we issued in September 2008,[5] two years after EPA had collected the 2006 data, because those data had not yet been made public. We had to re-analyze data and re-issue our report[6] when the initial 2006 dataset was finally released on December 30, 2008 – only to have that analysis rendered out-of-date by the fact that several hundred chemicals reported in 2006 were not included in the initial release because of errors in scanning and manually entering data from submissions received by the agency in paper copy. In another prominent, if older, example, EPA's own HPV Chemical Challenge, launched in 1998, had to rely on a list of HPV chemicals reported in 1990 because neither 1994 nor 1998 IUR data were available for use. This resulted in large numbers of chemicals being removed from the sponsorship list under the program – at massive administrative costs to EPA, participating companies and other stakeholders – because they were not reported at HPV production levels in later cycles, as well as large numbers of chemicals avoiding being subject to the program because they had not been reported at HPV levels in 1990 but were so reported in later cycles.

[5] Environmental Defense Fund. 2008. "Across the Pond: Assessing REACH's First Big Impact on U.S. Companies and Chemicals." Prepared by Richard A. Denison, Ph.D., Senior Scientist. (September).

[6] Environmental Defense Fund. 2009. "Across the Pond: Assessing REACH's First Big Impact on U.S. Companies and Chemicals".

C. **New definitions:** EPA is proposing to modify the definition of the term "consumer use," to remove current restrictions involving where a consumer would actually use the product.

We support this change, as the current definition unduly and unnecessarily limits the applicability of this term.

D. **Modification of triggers and thresholds for reporting:**

1. EPA is proposing to modify the trigger for reporting so as to require reporting if the production or import of a chemical exceeds 25,000 pounds/year at a single site during *any year* of the cycle starting after the last principal reporting year. This amendment would take effect in the cycle *after* the 2011 reporting cycle.

In the FR notice, EPA cites ample evidence of the need for this modification:

- Changes in which chemicals are reported from one cycle to the next that amount to as much as 30% of all reported chemicals;[7] that is, up to 30% of the chemicals reported in one cycle are not reported in the next, and instead are "replaced" by different chemicals not reported in the previous cycle that together comprise up to 30% of all of the chemicals reported in the later cycle.
- Large changes in the composition from one cycle to the next even of chemicals reported at production volumes exceeding one million pounds per year (so-called high production volume or HPV chemicals), as we described in section B above.
- Comments from industry representatives in the context of other EPA programs in which they themselves argue for reporting periods spanning longer times because the shorter time periods would misrepresent the chemical substances that are currently in commerce.

EDF has conducted its own comparison of the chemicals reported in the 2006 and 2002 IUR cycles, which corroborates and extends EPA's analysis and makes clear that the problems with cycle-to-cycle fluctuations continue to be seen even in the latest IUR data. See EDF's analysis in Appendix A of these comments.

[7] See 75 Federal Register 49664, as well as data discussed in the following report: EPA Office of Pollution Prevention and Toxics, "How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?" Broader Issues Work Group (BIWG), National Pollution Prevention and Toxics Advisory Committee (NPPTAC). October 6, 2005. Pg. 4. (http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf.)

EPA rightly concludes that the current IUR's use of a "1-year snapshot"[8] provides a grossly inaccurate representation of chemicals in commerce. We support EPA's proposal to consider the production volume from intervening years between principal reporting years to determine whether a chemical triggers a reporting obligation in the principle reporting year. This modification would help to reduce the information gaps present in the current IUR by incorporating information from the years between reporting cycles. However, as we discuss in more detail in section V.4.iii below, using a threshold of 25,000 pounds/year/site to trigger reporting allows far too many chemicals not to be reported.

While we support EPA's proposal to modify the triggering mechanism for reporting, we oppose its proposal to delay implementation of the new approach until the cycle after the 2011 reporting cycle, which would perpetuate the current distorted picture of chemical production in the U.S. for up to as many as 5 more years. A major point of contention in both EPA's current chemicals management program (e.g., witness the discussion of the pros and cons of EPA conducting a so-called TSCA Inventory reset) and in the debate over TSCA reform centers on the number of chemicals presently in commerce, to which any programs or new legislative provisions would apply. Gauging the health, environmental and economic benefits and costs of any step EPA is now taking or could take under its current or any new authority is made exceedingly difficult by the lack of clarity on this basic fact of how many chemicals are actually in commerce. Just as the U.S. is for the first time in decades considering major revisions to TSCA, it would be counterproductive and tragic if EPA were to implement an approach that would still further delay the point in time when it could get accurate annual production information on what could be hundreds or thousands of chemicals.

In our view, the extent of added burden on industry to institute the new triggering approach in the next cycle rather than wait until the following cycle should be relatively small. EPA has already proposed that, for companies with production or import volumes that meet or exceed the threshold in 2010, reporting of annual production volumes are to be required for 2006-2009. This means that those companies will have to collect and report data for those interim years. The added burden that would come from imposing the new triggering approach in this next cycle would fall, therefore, only on those companies that would not trigger based solely on 2010, but would trigger based on 2006-2009 data. That is, only those companies whose production or import actually is lower in 2010 than in earlier years would benefit from the delay. EPA has not provided an indication of how many companies would be so affected, but it clearly would be only a fraction of companies that will be subject to IUR reporting over time. ***By implementing the new triggering approach now, EPA would capture the very kind of fluctuation that needs to be understood so it does not distort the next picture we get from the IUR as to which chemicals are in commerce.***

[8] 75 Federal Register 49663 (13 August 2010).

2. **Elimination of the 300,000 pound/year/site threshold:** EPA is proposing to eliminate the 300,000 pound threshold for reporting processing and use data in order to acquire this information for all chemicals manufactured or imported in volumes greater than the reporting threshold.

EPA proposes reducing the threshold for reporting processing and use information to the threshold required for reporting of any information under the IUR, presently 25,000 pounds/year/site, because the information submitted under the 2006 IUR was insufficient even to conduct minimal screening-level exposure assessments.

EPA expected to obtain processing and use information on all HPV chemicals (those exceeding one million pounds/year aggregated across all producers and importers) by using the 300,000 pound/year/site threshold. Yet EPA states in the FR notice that it failed to get such data on 23% of HPV chemicals because they fell below the threshold of 300,000 pounds/year/site. The resulting serious deficiencies in exposure data available to the agency for conducting screening-level exposure and risk assessments of HPV chemicals are readily apparent from an examination of the poor quality of those assessments conducted under EPA's recently discontinued ChAMP initiative.[9]

We strongly support EPA's proposal to eliminate the separate, higher threshold for reporting of processing and use information and instead to require reporting of such information for all reportable chemicals. Such basic information on processing and use ought to be available for all chemicals in commerce. As EPA acknowledges in the Federal Register notice for these amendments, the Agency needs such data even to conduct simple screening-level exposure analyses. In its discussion of the need for this information, EPA establishes strong links between such information and a) EPA's ability to provide meaningful exposure characterizations and b) its ability to carry out all aspects of its mission to protect human health and the environment in regards to chemicals.

Moreover, exposure and risk are not intrinsically tied to production volume and many chemicals manufactured in lower volumes still have the potential to cause harm. Again, it is only with adequate use and exposure information that EPA can hope to successfully manage a risk-based regulatory system.

3. **Elimination of the 25,000 pound/year threshold for certain chemicals:** EPA is proposing to eliminate the 25,000 pound/year reporting threshold for chemicals

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[9] Denison, Richard. Environmental Defense Fund. Chemicals and Nanomaterials Blog posts on ChAMP (2009, 2010), (http://blogs.edf.org/nanotechnology/category/champ/)
Environmental Defense Fund. 2008. "Environmental Defense Fund's Comments on ChAMP: EPA's Recent Commitments and Possible New Initiatives for Existing Chemicals, Docket EPA-HQ-OPPT-2008-0319." Prepared by Richard A. Denison, Ph.D., Senior Scientist. (May 2).
(http://www.edf.org/documents/7871_Comments_ChAMP_May08.pdf.)

subject to rules and/or orders or civil actions under the Toxic Substances Control Act (TSCA). The relevant regulations are those developed pursuant to TSCA sections 5(a)(2) (significant new use notices), 5(b)(4) (chemicals of concern list), 6 (regulated chemicals that pose unreasonable risk to health and/or the environment), 5(e) (negotiated consent order), 5(f)(new chemicals of unreasonable risk), and relief granted through civil actions taken under sections 5 or 7.

Chemicals subject to EPA rules and/or orders or for which relief has been granted through civil actions have already been identified as chemicals about which EPA has concern as to their hazard, exposure potential or both. As such, EPA should be knowledgeable of their production or import and their processing and use regardless of the production volume at an individual site.

For this purpose, EPA identifies chemicals subject to any of the specific rules and regulations listed above, but these groups are only a starting point. Chemicals to which no reporting threshold applies should be expanded to encompass other well-established categories of chemicals of concern, including:

- known or suspected carcinogens, mutagens, reproductive toxicants,
- PBTs (persistent, bioaccumulative and toxic chemicals) and vPvBs (very persistent and very bioaccumulative chemicals),
- chemicals listed on the Toxics Release Inventory (TRI),
- chemicals regulated under other laws, such as priority pollutants and hazardous air pollutants,
- chemicals detected in biomonitoring, and
- chemicals for which submissions have been made pursuant to TSCA Section 8(e), the submitted data for which trigger EPA's Section 8(e) "triage" criteria for chemicals of concern.[10]

EPA should include any chemical meeting any of the above criteria identified by any authoritative government body, including not only EPA but also NTP, IARC, California's Proposition 65, Canada or the European Union. Given its highly constrained authority under TSCA to require testing, conduct assessments and hence to identify and designate chemicals of concern, it is essential that EPA include more than the relatively few chemicals meeting the

[10] For the purpose of reviewing Section 8(e) notices, EPA has developed explicit cutoff values for various health and environmental endpoints to flag chemicals that present evidence of serious concern. See EPA's Frequent Questions for Section 8(e) Notices. (www.epa.gov/opptintr/tsca8e/pubs/frequentlyaskedquestionsfaqs.html) (last updated April 29, 2010), refers to criteria in the "1996 EPA hazard ranking system for TSCA §8(e) triage evaluation."

above criteria it has identified and take advantage of the more extensive identification and assessment activities that have been conducted by other authoritative bodies. Moreover, such an approach would be consistent with efforts to better harmonize approaches across developed countries.

The Toxics Release Inventory (TRI) provides a precedent for reducing or eliminating reporting thresholds for certain chemicals of concern, in particular PBTs, for which the threshold was reduced to 100 pounds/year or less on a case-by-case basis. EPA justifies the change thus:

> "These PBT chemicals are of particular concern not only because they are toxic but also because they remain in the environment for long periods of time, are not readily destroyed, and build up or accumulate in body tissue. Relatively small releases of PBT chemicals can pose human and environmental health threats and consequently releases of these chemicals warrant recognition by communities."[11]

In the context of TRI, EPA established a precedent for applying expanded reporting requirements for hazardous chemicals by reducing or eliminating the threshold; the same logic applies in the current context of the IUR.

We also support eliminating the threshold for chemicals subject to *proposed* rules developed pursuant to TSCA sections 4, 5(a)(2), 5(b)(4), 5(f) or 6. As discussed in the Federal Register notice[12] and in these comments in section V.3, information on such chemicals gleaned through the IUR could assist EPA in a variety of ways, including in the finalization of such proposed rules.

E. **Changes to chemical substances subject to the IUR:**

3. Exemptions: EPA is proposing to designate chemical substances subject to Enforceable Consent Agreements as ineligible for IUR exemptions.

We strongly support EPA's proposal to include chemicals covered by Enforceable Consent Agreements (ECAs) in the list of chemicals ineligible for exemption from IUR reporting. As the Agency notes in the Federal Register notice: "Chemical substances covered by ECAs are of demonstrated high interest to EPA."[13]

[11] Environmental Protection Agency. "Fact Sheet on EPCRA Section 313 Rulemaking: Persistent Bioaccumulative Toxic Chemicals." (www.epa.gov/tri/lawsandregs/pbt/pbtrule-fs.pdf)
[12] 75 Federal Register 49677 (13 August 2010).
[13] 75 Federal Register 49665 (13 August 2010).

EPA should further clarify that such chemicals are also not subject to the 25,000 pounds/year/site threshold, for the same reasons discussed above under section III.D.3. It is essential that EPA have access to robust information about production, import, processing and use of such chemicals.

F. **Modifications to reportable data elements:**

3. i. Chemical name: EPA proposes to require reporting of the CA Index Name for reported chemical substances.

We agree with this proposal. The diversity and ambiguity of chemical names is a substantial impediment to the ability of the public (and we expect of EPA) to utilize chemical information. Standardization of reporting of chemical names using an established nomenclature system will ensure that IUR data are more compatible with other chemical data sources and facilitate cross-comparisons and analyses.

4. Production volume:

i. Report production volume for each of the years since the last principal reporting year:

We strongly support EPA's proposal to require companies to report the production volume for chemicals for each year since the last principal reporting year. This modification to the reporting requirements would eliminate the gaps and uncertainties in the information collected under the current IUR that result from infrequent collection and reporting of data. EDF's analysis presented in Appendix A quantifies the large extent of such inaccuracies and artifacts with respect to identifying which chemicals are in commerce at a given time and at what volumes.

ii. Volume of chemical substance used on-site

iii. Indicate whether imported chemical substances are physically at reporting site

iv. Report volume exported

We support requiring companies to report the production volume used on-site, whether an imported substance is physically present at the reporting site, and the volume exported. As EPA notes, these additional data improve the Agency's ability to estimate the portion of the production volume that is relevant with respect to associated processing and use information.

However, where a company reports that an imported chemical is not physically present on-site, it should be further required to report the site(s) at which the chemical is in fact received and held. The exposure relevance of such information should be obvious; in addition, EPA should know whether the imported chemical is being sent to more than one site.

7. Industrial processing and use information

8. Consumer and commercial use reporting

The modifications EPA proposes for reporting of industrial function, industrial sector and consumer/commercial product category (sections 7.i and ii and section 8.i) would increase the utility and specificity of the reported information, reduce confusion, and increase ease of reporting, while also facilitating harmonization of reported information across North America.

We strongly support requiring a textual description to accompany any designation of "other" as a category for industrial function, industrial sector, or commercial or consumer product category. Previously, this option has undermined the specificity and utility of information reported for these elements.[14] In the data summary for the 2006 IUR, EPA indicates that designations of "other" accounted for large fractions of all such designations, including 30% of the industrial function designations and nearly 30% of the commercial and consumer product category designations. (EPA also highlights this latter statistic in the Federal Register notice.[15]) Requiring a textual description will help to reduce the percentage of chemicals that are ambiguously classified.

We also strongly support the additional proposed requirements that submitter designate whether each use they report is a consumer or commercial use, and for each commercial use, also indicate the number of workers potentially exposed. These distinctions are critical to EPA's ability to assess exposure potential even at the most basic level.

Although we support these proposed amendments, we believe more detail regarding commercial and consumer use is needed if EPA is to be able to use the reported information to understand exposure potential. These basic exposure-determining characteristics of commercial and consumer uses, including in products, need to be reported:

- Physical form(s) of the substance as used, or as present in products, in each commercial and consumer use category; e.g., in solid, powder, liquid or gas form.
- The function of the substance in the product(s) in each commercial and consumer use category.
- Concentration or concentration range of the substance in each commercial and consumer use category.

[14] Office of Pollution Prevention and Toxics. 2008. "2006 Inventory Update Reporting: Data Summary." (http://www.epa.gov/iur/pubs/2006_data_summary.pdf)

[15] 75 Federal Register 49670 (13 August 2010).

- The method(s) or mode(s) of delivery or dispensing of the substance in products or otherwise as used in each commercial and consumer use category; e.g., released as an aerosol, spray-applied, poured as a powder or liquid.
- The intended site(s) of application or use of substance in products or otherwise as used in each commercial and consumer use category; e.g., hard vs. soft surfaces, delivery into air or water.
- For each category, an indication whether the substance is used in or on any consumer products to which children age 14 or younger may reasonably be expected to be exposed, including but not limited to any chemical substance used in or on any consumer products intended for use by such children. (See section V.2 of these comments for more detail.)

We recognize that, as may be the case for processing and use information more generally, these elements may not always be known to or ascertainable by chemical manufacturers or importers. EPA's allowance (see next section) for such submitters to claim that such information is not "known or reasonably ascertainable" will address this concern, while ensuring EPA obtains such information where submitters do have access to it. In addition, as we discuss further in section V.10 below, we strongly support the option EPA is considering to extend reporting processing and use requirements to processors. This expansion of the IUR is essential to ensure that EPA obtains such critical exposure-relevant information, whether it originates from manufacturers/importers, processors, or both.

G. **Changes to standard for the reporting of processing and use information:** EPA is proposing to require companies to provide use data on chemicals unless it is not "known or reasonably ascertainable." This will replace the former standard of "not readily obtainable."

This proposed amendment, which we strongly support, rectifies a major weakness in the current IUR reporting system because, as EPA indicates in the Federal Register notice, the ability of companies to assert "not readily obtainable" claims and not report required information severely compromised the quality of the data gathered on chemicals. Indeed, the use of "not readily obtainable" claims was so common that EPA coined the acronym "NRO" as shorthand. Designating information as NRO became a costly loophole during the 2006 IUR reporting cycle. EPA notes that 30% of all reports triggered processing and use reporting in 2006, yet 13% of these reports failed to report any such information, and commercial and consumer use information was absent for almost half.[16]

[16] 75 Federal Register 49671 (13 August 2010).

EPA indicates that availability of the "NRO" option impaired the reporting of processing and use data even more than these numbers suggest, because very few (12%) of the reports contained processing and use data corresponding to an aggregate production volume that equaled or exceeded the company's total production volume. EPA expected many reports to account for much more than 100% of the total production volume, given the frequency with which chemicals are used in more than one downstream use.[17]

Equally or more problematic are the portions of submitted forms covering processing and use that either declared information NRO or were left blank. EPA indicates that this occurred for 14% of product category information, 24% of children's product information and 40% of the maximum concentration data.[18] Moreover, for 20% of the substances for which processing and use information was required to be reported, the submitters did not do so.[19]

These major omissions more than justify EPA's proposal to eliminate the availability of the NRO option, which clearly became a major loophole in the last IUR cycle that severely limited the processing and use information EPA received from industry.

It is important to note that the "not reasonably ascertainable" reporting standard is the norm for other reporting regulations, including those under the new chemicals program. In fact, the similarity of IUR data requirements to those of the new chemicals program lead EPA to believe that companies (1) generally have processing and use information available and (2) are capable of filling out forms without excessive burden or cost. Because EPA deems the level of processing and use data for new chemicals sufficient for EPA's screening and risk assessment needs, using the "not reasonably ascertainable" designation will help ensure EPA receives adequate information under a system that is manageable for the submitters.

H. **CBI modifications:** EPA is proposing several changes to the process by which companies can claim Confidential Business Information (CBI).

The proposed amendments that address CBI seek to remedy the significant extent to which excessive CBI claims have limited access by the public and both federal and state governmental entities to information collected under the IUR.[20]

We support EPA's proposal to allow the Agency to make information public without having to notify submitters when a company has asserted the chemical identity to be CBI yet the chemical is already present on the public portion of the TSCA inventory. This will expedite processing of CBI claims in general and prevent the unnecessary withholding of information that should be available to the public. This modification is in line with recent Agency actions,

[17] 75 Federal Register 49672 (13 August 2010).
[18] Ibid.
[19] Ibid.
[20] Hampshire Research Associates. 1992. "Influence of CBI Requirements on TSCA Implementation." Prepared by Sheila A. Ferguson, Laurie C. Meree, Warren R. Muir, Ph.D. and John S. Young, Ph.D. (March).

such as that announced in a January 2010 Federal Register notice stating that chemicals listed on the public portion of the TSCA inventory cannot be claimed confidential in health and safety studies.[21]

We also support requiring upfront substantiation for any CBI claims for processing and use information, as this will help to limit such claims to information that in fact warrants protection as a legitimate trade secret. The Federal Register notice indicates that processing and use information subject to CBI claims ranged from 25% of all individual reporting elements to 50% of all use scenarios based on combinations of use elements.[22]

EPA questions the validity of many CBI claims asserted under the IUR as a result of discovering the same information on easily accessible websites, submitted under voluntary EPA programs and in other public sources.[23] The excessive assertion of CBI in the 2006 IUR is only the latest chapter in a long history of CBI claims made under TSCA.[24] EPA expects that requiring upfront substantiation for processing and use data will help address this problem by reducing the number of CBI claims made for these data. We agree with this expectation, in light of the dramatic reduction in CBI claims asserted for plant site information – which dropped from 28% of reports in the 2002 IUR to 7% in the 2006 IUR following imposition of a requirement for upfront substantiation.[25]

We also support EPA's proposal to disallow CBI claims for the reporting of the absence of information due to it having been deemed "not known or reasonably ascertainable" or "not readily obtainable." The fact that in the 2006 IUR companies opted to claim such data gaps as CBI is evidence of the gross abuse of CBI. Failure to report required information cannot possibly be construed as a legitimate trade secret, nor can disclosure of such a gap be construed as compromising the competitive position of a company.

Finally, we believe EPA should designate at least one of the processing and use reporting elements ineligible for CBI protection: indications of the use of a chemical in consumer products intended for use by children, and – as we discuss in section V.2 of these comments – in consumer products to which children age 14 or younger may reasonably be expected to be exposed. We fail to see any reason why such information should qualify for trade secret protection.

The CBI modifications proposed by EPA for processing and use information, and the additional one we propose, are consistent with both EPA's and the Obama Administration's focus on transparency, which we strongly support. EPA's efforts to reduce illegitimate or

[21] 75 Federal Register (21 January 2010).
[22] 75 Federal Register 49673 (13 August 2010).
[23] Ibid.
[24] Hampshire Research Associates. 1992. "Influence -of CBI Requirements on TSCA Implementation". Environmental Protection Agency, Office of Pollution Prevention and Toxics. 1994. "Final Action Plan: TSCA Confidential Business Information Reform." (June 20).
[25] EPA, TSCA Statistics from Congressional Briefing, 2010, provided to OMB Watch in response to a FOIA request.

unnecessary CBI claims and to make non-CBI information on chemicals available to the public will lead to better decision-making not only by government but by consumers and all actors in the chemicals marketplace.

Benefits of greater EPA, public and market access to chemical information

In an earlier Federal Register notice addressing disclosure of pesticide inert ingredients, EPA argued that:

- greater disclosure of, and reduction of CBI claims for, pesticide inert ingredients can empower market forces in driving positive change;
- increasing public awareness of the exposure risks associated with certain products is likely to create economic incentives for companies to ensure the safety of chemicals; and
- companies that respond to consumer demand by producing and using safer chemicals will have a competitive advantage.

EPA cites a 1987 decision that required inert ingredients of high concern to the Agency to be listed on labels, an action that led to their disappearance from the market. EPA states that the "lack of information available to consumers and users about the inert ingredients in pesticide products results in a *market failure* that causes pesticide products to contain inert ingredients that are more hazardous than is efficient."[26]

We believe there is an entirely analogous situation for chemicals regulated under TSCA and subject to the IUR. The lack of information on chemicals available to the public and the market due to excessive CBI claims, as well as infrequent reporting, high reporting thresholds, a failure of companies to report required information, and other problems EPA is now attempting to remedy, impairs the ability of the market as well as individual consumers to make informed decisions. We concur with EPA's belief that reducing superfluous CBI claims would help promote innovation through consumer-driven markets. In its earlier Federal Register notice, EPA remarks that "disclosure of inert ingredients in pesticides, particularly hazardous inert ingredients, may lead the market to provide more product choices that could reduce overall exposures to potentially hazardous chemicals."[27] EPA also emphasizes the importance of the public right to know independent of managing exposure: "EPA believes in the value of transparency to consumers and users of pesticides, above and beyond those issues pertaining to potentially hazardous inert ingredients."[28] Again, disclosure of information gathered through the IUR presents an entirely analogous case.

Both the current Federal Register notice proposing modifications to the IUR and EPA's 2006 IUR data summary point to the myriad ways in which IUR data are or could be used and

[26] 74 Federal Register 68218 (Wednesday, December 23, 2009); emphasis added.
[27] 75 Federal Register 68219 (13 August 2010).
[28] Ibid.

illustrate how more and better quality data would increase the IUR's utility. To name just a few:

- use by other federal and state agencies in addition to EPA to carry out their missions, which extend to worker, consumer, public and environmental protection;
- screening and prioritization of chemicals, which can enhance the cost-effectiveness and efficiency of subsequent activities; and
- cooperation and burden-sharing with other governments, a major goal of efforts to harmonize and align global efforts to enhance chemicals management.

J. **Change to Reporting Frequency:** EPA is proposing to return to a 4-year or shorter reporting cycle, in light of the large fluctuations in the identity and production volumes of chemicals reported in consecutive cycles of IUR reporting.

We strongly support reducing the length of the IUR reporting cycles. This proposed amendment reflects EPA's recognition of the inadequacy of a five-year cycle to effectively identify chemicals in commerce above the reporting threshold. In the past, EPA has claimed that the five-year cycle adequately satisfies the need for information. Upon introducing the five-year cycle for 2006 reporting, EPA assured the public that the IUR data "would still meet EPA's most critical data needs."[29] However, the fluctuations that occur during even a 4-year reporting cycle, let alone the present 5-year cycle, expose flaws in this statement. EPA acknowledges this in the current Federal Register notice by citing evidence presented on the extent of fluctuation in Environmental Defense Fund's "Across the Pond" report.[30]

As noted before (see Section III.D.1 above), EPA's own analyses demonstrate a 30% change in the identity of chemicals reported between consecutive 4-year cycles, and this statistic is referenced as one of the factors contributing to rising concern about the reliability of IUR data. EPA notes further that there is "mounting evidence that many chemical substances, even larger volume chemical substances, often experience wide fluctuations in manufacturing volume from year to year. This can result in the production volume of a chemical substance exceeding the threshold for several years, then falling below the threshold during the IUR principal reporting year." A longer reporting cycle only exacerbates this problem. EPA also notes that "industry representatives expressed concern that short reporting determination periods would drastically misrepresent the chemical substances that currently are in commerce ... [because] they manufactured or imported some chemical substances only occasionally, and that these chemical substances would not be captured if the reporting covered too short a period."[31]

[29] 68 FR 848 (January 7, 2003); and 70 FR 75059 (December 19, 2005)
[30] 75 Federal Register 49675.
[31] Ibid.

EDF has conducted its own comparison of the chemicals reported in the 2006 and 2002 IUR cycles, which corroborates and extends EPA's analysis and makes clear that the problems with cycle-to-cycle fluctuations continue to be seen even in the latest IUR data. See EDF's analysis in Appendix A of these comments.

These empirical data lead us to propose the following as the best way to respond to the large fluctuations in production, optimizing both the amount of information reported and the frequency with which it is reported. All three of the following elements in combination are essential to define the reporting cycle:

- EPA adopts a three-year reporting cycle;
- Any chemical that triggers the reporting threshold during any of those three years is required to be reported;
- For any such chemical, production volume data is required to be reported for each of the years of the reporting cycle.

Other information, including that on processing and use, would be reported in the principal reporting year of each cycle.

While an annual reporting system (coupled with rapid compilation and release of the data by EPA) would of course make information available in the timeliest manner, it would likely not optimize the number of chemicals for which reporting would occur in any given year, because any chemical not meeting the threshold in that year would not be reported. In contrast, while a three-year cycle would mean somewhat more delay in receipt and release of information for the first two years of the cycle than would be the case with annual reporting, annual data would be provided for more chemicals because the trigger would be based on exceeding the threshold in any year of the cycle, in which case data for all years of the cycle would have to be reported.

There is value in aligning IUR reporting with the annual reporting conducted under the Toxics Release Inventory (IUR), which would in part be met by requiring annual data to be reported even if the reporting is not annual. Similarly, EPA' and the public's ability to examine the data for trends would be enhanced through access to annual data.

V. Request for Comments

2. **Emphasis on protecting children**

The only IUR reporting element specific to children is one that requires a submitter to identify any chemical substance "used in or on any consumer products intended for use by children age 14 or younger." But the narrow scope of this element is far from sufficient to capture chemicals used in consumer products to which children may be exposed. Many products used in the home result in exposure to children – regardless of whether the products

are actually intended for use by children. In its ChAMP assessments, EPA frequently invoked the distinction between consumer products intended for use by children versus those to which children might be exposed to downgrade exposure potential to children even relative to other consumers.[32]

EPA should revise this reporting element to require a submitter to identify any chemical substance "used in or on any consumer products to which children age 14 or younger ***may reasonably be expected to be exposed***, including but not limited to any chemical substance used in or on any consumer products intended for use by such children."

3. Exclusion of chemical substances subject to proposed rules

We support retaining the exclusion of chemical substances subject to proposed rules under TSCA Sections 4, 5(a)(2), 5(b)(4) and 6 from the exemptions from IUR reporting provided in 40 CFR 710.46 and 710.49, for the reasons EPA notes in the Federal Register notice.[33] The information obtained through the IUR can inform a variety of EPA decisions, including finalization of such proposed rules.

As we noted in section III.D.3 of these comments, EPA should also preclude such chemicals from being subject to the reporting threshold for IUR reporting.

4. Frequency of reporting and threshold for reporting

i. Length of reporting cycle

As discussed in section III.J above, we believe the best way to respond to the well-documented large fluctuations in production, while optimizing both the amount of information reported and the frequency with which it is reported, is to:

- shorten reporting to a 3-year cycle,
- have reporting triggered by an exceedance of the production volume reporting threshold in any year of the cycle, and
- require reporting of annual production volume information for each year of the cycle, for any reportable chemical.

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[32] See, for example: Environmental Defense Fund, "Questionable risk decisions under ChAMP: Chlorobenzenes Category," Chemicals and Nanomaterials blog post dated April 27, 2009. (http://blogs.edf.org/nanotechnology/2009/04/27/questionable-risk-decisions-under-champ-chlorobenzenes-category/); and Environmental Defense Fund's Comments on ChAMP: EPA's Recent Commitments and Possible New Initiatives for Existing Chemicals, p. 4 (http://www.edf.org/documents/7871_Comments_ChAMP_May08.pdf).

[33] 75 Federal Register 49677 (13 August 2010).

Appendix B discusses limitations and deficiencies in the Economic Analysis accompanying the Federal Register notice that we believe do not adequately account for the benefits, and may overstate the costs, of shifting to a shorter reporting cycle.

iii. Lowering the reporting threshold from 25,000 pounds/year/site

EPA lacks the ability even to tell the American public how many chemicals subject to TSCA are in commerce in the U.S. This inability is in large measure due to the fact that many, if not most, such chemicals are not subject to reporting, due in large part to the substantial threshold of 10,000 pounds/year/site that has existed since the IUR began in 1986, which was raised even further for reporting in 2006 and resulted in even fewer chemicals being reported.

As a result, EPA and stakeholders have little empirical basis on which to assess the actual scope or reach of any past, current or possible future activities that EPA or others take or could take to address the safety of chemicals in commerce: For any of them, the all-important denominator is missing. This lack of fundamental knowledge impairs both the public and private sectors' ability to effectively screen, prioritize, assess and manage chemicals and their associated exposures and risks. It also undermines our ability to intelligently craft programs and policies, let alone provide the public and marketplace with any confidence as to their effectiveness. And it directly frustrates the public's right to know about chemicals to which they may be exposed.

EPA seeks comment on whether to return the threshold to its historical value of 10,000 pounds/year/site. While that is a move in the right direction, it is inadequate to address any of the problems just described.

The chemical industry and some regulators in government frequently argue that production volume is an inadequate surrogate for exposure and risk, resisting, for example, the increased data requirements imposed under the European Union's REACH Regulation as production volume increases. Yet when it comes to defining a threshold below which they bear no burden, industry is happy using production volume as a surrogate for exposure and risk, and constantly seeks to raise the floor, arguing without evidence that what it decides *a priori* are "small" amounts of chemicals pose no risk.

Of course, determining whether a chemical actually presents a risk requires access to information on its production, processing, use and exposure, as well as on its hazards. The IUR is the only systematic means for EPA to collect such information, not only for its own use, but also for use by other federal and state agencies, the private sector and the public.

We support significantly lowering the threshold, and believe EPA should strongly consider lowering the threshold to 1 metric ton (2,200 pounds), thereby harmonizing its reporting system with that of the European Union under its REACH Regulation. First, U.S. chemical manufacturers already have to comply with REACH standards to export chemicals in

quantities at or above the 1 metric ton threshold to the EU, which constitutes the largest share of global chemicals market. Second, adopting the REACH threshold would foster greater consistency and harmonization between U.S. and E.U. chemical regulations, facilitate information-sharing, and offer other trade-related benefits. Such international cooperation and harmonization is increasingly important in a globalized economy, not the least because chemicals manufactured in one country affect exposure and risk profiles in other regions of the world.

Finally, establishing a threshold on a *per-site* basis results in many chemicals produced in aggregate levels well in excess of that threshold not being reported at all. This argues for the need to set a much lower per-site threshold than the desired level above which one wants complete reporting of chemicals exceeding the threshold with respect to their aggregate production volume. As EPA notes, using a reporting threshold of 25,000 or even 10,000 pounds/year/site means that many chemicals the *aggregate* production and import of which exceeds the threshold will nevertheless not be reported because production or import at any single site does not exceed the threshold.[34] In the last cycle, EPA had hoped that establishment of a 300,000 pound/year *per-site* threshold for processing and use information reporting would be adequate to capture all HPV chemicals, which are those produced and imported in an *aggregate* amount of one million or more pounds/year. Yet it found that 23% of the reports submitted for known HPV chemicals had reported per-site production volume levels below 300,000 pounds/year.[35]

5. **EPA requests comment on the draft economic analysis to evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.**

Appendix B provides our analysis of the draft Economic Analysis that accompanies the proposed rule.

6. **EPA requests comment on the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.**

Appendix B provides our analysis of the draft Economic Analysis that accompanies the proposed rule.

[34] Ibid.
[35] 75 Federal Register 49664 (13 August 2010).

9. **Exposure data:** EPA is proposing to require manufacturers and processors of certain chemicals to report more detailed exposure data, modeling the data elements on those required of new chemicals subject to Premanufacture Notification.

We support EPA having information sufficient to conduct screening-level exposure assessments for all chemicals in commerce, and consider the requirements for new chemicals subject to Premanufacture Notification to be a good starting point. Recognizing, however, the large number of existing chemicals for which even such basic data are presently lacking, we acknowledge the practical need to apply the additional exposure-related information requirements in an incremental manner, phasing in its applicability to more chemicals over time.

We would argue, therefore, that EPA should apply those requirements to chemicals in a prioritized order. An initial list containing chemicals of highest concern should be developed, which should include the types of chemicals we discuss in section III.D.3 of these comments. These would be followed by other groups of prioritized chemicals, including HPV chemicals, chemicals found in consumer products, chemicals to which large number of workers may be exposed, and so on.

EPA presents several possible options for integrating exposure data reporting: including the enhanced exposure data elements in the IUR, using its TSCA Section 8(a) authority to promulgate a new reporting vehicle, or using subpoena authority. We believe the mechanism should be chosen based on application of at least these criteria:

- maximizing the ease (including with respect to both the length of time and the administrative resources required) with which EPA can develop and finalize the mechanism, and then apply it in sequential fashion to additional chemicals over time;
- ensuring the mechanism requires periodic updating of the reported information (as the IUR certainly would), as opposed to one-time reporting;
- minimizing the burden on EPA to collect, compile, analyze and use the information; and
- maximizing the extent of information to which the public has access, and how quickly the information can be made public.

10. **Processor reporting:** EPA is considering collecting exposure-related information from processors in addition to collecting the data from manufacturers (including importers)**.**

It is widely acknowledged that manufacturers are often in a very poor position to know much about the downstream processing and use of the chemicals they produce.[36] Even chemical manufacturers agree. For example, the now-named Society of Chemical Manufacturers and Affiliates (SOCMA), a chemical industry trade association, cited this very concern when it filed comments vigorously opposing EPA's addition of processing and use information to the IUR in the first place.[37] Such industry opposition likely helped it secure the opt-out provision included in the last round of IUR amendments that allows submitters to declare such information not to be readily obtainable, in what has turned out to be a huge loophole in the reporting requirements (see section III.G of these comments).

EPA's seeking comment on extending processing and use information reporting to downstream entities is no doubt motivated by the significant gaps in such information as reported by upstream entities in the last IUR cycle. We strongly support such a requirement, which is clearly well within EPA's authority under TSCA. TSCA Section 8(b) provides EPA with broad authority and a mandate "to compile *and keep current* an inventory of chemical substances manufactured *or processed* in the United States" (emphases added), and Section 8(a) establishes EPA's authority to require manufacturers (including importers) *and processors* of chemical substances to report information "as the Administrator may reasonably require."

Below is a summary of the current elements for processing and use information reporting under the IUR:

<u>Industrial processing and use information</u>

- Type(s) of industrial processing or use (by code)
- Industrial sector(s) (by code)
- Industrial function(s) (by code)
- *Estimated percentage of production volume associated with each combination of the codes above*
- Estimated number of processing and use sites associated with each combination of the first three codes above (by code for range)
- Estimated number of workers reasonably likely to be exposed to the substance associated with each combination of the first three codes above (by code for range)

[36] Richard A. Denison, Improving Information Flows—In Supply Chains and Beyond, paper presented at the North American Dialog on "Framing a Future Chemicals Policy," Boston, Mass., April 2005, *available at* http://www.chemicalspolicy.org/downloads/W3-Informationflow.doc; and Rachel Massey, *Sharing Knowledge about Chemicals: Policy Options for Facilitating Information Flow, in* OPTIONS FOR STATE CHEMICALS POLICY REFORM: A RESOURCE GUIDE 69-96 (Lowell Center for Sustainable Production, University of Massachusetts at Lowell 2008), *available at* http://www.chemicalspolicy.org/downloads/OptionsforStateChemicalsPolicyReform.pdf.

[37] See Society of Chemical Manufacturers and Affiliates, Inc., "Expanded Inventory Update Rule," (http://www.socma.com/governmentRelations/?subSec=26&articleID=94#Expanded.)

Commercial and consumer use information

- Commercial and consumer use category(ies) (by code)
- For each category, an indication whether the use is a commercial or consumer use
- For each category, an indication whether the substance is present in or on any consumer products intended for use by children age 14 or younger (yes/no/not known or reasonably ascertainable)
- *Estimated percentage of production volume associated with each commercial and consumer use category*
- Estimated typical maximum concentration of the substance in each commercial and consumer use category (by code for range)

We believe the above elements need to be part of any processor reporting system, with three caveats:

1. Processors would be reporting such information only for their own operations, unlike upstream entities that would report these elements for all downstream entities (subject to the "reasonably ascertainable" reporting standard).
2. *Italicized* items above would clearly be difficult or impossible for a downstream processor to know and report. However, they could be expected to know and report these modified formulations of the elements – again, limited to their own operations:
    - *Estimated percentage of the volume processed or used associated with each unique combination of the codes above*
    - *Estimated percentage of volume processed or used associated with each commercial and consumer use category*
3. Some industrial processing and use elements such as type of industrial processing or use or industrial function might not be directly applicable to downstream processors that only use a chemical as an ingredient in a product. Conversely, some consumer and commercial use information elements might not be directly applicable to downstream processors that only use a chemical in an industrial use.

As we noted above (in section III.F.8) in association with reporting of consumer and commercial use information elements by manufacturers, additional elements are needed if EPA is to be able to use the information reported by processors to understand exposure potential. These basic exposure-determining characteristics of commercial and consumer uses, including in products, need to be reported:

- Physical form(s) of the substance as used, or as present in products, in each commercial and consumer use category; e.g., in solid, powder, liquid or gas form.
- The function of the substance in the product(s) in each commercial and consumer use category.

- Concentration or concentration range of the substance in each commercial and consumer use category.
- The method(s) or mode(s) of delivery or dispensing of the substance in products or otherwise as used in each commercial and consumer use category; e.g., released as an aerosol, spray-applied, poured as a powder or liquid.
- The intended site(s) of application or use of substance in products or otherwise as used in each commercial and consumer use category; e.g., hard vs. soft surfaces, delivery into air or water.
- For each category, an indication whether the use is a commercial or consumer use
- For each category, an indication whether the substance is used in or on any consumer products to which children age 14 or younger may reasonably be expected to be exposed, including but not limited to any chemical substance used in or on any consumer products intended for use by such children. (See section V.2 of these comments for more detail.)

In devising an information reporting approach applicable to processors, EPA would need to address one timing issue: Unlike manufacturers, processors (unless they were also the manufacturers of reportable chemicals) would not know which chemicals were being reported prior to the submission deadline applicable to manufacturers, and hence would not know for which chemicals they would be required to report processing and use information. For this reason, EPA would likely need to employ a phased approach, under which shortly after the initial reporting deadline, EPA would compile a list of chemicals reported under the IUR and make it available to processors, who would then report processing and use information for any of those chemicals they process. We suggest that, with mandatory electronic reporting in place, EPA could produce and make available such a list within 90 days of the initial deadline, and could then require processors to report their information within an additional 90 days.

There are two subsets of chemicals for which a different approach could or would need to be devised:

- For chemicals for which EPA has eliminated the reporting threshold due to indications of concern (see section III.D.3 of these comments), there would be no need for a delay, as EPA would be able to identify such chemicals in advance and processors would be able to identify from such a list those chemicals they process and report on them in the same timeframe as would apply to manufacturers.
- For reported chemicals the identity of which is not able to be made publicly available due to CBI claims, processors would not be able to know those chemicals had been reported. EPA would need to consider other alternatives for such chemicals, for example, identifying such chemicals by trade name or generic name.

Appendix A:
Fluctuations in Chemicals and Production Volumes Reported in the 2002 and 2006 IUR Cycles

EDF has analyzed two types of fluctuations in chemical information reported in the 2002 and 2006 IUR cycles: Chemicals that were reported in one of the cycles but not the other; and for chemicals reported in both cycles, changes in their aggregate production volume range from one cycle to the next.

Disappearances/Appearances of HPV Chemicals between 2002 and 2006

Disappearances: From 2002 to 2006, 32% of the 2002 IUR chemicals "disappeared" from the list of reported chemicals. Some changes are expected due to differences in the reporting requirements in 2002 and 2006. In particular, the 2006 IUR cycle raised the minimum reporting threshold from 10,000 pounds/year/site to 25,000 pounds/year/site and for the first time mandated reporting of inorganic chemicals. These alterations would explain the disappearance in 2006 of some chemicals in the lowest production volume range due to the elevated threshold, and a slight increase in 2006 across all ranges due to the inclusion of inorganic chemicals. Indeed, most of the chemicals that were reported in 2002 but not in 2006 were produced in volumes below 500,000 pounds/year/site. The lowest production volume range accounts for 82% of the chemicals that were reported in 2002 but not in 2006.

However, the disappearances of chemicals from 2002 to 2006 become increasingly odd as the production volume rises. There are 6 chemicals produced in excess of 1 billion pounds/year reported in 2002 that were not reported in 2006.[38] The "disappearances" include the following HPV chemicals:[39]

- 6 chemicals with aggregate production and import over 1 billion pounds/year
- 8 chemicals in the range of 500 million to 1 billion pounds/year
- 18 chemicals in the range of 100 to 500 million pounds/year
- 18 chemicals in the range of 50 to 100 million pounds/year
- 38 chemicals in the range of 10 to 50 million pounds/year
- 219 chemicals in the range of 1 to 10 million pounds/year

In addition, 111 chemicals in the range of 500,000 to 1 million pounds/year disappeared. From these data, many chemicals that were highly prevalent in 2002 appear to have been completely abandoned four years later – hardly a likely phenomenon.

[38] CBI claims should not appreciably influence calculations for production volume ranges because EPA determines that the reporting of aggregated volume ranges protect confidentiality, and CBI designations for chemical identity do not change significantly over time.

[39] Defined as chemicals produced and imported in aggregate quantities equaling or exceeding 1 million pounds/year. See: "High Production Volume (HPV) Challenge Program: Basic Information". epa.gov . Accessed 1 October 2010. (http://www.epa.gov/hpv/pubs/general/basicinfo.htm)

While it is conceivable that the increase in the reporting threshold from 10,000 pounds to 25,000 pounds/year *per site* may have contributed to these disappearances, this would require that an HPV chemical be made at many sites. For example, if a chemical produced in aggregate quantities of 1 to 10 million pounds/year were produced in equal quantities at more than 40 sites, the average pounds/year per site would drop below 25,000 and none of those sites would trigger reporting. Production at "40 sites" is the magic number for this range and the higher production volume ranges would require even more sites per chemical to account for the disappearances.

However, our examination of the number of reporting sites per chemical in the 2002 IUR found that they never exceed the magic number for any of the production volume ranges. Moreover, for the 2006 IUR, the average number of sites per chemical is 6.8, further illustrating the low likelihood that production being spread out over a large number of sites accounts for the disappearance of HPV chemicals witnessed from 2002 to 2006.

If there were many CBI claims for sites, it would be reasonable to argue that the above analysis is undermined as the number of sites per HPV chemical we were able to access on the public versions of the 2002 and 2006 IURs would not be representative of the true number of sites. However, EPA data[40] indicate that site information is claimed CBI sufficiently infrequently (28% of records in 2002, 7% of records in 2006) that this explanation is not plausible.

Appearances: In addition to the disappearance of chemicals from the 2002 IUR list, there are 1,774 chemicals that *appear* in the 2006 IUR, totaling 26% of the chemicals reported in the 2006 IUR. The addition of inorganic chemicals to the reporting requirements for the 2006 cycle accounts for many of these additions. However, the large number of organic HPV chemicals that appear in 2006 suggests that there is more to the story.

The overall "appearances" in 2006 include the following:

- 36 chemicals over 1 billion pounds/ year (2 organic, 34 inorganic)
- 22 chemicals in the range of 500 million to 1 billion pounds/year (4 organic, 18 inorganic)
- 47 chemicals in the range of 100 to 500 million pounds/year (12 organic, 35 inorganic)
- 25 chemicals in the range of 50 to 100 million pounds/year (10 organic, 15 inorganic)
- 112 chemicals in the range of 10 to 50 million pounds/year (33 organic, 79 inorganic)
- 275 chemicals in the range of 1 to 10 million pounds/year (140 organic, 135 inorganic)

In addition, 147 chemicals in the range of 500,000 to 1 million pounds/year (90 organic, 57 inorganic) appeared.

Overall, there are 517 HPV chemicals among the 1,774 chemicals that appear in the 2006 IUR cycle but not in the 2002 cycle. Of these, approximately 201 (39%) are organic chemicals while roughly 316 (61%) are inorganic chemicals. These data indicate that the

[40] EPA, TSCA Statistics from Congressional Briefing, 2010, provided to OMB Watch in response to a FOIA request.

addition of inorganic chemicals to the 2006 IUR cannot adequately explain all the appearances. Organic chemicals account for approximately 39% of the newly appearing HPV chemicals, confirming the dramatic fluctuations between the 2002 and 2006 IUR cycles.

The appearance in 2006 of so many organic HPV and near-HPV chemicals would appear to suggest there were dramatic changes taking place in the chemical industry over the intervening four years. Far more likely an explanation is that the "1-year snapshot" is masking a far less dramatic set of changes in average production volumes over time.

Changes in Production Volume Ranges

The differences in the composition of chemicals reported for the 2002 and 2006 IUR cycles illustrate the variability between cycles. In order to further illustrate the magnitude of the fluctuation, we utilized the publicly available data on chemicals subject to reporting requirements through the TSCA IUR databases.[41] These databases assign chemicals to annual production volume ranges. Only the lowest of these ranges differed between the two cycles, due to the change in the reporting threshold. The ranges, which are quite broad, are as follows:

For 2002:

10,000 pounds - 500,000 pounds/year

For 2006:

25,000 pounds - 500,000 pounds/year

For both cycles:

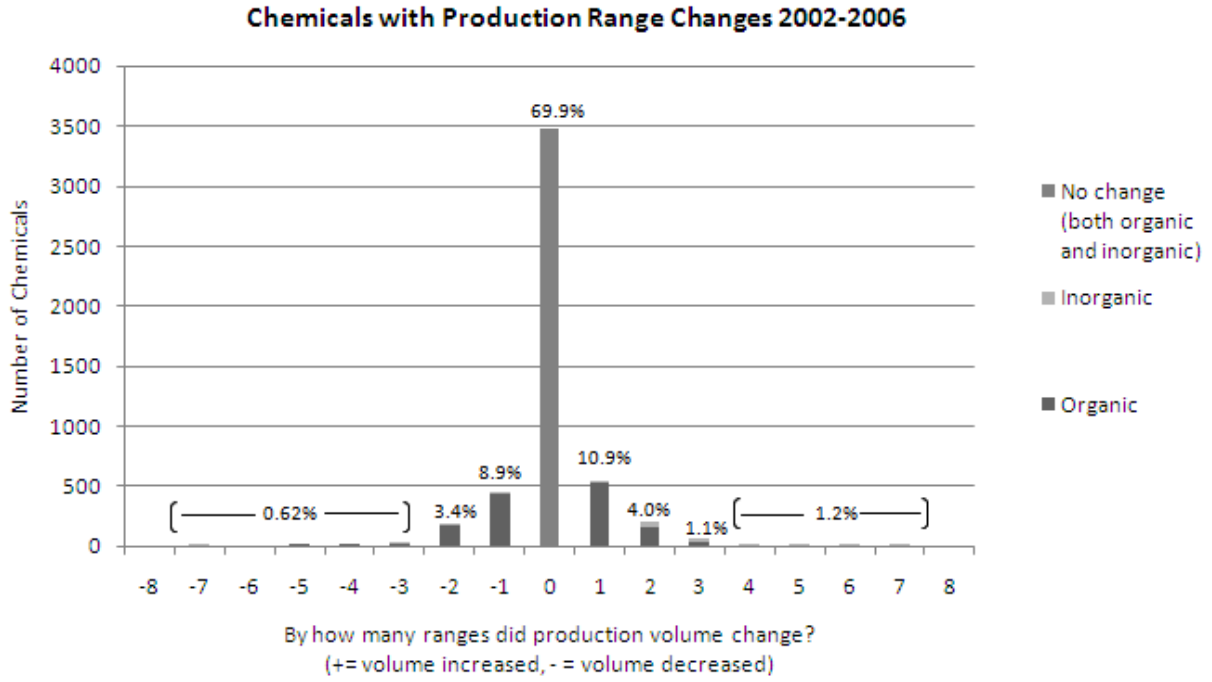
>500,000 - 1 million pounds/year
>1 million - 10 million pounds/year
>10 million - 50 million pounds/year
>50 million - 100 million pounds/year
>100 million - 500 million pounds/year
>500 million - 1 billion pounds/year
>1 billion pounds/year

[41] For 2002 production volume data, we accessed "Non-confidential Production Volume Information Submitted by Companies for Chemicals Under the 1986- 2002 Inventory Update Rule," available for download at www.epa.gov/oppt/iur/iur02/search03.htm. Only those chemicals produced/imported in quantities exceeding 10,000 pounds annually were subject to the reporting requirement and hence included in the database; for 2006 production volume data, we used data available for download at www.epa.gov/iur/tools/data/index.html; the 2006 IUR includes only those chemicals that are produced/imported in quantities exceeding 25,000 pounds annually and, unlike previous cycles, inorganic chemicals.

We first identified chemicals that were reported in both the 2002 and the 2006 cycles. The most important changes in the data from 2002 to 2006 are as follows:

- the production volume range changed for 1503 (30%) of the chemicals;
- the production volume range increased from 2002 to 2006 for 861 (17%) of the chemicals and decreased for 642 (13%);
- of the chemicals that showed an increase in production volume range, 138 (16%) were inorganic and 723 (84%) were organic;
- of the chemicals that showed a decrease in production volume range, 15 (2%) were inorganic and 627 (98%) were organic; and
- for 10% of the chemicals, the production volume range changed by more than one range (6% increased by two or more ranges, while 4% decreased by two or more ranges).

The histogram below illustrates these findings.



Our analysis highlights the dramatic fluctuations in aggregate production volume reported for almost a third of the IUR chemicals common to both the 2002 and 2006 cycles. Considering the magnitude of each range, changes of even a single range may signify a large shift in production volume for the chemicals in question. The fluctuations observed in production volume over a four-year period suggest that the current five-year reporting cycle cannot possibly accurately characterize the production and use of industrial chemicals in the U.S.

The following section illustrates in greater detail the specific nature of the gaps that the fluctuations we have documented likely yield with respect to use data available to EPA and the public, and demonstrate that they encompass chemicals to which exposure may well occur and that are of relevance to the average consumer.

Use Data

The 2006 IUR for the first time required companies to report processing and use data for higher volume chemicals, including an indication as to whether a chemical was used in or on products intended for use by children. Although EPA was unable to collect complete data, use data on the chemicals that were provided in 2006 amply illustrate the potential for exposure to many of these chemicals in daily life. We restricted our analysis only to HPV chemicals that appeared on the 2006 IUR but not the 2002 IUR (hereafter "new HPVs"). Of these chemicals, those for which use information was reported have the following uses:

- Adhesives and sealants
- Agricultural products (non-pesticidal)
- Automotive care products
- Electrical and electronic products
- Fabrics, textiles and apparel
- Glass and ceramic products
- Leather products
- Lubricants, greases and fuel additives
- Metal products
- Other
- Paints and coatings
- Paper products
- Photographic supplies
- Rubber and plastic products
- Soaps and detergents
- Transportation products
- Wood and wood furniture

Many of these categories obviously encompass products to which consumer exposure is to be expected. For this reason, the lack of confidence in the IUR data that arises from the large fluctuations we have documented translates into a lack of confidence in the ability of EPA to use such data to make any reasonable predictions or projections of exposure potential for the associated chemicals.

Of course, this problem was further exacerbated by the relatively low level of reporting of use information in the 2006 IUR, as well as the extent to which such information was claimed

CBI. To further illustrate this, we examined the nature and extent of use information reported for the new HPVs in more detail.

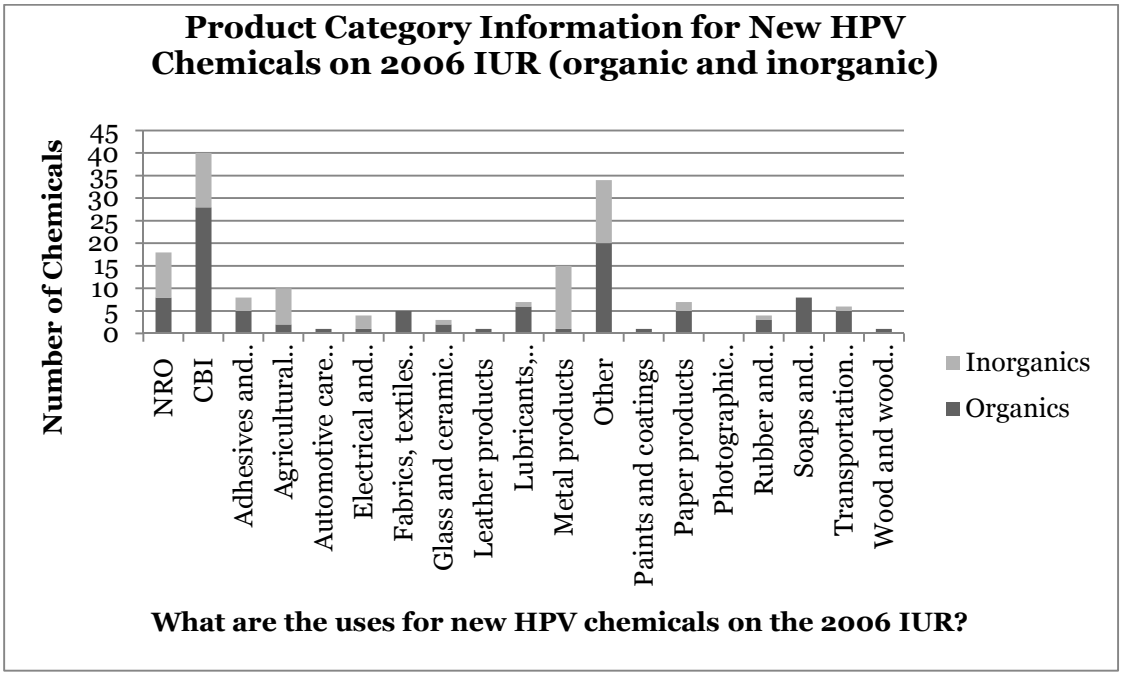
Although the 2006 IUR required companies to report product category information as one of the data elements for processing and use, EPA only received information for 82 of 517 new HPVs. Designations of CBI, not readily obtainable (NRO) and "Other" account for 91 additional HPV chemicals. Figure 1(a) below presents the product category distribution for these new HPV chemicals, whether organic or inorganic. Figure 1(b) more directly illustrates the high frequency of CBI, NRO and "Other" designations.

Another oddity of the 2006 data is that few if any chemicals were reported as being used in multiple product categories, suspicious given that it does not reflect the reality for many chemicals. The 2006 IUR did not require use data for inorganic chemicals, but because use data were reported for a number of them, we have included these chemicals in our calculations. Approximately 201 (39%) of the new HPVs with reported use data are organic chemicals, while approximately 316 (61%) are inorganic chemicals.

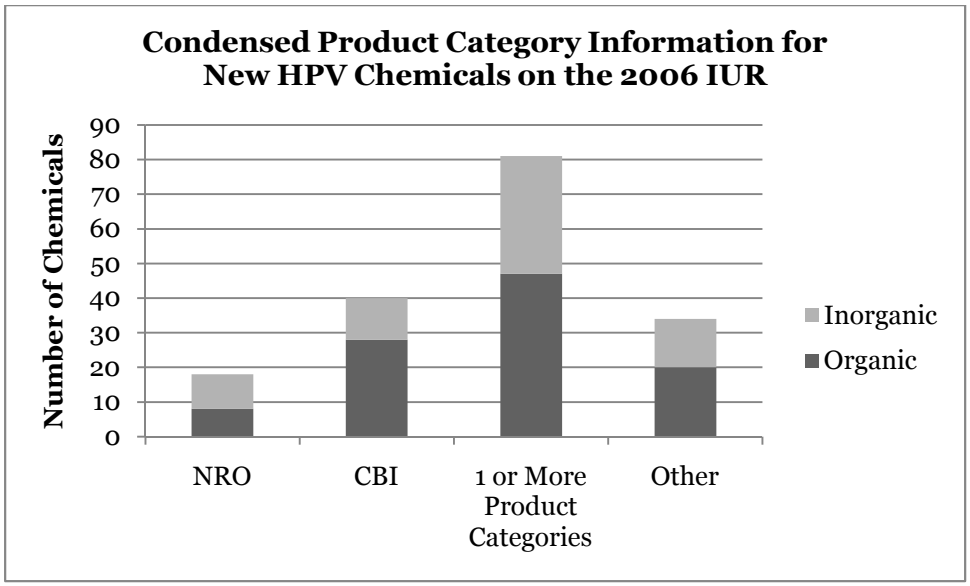
Figure 1:

(a) Product category information for new HPV chemicals on the 2006 IUR, organic and inorganic

(b) Condensed product category information for new HPV chemicals on the 2006 IUR



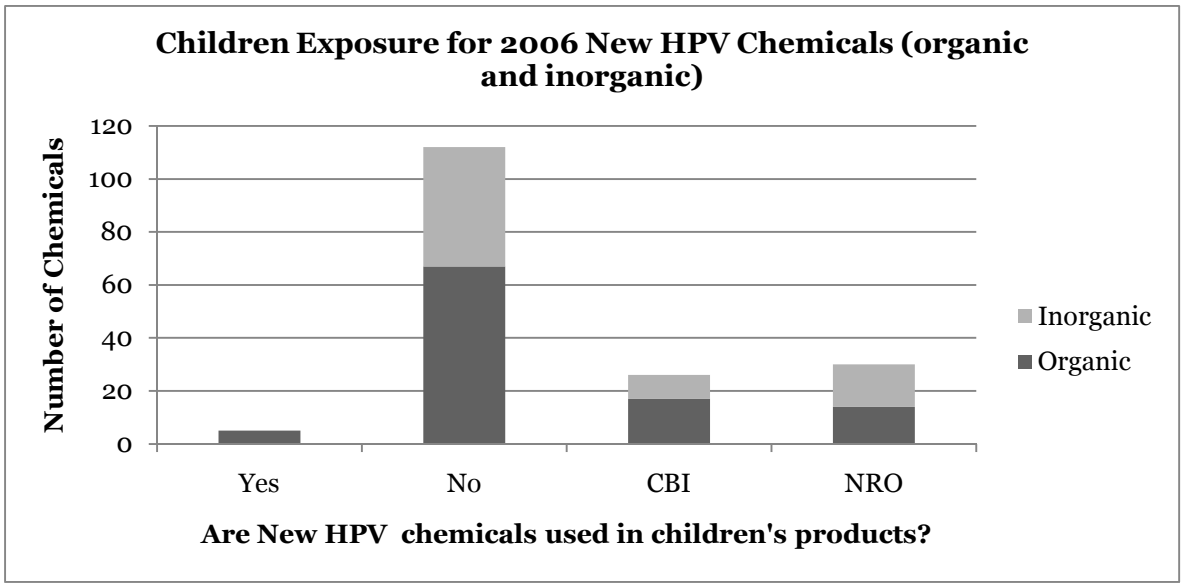
(a)



(b)

Perhaps even more disturbing is the extent to which CBI and NRO designations were made for data elements reflecting the use of a chemical in products intended for use by children. Figure 2 illustrates that a far from trivial percentage of companies claimed that information to be CBI or NRO in the 2006 IUR. In our view, these data should be ineligible for CBI protection.

Figure 2:
Children's exposure data reported for new HPV chemicals, both organic and inorganic, in the 2006 IUR



Appendix B: Comments on the Economic Analysis

EPA's 2010 Economic Analysis does not fully acknowledge the benefits of the proposed amendments and likely overestimates the burden and cost to industry. The tendency of the analysis to overlook the benefits, both qualitative and quantitative, makes the analysis incomplete. The overestimates are mainly the result of out-dated sources.

a. Evidence of an incomplete economic analysis

The 2010 Economic Analysis focuses in detail on the burden and cost to industry posed by the proposed amendments, but fails to include a monetary valuation of the expected benefits. Although *Section 7* is dedicated to the expected benefits of the IUR, specific monetary values would create a more level playing field for considering costs and benefits. While we recognize the difficulties in monetizing the benefits of better information, not quantifying any risk reductions (whether in monetary or psychical units) draws attention to the social costs and not the benefits. The costs are summed up neatly as $92 to $199 million in the 2011 reporting cycle. The benefits as described do not carry as much weight.

Moreover, there is a clear lack of description of benefits to the public at large or the population groups at risk. The benefits are primarily described in terms of what the proposed amendments will allow the Agency to do in terms of targeted regulation, education or enforcement. But these Agency actions in turn would lead to tangible health benefits and this link could have been more clearly demonstrated.

b. Overestimates resulting from use of a 1996 industry survey

The main driver for the industry cost estimates is the burden to industry, in terms of number of hours spent by employees to comply with the proposed reporting requirements. It is therefore crucial to ensure these estimates are based on up-to-date and objective data. However, it seems as though the burden estimates rely essentially completely on out-dated estimates derived exclusively from industry. Although the 2010 Economic Analysis refers to the "industry survey conducted for the 2002 economic analysis," the survey was actually conducted during the spring/summer of 1996 when "the Agency conducted a survey (under Office of Management and Budget clearance #2070-0034) to assess the potential burden associated with reporting for the proposed IURA under TSCA §8.1."[42]

The considerable lapse of time between the actual survey and now (14 years) is important because of two main developments over this period:

1. Since the mid 1990s there has been a revolution in electronic record keeping and transfer which has no doubt led to substantial increases in productivity. This is important because it implies that the 1996 burden estimates (in terms of hours

[42] This survey can be found in Appendix E of the 2002 Economic Analysis.

estimated) are almost certainly overestimates. Although, there have been adjustments made to account for the efficiency savings from electronic submission (see Section 4.4.27 of the 2010 Economic Analysis), there have been no apparent adjustments of burdens to account for the ease of record keeping and transfer with the latest available Information Technology.

2. The regulated community for the IUR rule (chemical manufacturers, refiners, and, potentially, a variety of chemical processors) has changed considerably. The mid to late 1990s saw a wave of consolidation for many chemical and oil companies. For example, testimony to the U.S. House of Representatives states that "over 2,600 merger transactions occurred from 1991 through 2000 involving all three segments of the U.S. petroleum industry."[43] This trend is of importance in the 2010 Economic Analysis because every reporting cost is based on a weighted industry average derived from the surveys. As the burden is very different among small, medium and large companies, changes in industry structure can have dramatic impacts on the average results used to extrapolate and calculate total industry cost. If consolidation has increased the number of big and small companies and reduced the number of medium companies, then using data from 1996 would lead the EPA to overestimate costs because data from the 1996 survey show that medium companies had the highest per-unit costs.

Furthermore, the 2010 Economic Analysis also lacks a sensitivity analysis to show that the burden may actually be considerably lower. As it stands, the 2010 Economic Analysis presents a range of $91.387 to $198.84 million for the 2011 reporting cycle, indicating the $91 million to be a lower bound. An updated survey or sensitivity analysis would likely indicate an even further reduced "lower" bound.

c. The estimates of efficiencies gained from the first to future reporting cycles are too conservative

The 2010 Economic Analysis estimates efficiencies gained in future reporting cycles by applying a 20% or 80% reduction in burden and cost, depending on the nature of the data element. These percentages are static across future reporting cycles (see Section 4.2.6 of the 2010 Economic Analysis). However, reporting would be expected to lead to more than the estimated "future cycle" reductions. Instead of a constant burden reduction, be it 20% or 80% of the initial burden occurred, we could envisage a sliding scale of additional reductions from a

[43] Source: Testimony Before the Subcommittee on Energy and Air Quality, Committee on Energy and Commerce, House of Representatives on "Energy Markets. Mergers and Other Factors that Affect the U.S. Refining Industry" Statement of Jim Wells, Director, Natural Resources and Environment, July 15 2004, GAO-04-982T. (http://www.gao.gov/new.items/d04982t.pdf)

yearly data collection and/or reporting requirement. The 2010 Economic Analysis overly relies on outdated sources for estimating efficiencies when more recent and refined estimates would provide an improved estimate that could well present lower burdens and costs.

d. The analyses for the alternative regulatory options are insufficient

1. Annual reporting: Although considerable benefits would accompany more frequent reporting, especially annual reporting or reporting of annual data, the 2010 Economic Analysis makes no comment on such benefits at all. In fact, an economic analysis of the costs and benefits of annual reporting or reporting of annual data is not even present. This falsely implies that such an option is unattainable and impractical when, in fact, there are clear efficiencies to be gained. Annual reporting or reporting of annual data would prevent the loss of learning that is likely to occur in the long expanse between reporting years in a four or five-year reporting cycle that requires reporting of data for only a single year in each cycle. More frequent collection and reporting is likely to increase efficiency as a result of decreased staff turnover in a shorter time period and a smaller impact of "the forgetting phenomenon."[44]
2. Lowering the threshold for reporting: Changing the threshold to 10,000 pounds/year/site or lower has fundamental benefits for exposure assessment and, therefore, improved safety of chemicals. However, appendix G of the 2010 Economic Analysis, which considers the Alternative Regulatory Options, only considers changes to the costs and burdens, and not the benefits. Again, this approach skews the discussion towards the costs and overlooks the reasons why this rule is being proposed in the first place: enhancing the ability of EPA, the market and the public to identify, assess and reduce the risks of chemicals in commerce.
   The main driver for the industry burden as a result of lowering the threshold is the number of additional sites that would need to submit reports. Unfortunately, these data are estimated using data from the year 2000:[45] "To estimate the total number of additional sites submitting reports as a result of the proposed option, EPA applied the percentage of total sites with production volumes between 10,000 lb. and 25,000 lb. in 2002 (19 percent), to the total number of sites in 2006; 4,085 (baseline 2006 numbers are presented in Table 4-6)". (It appears that the 2002 data were actually taken from a data base from 2000.[46]) As noted before, however the

[44] "Production breaks and the learning curve: The forgetting phenomenon" (M.Y. Jaber and M. Bonney, Applied Mathematical Modelling, 20. 2, February 1996, P. 162-169). (http://www.sciencedirect.com/science/journal/0307904X)

[45] See Table 2.3, p.2-14 of the 2002 Economic Analysis. Source for this Table is: "CUS Database. 2000. Information from the Chemical Update System Database maintained by the Information Management Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Washington, DC."

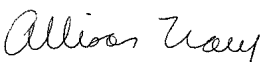
[46] 2010 Economic Analysis, p. G-13.

structure and extent of consolidation of the regulated community has changed considerably since 2000 or 2002, calling into question whether such data can be used today to accurately estimate the number of sites affected by the proposed amendments.

We appreciate your consideration of these comments.

Sincerely,

Richard A. Denison, Ph.D.
Senior Scientist
Environmental Defense Fund



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