Analysis&Perspective

TOXIC SUBSTANCES

LEGISLATION

The author of this article proposes suggestions for a revised Toxic Substances Control Act that are intended to make the law ''both effective and workable in meeting its goals and purposes.'' The author discusses a general statutory approach to testing and exposure information gathering for existing chemicals that he says would help to deal with the current weaknesses and to obtain more effectively the key hazard and exposure information reporting needed to ensure EPA's understanding remains current and informed. The article also outlines a possible approach for obtaining chemical reviews prepared by industry as well as some thoughts on possible uses of that information and concludes with a section on legislative considerations in developing and implementing these information requirements.

Periodic Reporting of Hazard Data, Exposure Information on Existing Chemicals

BY CHARLES M. AUER

A recent co-authored paper[1] discussed a number of fundamental changes in U.S. regulation of commercial chemicals that should be considered in revising the Toxic Substances Control Act.[2] As discussed in that paper, while the Environmental Protection Agency under TSCA has broad authority to require testing and reporting of hazard and exposure information on existing chemicals via rulemaking, deploying these authorities have proven cumbersome and inadequate for dealing effectively with the thousands of chemicals in commerce. Among the points explored in the paper was the need to establish requirements for regular periodic updating of basic hazard and exposure information and an approach was outlined for obtaining test data on new chemicals in a way that also helps to encourage continued innovation.

This paper presents a more detailed discussion of a general statutory approach to testing and exposure information gathering for existing chemicals which would help deal with the current weaknesses and more effectively obtain the key hazard and exposure information reporting needed to ensure that EPA's understanding remained current and informed. The paper also outlines a possible approach for obtaining chemical reviews prepared by industry as well as some thoughts on possible uses of the information collected, and concludes with a section on legislative considerations in developing and implementing the information requirements discussed in the paper. The intent of the approach proposed here is to help ensure that a revised statute is both effective and workable in meeting its goals and purposes.

[1] Charles M. Auer, *et al.*, ''Fundamental Changes Could Be in Store for Regulation of Commercial Chemicals,'' (195 DEN B-1, 10/13/09).

[2] 15 U.S.C. 2601-2629.

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The opinions expressed here do not represent those of BNA, which welcomes other points of view.

1.0 Introduction

1.1 General Approach

The elements of the approach discussed in the earlier paper include authorities for:

- regular periodic reporting of tiered ''basic'' hazard and exposure information with production/import volume triggering the reporting tier,
- extending reporting requirements to include downstream businesses such as users to ensure an adequate understanding of uses and exposures, and
- applying the reporting in a generally consistent manner to both new and existing chemicals.

Under this scheme, EPA should also have the flexibility to:

- exempt chemicals from requirements when the information is not believed to be needed or useful;
- accept ''read-across'' data, category information, and the results of (Quantitative) Structure Activity Relationships ((Q)SAR) analysis where scientifically justified;
- increase testing beyond basic data requirements where needed, *e.g.*, based on high exposure potential, exposure to vulnerable sub-populations such as children, or if EPA determines that special data needs exist (such as for endocrine-related testing) for a given chemical;
- implement the testing and reporting requirements (and changes to those requirements) by rule and by order; and
- share Confidential Business Information (CBI) with and receive CBI from states and foreign governments that can satisfy legal requirements and provide needed assurances of their ability to protect CBI from disclosure.

The resultant data and information would at a minimum be

- made publicly available by EPA (subject to CBI requirements),
- used by EPA to support prioritization, risk assessment, and risk management[3] of chemicals, and
- used by industry, as appropriate, to advise downstream customers as to hazards and risks and risk mitigation measures that should be applied.

1.2 Setting the Stage: TSCA Inventory Chemicals Known to Be in Production

The TSCA Inventory was originally created during the late 1970s based on information reported to EPA. It consisted of approximately 62,000 ''existing'' chemicals that were in commerce for TSCA uses at that time. Since then EPA has received Premanufacture Notifications (PMNs) on over 40,000 ''new'' chemicals (*i.e.*, chemicals not on the TSCA Inventory which are intended for commercialization) and, of these, approximately 20,700 have ''commenced manufacture'' and been added to the Inventory, subject to any testing requirements or controls imposed by EPA during its review.[4] Since 1986, EPA has obtained periodic reporting under the Inventory Update Rule (IUR) which ''updates'' the Agency's understanding of the organic (nonpolymeric) chemicals which were in commerce above certain production volumes. In 2003, EPA amended the IUR reporting requirements to also include inorganic chemicals and increased the reporting trigger to 25,000 pounds or more at a site with additional ''exposure/use'' information required to be submitted for chemicals produced at 300,0000 pounds or more at a site.[5]

Table 1 presents summary statistics on the current TSCA Inventory and also provides information on the reporting which was received under the most recent (2006) Inventory Update Rule (IUR). As the table shows there are presently almost 83,000 chemicals on the TSCA Inventory and of these, approximately 60 percent (50,000) are organic substances, 4 percent (3,200) are inorganic substances, and 36 percent (29,500) are polymeric substances.

The reporting under the 2006 IUR indicates that among the approximately 53,000 organic and inorganic chemicals on the Inventory (polymers are not subject to reporting under the IUR), fewer than 12 percent (6,200) were reported as being produced at 25,000 pounds or more at a site. Thus, over 88 percent of the 53,000 organic and inorganic chemicals on the Inventory were produced at less than 25,000 pounds at a site, if they were produced at all, during the IUR reporting year.

These figures help to provide some perspective on the scope of the task that is before EPA in assessing and managing TSCA chemicals and will also be important to consider in shaping new legislation.

2.0 Exposure Information Reporting

Basic exposure information reporting under a revised statute should include production/import volume, use information, and other relevant exposure information which would be needed to provide an initial understanding of how and at what scale a chemical is used and the nature of the exposures associated with the chemical. EPA should have the ability to use rulemaking or order authority to obtain additional more detailed information when needed to adequately assess a chemical. A starting point in developing the legislation is to use the then current Inventory Update Rule (IUR) ''exposure/use'' reporting tier as a model for the periodic reporting requirement (see the discussion of possible reporting triggers later in this section and in the next section).

Based on the experience with reporting under the IUR (which was limited to manufacturers and importers

[3] ''Risk assessment'' involves the integrated assessment of hazard (or ''toxicity'') and exposure data and information; ''risk management'' involves identification and implementation of the control measures needed to adequately mitigate risk in accordance with the relevant statutory requirements.

[4] Statistics taken from EPA's ''Overview: Office of Pollution Prevention and Toxics, Laws and Programs,'' March 2008 (http://www.epa.gov/oppt/pubs/oppt101-032008.pdf).

[5] Under the current IUR requirements (40 C.F.R. Part 710, Subpart C), manufacturers/importers of 25,000 pounds or more of a nonpolymeric chemical substance at a site, must report basic manufacturing information. If a manufacturer produces/imports 300,000 pounds or more of the chemical at a site, they must also report ''exposure/use'' information, including: number of workers reasonably likely to be exposed to the chemical; percent of the total volume associated with each processing or use activity, including commercial and consumer use product categories; maximum concentration information; and whether the chemical is used in products intended for children (see http://www.epa.gov/iur/pubs/2006_data_summary.pdf).

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and which showed that manufacturers/importers often did not have a good understanding of the uses and exposures which occurred after sale to ''downstream'' customers), it will be important to include authority for requiring exposure/use information reporting by downstream commercial entities (*e.g.*, processors,[6] users) to ensure that EPA has an appropriate and clear understanding of the uses and exposures throughout the chain of commerce. While expanding the reporting universe in this manner would undoubtedly strengthen the value of the information, it would also greatly increase the universe of reporting entities and the associated reporting burden, particularly if the requirements were extended to processors and users.[7]

To simplify the reporting requirements, the reporting trigger might be based on the volume associated with a given site for manufacturers/importers and possibly processors and EPA should consider if it would be more effective to consolidate reporting at the company level in the case of users. There would be value in requiring at least minimal reporting from all downstream entities (processors, users) to ensure EPA has a good understanding of the number and identity of such entities.

To limit ''exposure/use'' reporting burdens, consideration should be given to alternatives to such reporting by processors/users as a general requirement. Possible options include developing approaches whereby processors and users could decide to meet some of their exposure/use reporting obligations by working with the relevant manufacturer/importer or by including some ''for cause'' component which would trigger the requirement for processors and/or users to report exposure/use information. Use in products intended for use by children or use in consumer products are examples of general ''for cause'' triggers for exposure/use reporting by processors/users and EPA should also have authority to identify a priority for such downstream reporting in other cases (for instance, when EPA identifies a chemical as presenting significant potential hazards). EPA should also have the ability to require more extensive reporting on uses, exposures, and releases when it believes that the exposure/use level of reporting is not adequate to meet its needs on a given chemical (*e.g.*, one undergoing a more extensive assessment).

Finally, recognizing the volatility in reported production volumes from one IUR reporting cycle to the next, the exposure reporting should include annual production volume information from each of the intervening years and the requirement triggering exposure/use information reporting for a given entity could be based on that entity's highest annual volume during a given reporting period.

3.0 Test Data Reporting

3.1 Overview of testing strategies and costs. Testing strategies frequently apply the concept of ''tiered'' data where more basic screening level information is used to assess the need for and value in additional more detailed or comprehensive information.

This is the concept that was developed and applied by the Organization for Economic Cooperation and Development (OECD) with its Screening Information Data Set (SIDS). The SIDS is an internationally-agreed screening-level testing menu ''regarded as the minimum information needed to assess an HPV chemical to determine whether any further work should be carried out.''[8] Under the OECD's effort this test menu was applied to international High Production Volume (HPV) chemicals to provide a basic level of understanding which could be followed as needed by additional higher tier or ''confirmatory'' testing. The SIDS menu includes internationally agreed screening level testing in the areas of physical-chemicals properties, environmental fate, environmental toxicity, and human health endpoints. Table 2 presents the OECD SIDS test menu for human health endpoints, environmental toxicity, and environmental fate data and information as applied by EPA in the HPV Challenge Program[9] and in TSCA section 4 test rules to U.S. HPV chemicals (substances which have a total annual volume of 1 million pounds or more). The SIDS menu applied under TSCA section 4 test rules costs approximately $197,00-222,000 (in 2003 U.S.$), depending on the specific tests needed,[10] and, while generally appropriate for high volume chemicals, the cost might present affordability issues for lower volume chemicals.

Recognizing this, it is possible to design lower tiers that provide useful information at a more affordable cost. There may also be interest in developing a more robust tier that could be used as a general matter for high volume chemicals or on a more specific basis (*e.g.*, higher volume chemicals having high exposure or release potential). The concept of lower and higher tier testing can be seen in the test menus applied under the European Union's (EU's) REACH[11] regulation (also shown in Table 2) which arrays testing requirements for tiers ranging from 1 ton/yr (2,200 pounds/yr) to > 1,000 tons/yr (2.2 million pounds/yr). In general, the REACH test menu scheme requires a higher level of testing (a more confirmatory battery of tests) than is present in the OECD SIDS menu. Attempts to locate cost information for the final REACH test menus were not successful, however, based on a 2003 analysis done for the European Commission[12] and a 2007 research paper done on behalf of the European Chemical Industry Council (CEFIC),[13] an approximate range of esti-

[6] ''Processors'' can be involved in a variety of activities including blending chemicals and formulating products.

[7] The 2006 IUR involved reporting by approximately 1,500 companies at 3,800 sites for production/importation of subject chemicals. The total number of downstream entities processing or using these chemicals is not known but is likely to be one to several orders-of-magnitude higher (especially depending on whether the reporting is by company or by site).

[8] OECD, Manual for Investigation of HPV Chemicals: Description of OECD work on Investigation of High Production Volume chemicals; http://www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html.

[9] http://www.epa.gov/hpv/.

[10] EPA, Economic Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals: Final Report, EPA-HQ-OPPT-2005-0033, Oct. 8, 2005.

[11] ''Registration, Evaluation, Authorization and Restriction of Chemicals;'' Regulation (EC) No. 1907/2006.

[12] RPA, Assessment of the Business Impacts of New Regulations in the Chemicals Sector Phase 2, see p. 38 (''total testing costs per statistical phase-in substance'' used), October 2003 (http://ec.europa.eu/enterprise/reach/docs/reach/rev_bia-2003_10_29.pdf).

[13] Fleisher M, ''Research Paper Testing *Costs* and Testing Capacity According to the REACH Requirements – Results of a survey of independent and corporate GLP laboratories in the

mated costs for the REACH test menus can be provided. Cost estimates range from €51,404 to 56,360 for the > 1 ton/yr tier, €279,838 to 525,000 for the > 10 tons/yr tier, €799,562 to 927,208 for the > 100 tons/yr tier, and €927, 208 to 1,582.616 for the > 1,000 tons/yr tier.

Finally, Table 2 offers another perspective on a confirmatory level of testing, that from EPA's Voluntary Children's Chemical Evaluation Program (VCCEP). VCCEP testing is limited to human health endpoints and is similar to the testing found in REACH's highest tiers with differences in several key areas (*e.g.*, REACH includes a ''long term'' test for repeated dose toxicity while VCCEP recommends a 90-day study; VCCEP includes testing for immunotoxicity, neurotoxicity, and developmental neurotoxicity endpoints which are not included in the REACH menu). Cost information could not be located for this menu.

3.2 Approach elements. This section considers different ways of approaching the issue of developing and applying test menus to achieve a workable and effective scheme for obtaining hazard information.

3.2.1 Production triggers and tiered testing menus. The current U.S. HPV production trigger of > 1 million pounds/yr seems to offer a good starting point for requiring that a basic set of test data be developed, with lesser requirements for lower volume chemicals (*e.g.*, >100,000 pounds, >25,000 pounds, <25,000 pounds (25,000 pounds at a site is the reporting threshold for the current IUR and also approximates the 10 metric ton/yr trigger under the EU's REACH regulation)).[14] The minimum requirements for a basic set of hazard and fate test data should parallel those found in the OECD SIDS menu (as discussed above and presented in Table 2), including the need to compile and report available information on ''non-SIDS endpoints'' (*e.g.*, carcinogenicity, sensitization, etc.) as outlined by OECD in its ''Manual for Investigation of HPV Chemicals''.[15]

As an alternative to the OECD SIDS menu as the basic requirement for HPV chemicals, the more extensive test data requirements included in the highest tiers under REACH or, for the health effects subset of the testing, in the VCCEP program provide other models (see Table 2 for a comparison) for a confirmatory testing tier. However, rather than requiring these ''confirmatory'' test menus as a general matter, a better approach may be to rely on the OECD SIDS menu as a minimum and basic ''one size fits all'' set of test data required for HPV chemicals and then, as discussed later in this section, add to those requirements where circumstances warrant additional requirements for test data.

The basic test menu at the > 100,000 lb/yr tier might include all SIDS requirements other than the repeat dose, reproductive, and developmental toxicity endpoints which could be triggered for cause (*e.g.*, when used in children's products at significant volumes and/or concentrations) and also when the cumulative production over multiple years totals more than some value (*e.g.*, 1 million pounds might work although a higher value might deal better with possible affordability issues). Under such an approach, higher volume chemicals within the production tier would quickly become subject to the requirement, whereas lower volume chemicals within the tier would become subject over time. The lowest volume tiers (*e.g.*, > 25,000 pounds/yr, < 25,000 pounds/yr) might not include some or all of the repeat dose, reproductive, and developmental toxicity endpoints from the SIDS menu unless there is some other need or issue which prompts such a requirement for specific chemical.

3.2.2 Determining the reporting tier and any additional requirements for hazard data. The determination of the hazard data tier required for a given chemical should be based on the *total* U.S. production/import volume for the chemical, rather than relying on the more complex approach of considering hazard data requirements to be triggered on a company- or site-specific volume basis. Such a ''national'' approach was used under the current TSCA to support ''substantial production'' findings for test rules and also to identify the chemicals included in EPA's HPV Challenge Program. Under this approach, the production information reported in the *preceding* IUR reporting cycle would be used by EPA to identify the appropriate tier for each chemical in the *subsequent* cycle of test data reporting by industry. This approach also has the benefit of keeping testing requirements current with commercial developments. After each reporting cycle, EPA would need to promptly identify and publish information on the basic tier which is applicable for each chemical to provide notice and the time needed to comply.

Chemicals having certain uses with high or widespread exposure potential *(e.g.*, use in consumer products) or exposures involving vulnerable subpopulations (such as use in children's products), or that combine persistence, bioaccumulation, and toxicity (PBTs), or that present other significant issues (e.g., based on the results of screening level testing in the basic tier), could be subject to additional test data requirements.[16] One approach for such chemicals is to require the reporting corresponding to the next *higher* production tier. Such chemicals with HPV levels of use involving such exposures or that were HPV PBTs (especially if there were also indications of significant exposure or environmental release) might be required, possibly through a rulemaking involving consideration of ''factors'' or a combination of factors and findings, to develop some or all of the testing in a ''comprehensive'' data set; a starting point for a ''comprehensive'' set of test data might be the highest tier used under REACH or that used in VCCEP[17] (see Table 2). Procedurally, this could be done by applying the approach discussed above in determining total U.S. production, wherein EPA after each reporting cycle would need to promptly identify such chemicals and, through rulemaking, inform the regulated industry regarding the testing end-

EU and Switzerland,'' see p. 104 (figures for ''average price, all labs'' used), 2007, (www.businesschemistry.org/downloads/articles/Issue09-2007_52.pdf).

[14] Based on the 2006 IUR reporting, there were approximately 3,000 HPV chemicals produced between 25,000 and <1 million pounds during calendar year 2005. It is not known how many chemicals were made in the <25,000 pounds range.

[15] http://www.oecd.org/document/7/0,3343,en_2649_34379_1947463_1_1_1_1,00.html, section 2.4.4, p. 22.

[16] Nanoscale materials are also likely to present specialized needs for testing.

[17] The ''comprehensive'' testing might be focused on endpoints that were relevant to the ''for cause'' issue that triggered the increased testing—e.g., use in consumer products would trigger additional health effects endpoints *only* unless there were also indications of significant environmental release that warranted additional environmental testing.

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points which would be required for the next reporting cycle. This would provide notice and the time needed to meet the additional testing requirements.

3.2.3 Responsibility for compiling and reporting existing test data and for data compensation. One of the loose end questions concerns the commercial entities that would be responsible for compiling and reporting existing data and developing the new test data needed to meet the applicable requirements. There may be value in making producers and importers the default entities having responsibility for compiling existing data, identifying the needed basic testing, and then meeting these test data requirements at each tier, while including an ability to legally extend the responsibility to downstream entities when testing beyond the basic level is needed. This approach would be simpler than requiring that *all* commercial entities be involved in developing basic test data while allowing for expansion of the responsible entities where appropriate. Such an approach would also have the benefit of simplifying data reimbursement aspects insofar as it would initially limit the number of entities that would need to be involved in that process.

In the case of requirements for higher levels of testing due to exposures associated with downstream uses, the default might be to include the downstream processors/users in the data development process when requirements go beyond basic test data, although perhaps the simpler approach of initially requiring manufacturers and importers to handle the responsibility while providing a legal ability for them to obtain data compensation from downstream entities when needed would work.

3.2.4 Responsibility for determining ''data adequacy'' and needed testing. A related question is how to handle the responsibility for data adequacy determinations (*i.e.*, are the currently available test data adequate to meet the need without new testing) which currently falls to EPA under TSCA subsections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii). It is recommended that this responsibility be placed on industry wherein it would review and consider the scientific acceptability of the existing test data which are relevant to each required test and either proceed to conduct the test or articulate why the existing database is scientifically adequate to meet the need (this could also include a role for an independent third party entity as discussed in Section 5.0). Placing this responsibility with industry is consistent with the approach used in the OECD's HPV SIDS program, the U.S.'s HPV Challenge Program, and the EU's REACH regulation. In all these schemes government officials retain the ability to review the industry decisions and to call for or otherwise require testing where it is believed to be needed. (or, alternatively, believed not to be needed). This aspect should be retained in the new law. In a rulemaking to require testing beyond the basic level, the responsibility for evaluating data adequacy should reside with industry and EPA would consider that input in finalizing the testing requirements.

In doing the analysis of data adequacy and testing needs, industry would also be able to consider other information such as read-across studies, category analyses, (Q)SAR analysis, etc. in considering the adequacy of the existing data set. These approaches were used in the OECD and U.S. HPV efforts and can also be applied under REACH in the European Union. It is recommended that EPA have the authority to review industry's use of these other approaches and to require testing where EPA determines it is needed.

4.0 Should Hazard, Exposure Information Be Collected on Polymers?

A key question is whether and to what extent the new law should treat the 29,500 polymers on the TSCA Inventory in the same manner for hazard and exposure information reporting purposes as the over 50,000 organic and inorganic chemicals also included on the Inventory. While some polymers may be of concern, most are generally considered to present low hazard, especially those that have high molecular weights such that absorption is limited. Polymers also present some practical difficulties. For TSCA Inventory purposes, polymers are named based on the monomers which are used in their production. Thus, an Inventory polymer can be named as ''Polymer of A, B, C, and D'' where A to D are monomers used in producing the polymer and the chemical name does not otherwise provide any details on the reaction sequence or conditions, on the ratio of the monomers, the molecular weight (an indication of the molecular size of the polymer), or other critical information in determining the nature of the resultant polymer. In fact it is possible to make multiple, distinctly different polymers from a given Inventory listing by adjusting factors such as these. In reviewing new chemical polymers, EPA principally considers the polymer that the submitter intends to produce, an approach which gives a specific focus to EPA's assessment task.

Because of such considerations and practical complexities, polymers were not subject to reporting under the IUR and, accordingly, were not included in EPA's HPV Challenge Program. In Europe, the approach to polymers has differed historically from that in the United States, in that polymers were generally not subject to the legal regime which preceded REACH (*e.g.*, polymers were not included on the European inventory). Under REACH, polymers are exempted from the registration requirements that otherwise apply to organic and inorganic chemicals.[18] The Congress should consider this point with some care given the large number of Inventory-listed polymers which could be subject to testing and exposure information requirements, and also recognizing some of the practical issues briefly noted in this section. One alternative is to generally exempt existing chemical polymers from the otherwise generally applicable requirement for periodic reporting of hazard and exposure information while giving EPA the authority to require appropriate testing and exposure/use information reporting for specific polymers or classes of polymers when there is a concern and a need for such information has been identified by EPA.

5.0 Chemical Reviews Prepared by Industry

A possible component in the new law is a requirement that industry evaluates the hazards, exposures, and risks associated with chemicals and, as a second requirement, provide that evaluation, potentially in the form of a risk/safety assessment, to EPA. While there is

[18] Van Leeuwen, CJ, *et al.*, ''The Management of Industrial Chemicals in the EU,'' in *Risk Assessment of Chemicals: An Introduction*, 2nd ed., Springer, The Netherlands, p. 520, 2007.

merit to the concept of imposing such requirements on industry, there are, however, a number of possible complications that would need to be considered. While ''hazard'' (or toxicity) can be considered to be intrinsic to a given chemical, exposure and risks (risk assessment involves integration of the hazard and exposure analyses) will vary depending on the specific ways that different companies make or use the chemical. This difference is reflected in the differing approaches recommended in this paper for the collection of hazard information (a general requirement based on aggregated total volume) versus exposure information (specific reporting by site or by company). Another complication of exposure and risk assessments is that the underlying exposure and use information can be considered Confidential Business Information (CBI) which means that it cannot be easily shared.

For the hazard assessment, given that hazard is intrinsic to a given chemical, there would be value in avoiding the possibility of differing or ''dueling'' assessments being developed and provided to EPA. This could prove confusing to the public and might place EPA in the position of having to sort through multiple assessments. While this might not be a problem in the case of priority chemicals that EPA planned to assess, it could be a problem for the potentially large number of non-priority chemicals that EPA did not have the resources or the intention to assess at a given point in time. For the exposure and risk assessments, given the likelihood that the exposures and uses would differ among companies, it is almost guaranteed that these assessments will differ from company to company and as one goes down the supply chain to the final users. Efforts by EPA to develop and release assessment guidance for industry to apply in conducting the hazard, exposure, and risk reviews would be a helpful step but it is unlikely to avoid the problem entirely. Developing general guidance is one thing, developing more detailed/comprehensive guidance could prove quite difficult.

5.1 Possible role for independent third party entities in conducting chemical reviews? To help deal with these issues, there may be merit in considering setting up one or more independent third-party entities which could be jointly funded by EPA and the chemical industry and which would serve to prepare a unified hazard assessment, or to review and consolidate multiple industry hazard assessments to produce a single assessment, which would be provided to EPA for review and possible use in its further efforts. Third-party entities could also be set up to receive and utilize confidential exposure/use information in preparing exposure and risk assessment and would prepare confidential and non-confidential versions for release to EPA and to the public, respectively.[19] As an alternative, companies, while they might need to work with a third party entity on the hazard assessment, could have the ability to conduct their own exposure and risk assessments using EPA guidance, and to either provide the assessments directly to EPA or to run them through a third party entity for review prior to submittal to EPA.

A possible model for establishing one or more independent third party entities is that provided by the Health Effects Institute (HEI), a ''nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the health effects of air pollution'' which ''typically. . . receives half of its core funds from the (EPA) and half from the worldwide motor vehicle industry.''[20] Note that HEI's efforts also include conducting research studies on air pollution issues and an ability to use such an approach to obtain scientific studies might be useful in instances where a chemical or issue is particularly controversial or complex.[21]

6.0 Use of the Information

The information reported under the approach described above could be used for several purposes, including to:

- Provide the **source information for an EPA database of hazard and exposure information** which would be made publicly available to the extent non-CBI and be provided to the OECD's e-ChemPortal[22] to allow use domestically and internationally via the internet. Taking steps to engage with the EU to ensure that the test data being collected/generated under the REACH regulation is *promptly* available to EPA will also be a key step. Based on existing commitments, the REACH test data will be available more generally on eChemPortal as well as EU web sites such as those maintained by the European Chemicals Agency (ECHA).
- **Inform EPA efforts** under the new statute **to prioritize and assess chemicals and take needed risk management action**.
- **Periodically reset the TSCA Inventory** to reflect the chemicals actually in commerce. Chemicals for which no reports are received in one or possibly more[23] IUR reporting cycles can be viewed as no longer produced, imported, processed, or used in the U.S. (whether all of these judgments would be available will depend on the specifics of the reporting required) and should be considered eligible for removal from the Inventory. The potential significance of an Inventory reset authority is evident in the statistics discussed in Section 1.2 which indicate that of the 53,000 organic and inorganic chemicals on the Inventory, over 88 percent of these chemicals were produced at less than 25,000 pounds at a site during calendar year 2005 (which is the period covered in the most recent IUR reporting). It is considered quite likely that some significant number of these chemicals were not produced at all and may in fact be out of commerce.
- **Determine whether chemicals**, based on their total production/import volume or on the volume associated with uses having high or widespread exposure potential, **have triggered higher tier testing and exposure reporting requirements** in the next reporting cycle.

[19] Although legislation may not be needed to set up one or more independent third party entities, if there is interest in this concept there may be need for legislative language clarifying the entities' ability to receive CBI from companies and to provide it to EPA.

[20] http://www.healtheffects.org/about.htm.

[21] The EPA history web pages include an interesting discussion with former Administrator Douglas Costle concerning HEI and the motivations that encouraged EPA and the auto industry to establish an independent entity (http://www.epa.gov/history/publications/costle/17.htm).

[22] http://webnet3.oecd.org/echemportal/.

[23] An additional reporting cycle or two may be needed to adequately account for those chemicals which are only periodically produced in batches.

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- **Inform environmental hazard communication for chemicals and products**. At present, industry is obliged to engage in hazard communication regarding health and safety hazards posed by chemicals by virtue of hazard communication requirements implemented by the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC).[24] In revising TSCA, consideration should be given to imposing a similar requirement for hazard communication of environmental effects and environmental fate information. This would ensure that the entire supply chain is aware of important environmental information and can take appropriate precautions.

Hazard communication for environmental effects/fate information should be done so as to complement existing requirements under the Occupational Safety and Health Act and the Federal Hazardous Substances Act and in a manner generally consistent with the internationally agreed criteria for environmental effects information under the Globally Harmonized System (GHS) for classification and labeling.[25] In meeting the new environmental hazard communication requirements, industry should be required to apply the information contained in the EPA hazard data base discussed in this section (which should represent a comprehensive compilation of the available information, including key studies when multiple tests (*e.g.*, for acute aquatic toxicity) are likely to exist). Including this as a requirement would help to ensure more consistent and more fully informed hazard communication.

- **Provide a basis for determining and collecting fees from industry**. The approach of requiring regular periodic reporting which extends throughout the chain of commerce from manufacturers to users could also serve as the basis for determining who is subject to and for the collection of ''maintenance fees'' for chemicals which continue to be produced/used and as such could provide a portion of the basic resources needed to support EPA's work under the new law. Under such an approach, volume-based fee schedules (*e.g.*, for high/moderate/low volumes (H/M/L)) could be developed for each of the entity groupings throughout the chain of commerce (*e.g.*, manufacturers, processors, users) and be differently applied for each of these H/M/L entity groupings (such as H/M/L manufacturers and importers versus H/M/L processors versus H/M/L users of chemicals). The fees could be levied based on the periodic IUR reporting by each entity and be collected at the time of each report. Other factors that could be incorporated into the fee structure include: increased fees for specific chemicals or specific uses/types of uses of those chemicals that EPA had scheduled for more detailed review (this could be done prospectively, retrospectively, or both); and appropriate fee reductions for small businesses.

The general approach of using the regular periodic reporting to determine and collect appropriately differentiated fees (or a range of fees) would have several benefits including:

- o spreading the fee responsibility to all companies throughout the chemicals chain of commerce;
- o establishing a periodic triggering event for the collection of fees on existing chemicals. While new chemical notifications would presumably continue to be required and could be made subject to their own fees, the periodic reporting requirement could serve a similar function for existing chemicals for fee purposes (including former new chemicals after some initial commercialization period); and
- o being relatively simple to administer since the fee amount for a given entity could be determined based on the information submitted in meeting the periodic reporting requirements and also be collected with the report.

Obviously, careful analyses would need to be done to determine the viability of the approach proposed as well as other possible approaches. While EPA has IUR information on the number of manufacturers and importers (including volume information) of nonpolymeric chemicals manufactured/imported above 25,000 pounds at a site, it

- o does not currently collect information from processors nor
- o does it require reporting on lower volume chemicals or on polymers (which, as discussed in Section 1.2, represent about 57 percent and 36 percent, respectively, of the 80,000+ chemicals included on the TSCA Inventory), and
- o currently lacks authority under TSCA to collect information from users.

An understanding of the key information relating to such entities (starting with an answer to the question of ''how many?'') would be of great value in determining the potential structure and workability of a fee collection effort based on periodic reporting requirements.

7.0 Legislative Considerations in Developing, Implementing Information Requirements

7.1 General approach. The establishment of clear and appropriately tiered production volume-based reporting triggers and the hazard data and exposure information reporting that will be required at each tier will be important issues to get right. While specifying the reporting triggers in the statute would provide valuable clarity, attempting to do the same for the test data and exposure information requirements at each tier would present legislative complexities and could have the effect of ''locking-in'' the specifics as future data and information needs change or new needs emerge. The better approach would be to provide policy objectives and instructions to the agency concerning the elements to consider in establishing the tiered reporting requirements by regulation, and establish a statutory deadline for completing the regulation.

The revised statute should extend testing and exposure information reporting authority beyond manufacturers and processors to include downstream commercial entities such as distributors and users. The reporting tier triggers for a basic level of testing should be based on the total production and import of the chemical in the U.S. while the exposure information reporting trigger should be based on site-specific volumes in some cases and company-specific volumes in other cases as discussed in Section 2.0. EPA should have authority to obtain, via rulemaking and orders as appropriate, additional or more detailed hazard or exposure information when needed using considerations such as those discussed in Section 3.2. This section also discussed some possible approaches to simplify data com-

[24] http://www.osha.gov/dsg/hazcom/index.html; http://www.cpsc.gov/businfo/fhsa.html.

[25] http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

pilation, data reimbursement, and data adequacy determination elements, such as limiting responsibility in some cases to manufacturers and processors but allowing for downstream entities to be included in the data compensation requirements when additional higher levels of testing are needed.

7.2 Timing of initial reporting and an option for a ''prompt start'' approach to reporting. The timing for the initial reporting under the revised statute should occur following some appropriate delay (*e.g.*, it might be set to occur three years after the deadline for completing the implementing regulation) to provide the time needed for information to be collected or testing conducted. Reports should be updated periodically thereafter (*e.g.*, every 3-5 years). If Congress desires a more prompt start to the testing and exposure reporting, it might consider an approach to statutorily extend the exposure/use reporting under the then current IUR rule to additional downstream entities with an appropriate due date for reporting while also applying the OECD SIDS test menu (as reflected in the testing requirements and guidance applied in the relevant TSCA test rules) to all HPV chemicals (EPA considered production/import at or above 1 million pounds/yr to be ''HPV''). EPA could then have more time to develop and promulgate the upgraded testing and reporting regulations which would take effect in the second reporting cycle. And in the meantime, EPA could apply the additional information obtained via this ''prompt start'' approach in meeting the assessment and management requirements contained in the new statute.

7.3 Other legislative points. Among other legislative points raised in the article, EPA should, as discussed in Section 6.0 of the paper, receive explicit authority to:

- periodically reset the TSC Inventory to reflect the chemicals actually in commerce;
- implement a hazard communication requirement for environmental fate and effects information which is implemented in a manner complementary to the hazard communication approaches used by OSHA and CPSC for health and safety information and which applies as appropriate the internationally agreed GHS approach.

Finally, EPA should receive authority to share CBI with and receive CBI from States and foreign governments that can satisfy legal requirements and provide needed assurances of their ability to protect CBI from disclosure. Inclusion of such a provision would allow for broader sharing of information where there is a need for the information and could also open the door for sharing of assessments and possible collaboration with States and foreign governments where appropriate in assessing and possibly managing chemicals.

8.0 Conclusions

While revision of TSCA is needed and overdue, it is essential that the final product produce an approach that is both workable and effective. ''Getting it right'' will require the Congress to consider and appropriately resolve a number of key and complex issues. This is clearly an effort where the details matter. This paper has provided several practical suggestions which could contribute to the development of new legislation which can meet its goals and objectives while being both workable and effective in its implementation. Given the critical role of chemicals in U.S. society and commerce, getting the approach right will be essential to meeting health and environmental protection goals while ensuring the future competitiveness of the United States in this key and encompassing sector of the economy.

Table 1. Summary statistics on the current TSCA Inventory and reporting under the most recent IUR[24]

Type of chemical	TSCA Inventory chemicals (approx. values) as of 2006	Nonpolymeric chemicals reported at >25,000 lbs. at a site in the 2006 IUR	Nonpolymeric chemicals *not* reported in the 2006 IUR[25]
Organic	50,200 (60%)	5,546	44,654
Inorganic	3,200 (4%)	654	2,546
Polymer	29,500 (36%)	NS[26]	NS
Totals	82,700	6,200	47,218

[24]Statistics taken from EPA's ''Overview: Office of Pollution Prevention and Toxics, Laws and Programs,'' March 2008 (http://www.epa.gov/oppt/pubs/oppt101-032008.pdf) and its ''2006 Inventory Update Reporting: Data Summary'' (http://www.epa.gov/iur/pubs/2006_data_summary.pdf).

[25]These existing chemicals were thus produced at less than 25,000 lbs at a site, if they were produced at all during the IUR's 1 year reporting period.

[26] Polymers are not subject (NS) to reporting under the IUR.

Table 2. Comparison of Hazard and Environmental Fate Information/Data Requirements in OECD HPV SIDS, EU REACH,[27] and U.S. VCCEP[28]

INFORMATION / TEST DATA REQUIREMENTS	OECD HPV SIDS[29]	EU REACH				U.S. VCCEP
		>1 ton	>10 tons	>100 tons[30]	>1000 tons[30]	
Human health endpoints						
Skin irritation or skin corrosion		X(*in vitro*) , unless	X*(In vivo)*, unless			
Eye irritation		X(*in vitro*) , unless	X*(In vivo)*, unless			

  DEN ISSN 1060-2976

INFORMATION / TEST DATA REQUIREMENTS	OECD HPV SIDS[29]	EU REACH				U.S. VCCEP
		>1 ton	**>10 tons**	**>100 tons[30]**	**>1000 tons[30]**	
Skin sensitization		X, unless				
Mutagenicity						
In vitro gene mutation study in bacteria	X	X				X
*In vitro*cytogenicity study in mammalian cells	X		X, unless			X
*In vitro*gene mutation study in mammalian cells			X, if + unless			
*In vivo*mutagenicity studies	X, if			X, if	(X)	X, if
Acute toxicity	X (1 route), unless	X (oral), unless	X (1 other route), unless			X (1 route), unless
Repeated dose toxicity	X (28 day), unless		X (28 day), unless X (90 day), if	X (90 day), unless	(X (long term))	X (90 day)
Immunotoxicity						X
Reproductive toxicity						
Screening for reproductive/ developmental toxicity	X, unless		X, unless			
Developmental toxicity study			X, if	X, unless		X (2 species)
Two-generation reproductive toxicity study			X (1^{st} species), if	X (1^{st} species), unless	X (2^{nd} species), unless	X (1^{st} species)
Toxicokinetics			Assessment derived from the relevant available information			X
Carcinogenicity					(X)	X (or chronic/onco)
Adult neurotoxicity						X
Developmental neurotoxicity						X
Ecotoxicological and environmental fate information						
Aquatic toxicity						
Short-term toxicity testing on*Daphnia*	X, unless	X, unless				
Growth inhibition study on algae	X, unless	X, unless				
Short-term toxicity testing on fish	X, unless		X, unless			
Long-term toxicity testing on*Daphnia*	X, if	X, if	X, unless			
Long-term toxicity testing on fish	X, if			X, unless		
Degradation			X, if	X, unless		
Biotic Ready biodegradability	X, unless					
Simulation testing on ultimate degradation in surface water			X, unless			
Soil simulation testing			X, if	X, unless		
Sediment simulation testing			X, if	X, unless		
Abiotic Hydrolysis as a function of pH	X, unless					
Identification of degradation products			X, unless			
Further degradation testing				X, unless		

INFORMATION / TEST DATA REQUIREMENTS	OECD HPV SIDS[29]	EU REACH				U.S. VCCEP
		>1 ton	>10 tons	>100 tons[30]	>1000 tons[30]	
Fate and behavior in the environment				X, if		
Adsorption/desorption screening study						
Bioconcentration in (one) aquatic species, preferably fish			X, unless			
Further studies on adsorption/desorption				X, unless		
Further environmental fate and behavior studies				X, unless		
Effects on terrestrial organisms (short term)	X, if				X, if	
Effects on terrestrial organisms (long term)				X, unless		
Long-term toxicity to sediment organisms					X, if	
Long-term or reproductive toxicity to birds					X, if	

[27] Taken from OECD Manual for Investigation of HPV Chemicals (Annex 1 to chapter 1):
http://www.oecd.org/document/7/0,3343,en_2649_34379_1947463_1_1_1_1,00.html.

[28] http://www.epa.gov/oppt/vccep/pubs/basic.html#basic4. Note that VCCEP does not include any ecological or fate testing and the contents of the higher ''comprehensive'' tier would need to be developed for these endpoints.

[29] As applied by EPA in the HPV Challenge Program and HPV test rules (http://www.epa.gov/hpv/).

[30] Subject to alternative fulfilment of information requirements as outlined in Annex VI of REACH.

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