

## **Initial Thought-Starter:**

### **How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?**

**Developed by  
Broader Issues Work Group (BIWG)  
National Pollution Prevention and Toxics Advisory Committee (NPPTAC)  
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#### **I. Background to Thought-Starter**

In February 2005, NPPTAC directed the Broader Issues Work Group (BIWG) to develop and return with a discussion of some of the challenges faced by EPA in determining when and how the Agency should undertake, or facilitate others in, risk reduction actions. The NPPTAC was interested in a discussion of both formal and information actions available to the Agency under its present TSCA and agency discretionary authorities. BIWG gathered information, discussed various approaches to this topic, analyzed a number of situations faced by EPA, and proceeded in the following manner.

First, the group worked with EPA and developed two documents, *EPA Authorities Under TSCA*, and a draft *TSCA Authorities Matrix*. Both of these documents highlight, in different formats, the current authorities available to the Agency under TSCA (the first document was the subject of a briefing in the June 2005 NPPTAC meeting).

Second, in preparation for the June 2005 NPPTAC meeting, BIWG developed, agreed on and presented the following statement to focus discussions:

#### **Problem Statement**

In light of the following factors, including the:

- Influx of more information on chemicals as a result of the HPV Challenge Program and other programs;
- Need, at times, for EPA to act in light of uncertain, but significant information; and
- Public expectations that government is effectively managing risk,

The Broader Issues Work Group agrees to develop and coordinate a discussion by NPPTAC of the following question:

*In situations where information is uncertain, when and how should EPA undertake and facilitate risk reduction actions, both informal and formal?*

Third, as a result of discussions in June, BIWG chose to further focus their discussions by selecting a specific case where EPA was likely to face the types of risk assessment and risk management decisions alluded to in this problem statement. BIWG examined several potential

issues, and determined that chemicals not covered by the new chemicals program, High Production Volume Program or the Extended High Production Volume Chemical program (the “Non-HPV Chemicals”) might be an area in which EPA could develop new approaches using informal, as well as formal, TSCA authorities.

The HPV program will provide Screening Information Dataset SIDS data on about 2,500 of the High Production Volume chemicals. In addition, industry has already agreed to an Extended High Production Volume Chemical (EHPV) program that would provide SIDS data on some 575 additional chemicals. While these constitute only part of the chemicals on the TSCA Inventory or the over 8,300 chemicals manufactured at 10,000 pounds or more per year, they constitute >90%, by volume, of chemicals in commerce. Therefore, BIWG focused discussions on the options available to EPA with the non-HPV existing chemicals (all HPV chemicals are excluded from this group whether they are being addressed under the HPV Challenge Program, EHPV, OECD SIDS, ICCA HPV Initiative or by a Section 4 test rule) to “more efficiently identify potential risks” and “facilitate risk reduction decisions.” Thus for purposes of this discussion, all chemicals produced at levels below 1 million lbs/yr are termed “non-HPV,” while those produced between 10,000 to less than 1 million lbs/yr are termed “lower volume chemicals,” while those produced below 10,000 lbs/yr are termed “low volume chemicals.” Within these latter groups, consideration can be given to whether former new chemicals should be included or excluded from such groupings for purposes of the options described below.

Therefore, as a case example to address the problem statement above, and to support the October 2005 NPPTAC discussion requested, BIWG has developed this initial thought-start to address the following question:

*How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?*

BIWG offers, below, an overview of the existing Non-HPV chemicals believed to be in commerce at this time (this Overview was prepared by EPA), to inform and support the NPPTAC discussion. After reviewing this information, BIWG decided to present a range of risk assessment and risk management options available to EPA to efficiently gather information to identify potential risks, and to efficiently facilitate risk reduction decisions (NOTE: BIWG outlines options for many types of action, whether undertaken by EPA or by others, including industry, other Federal agencies, interested stakeholders, or the public). ***The options outlined in this thought-starter illustrate the types of actions that can be undertaken by EPA, and ultimately others, and DO NOT represent an endorsement of any particular action to be undertaken by the Agency or a recommendation by BIWG for NPPTAC endorsement.***

Therefore, following the overview of Non-HPV Chemicals, this thought-starter outlines five options for NPPTAC discussion during its October 2005 meeting, ranging from information gathering to regulatory actions. Each option is described, and supplemented with BIWG information on some of the potential benefits to the option, as well as some of the considerations in executing the option. Members of the Broader Issues Work Group look forward to an engaging discussion as to whether, and if so how, BIWG should continue efforts to answer the previously identified question.

## **II. Overview of Non-HPV Chemicals**

The following description of the number, type and nature of non-HPV chemicals that could be predicted to be in commerce was developed through a series of questions, posed by BIWG members, and answers, provided by EPA. This description is provided to illustrate the nature and breadth of the chemicals to which the options described in Section III. of this paper would be applied.

### **1. How many non-HPV chemicals are in commerce?**

There are currently over 82,000 chemicals on the TSCA Inventory. When the Inventory was developed was in 1976, companies were provided the opportunity to report those chemicals that they were then using – approximately 62,000 were reported and placed on the original Inventory. Since that initial call, EPA has implemented its New Chemicals Program. As a result, the only manner in which subsequent chemicals could be added to the Inventory has been to go through the New Chemicals Program as a “new chemical”. EPA has reviewed approximately 33,000 such submissions, of which about 20,000 have been added to the inventory.

The Inventory does not include chemicals that are exempt from the PMN program under the Low Volume, Low Release, and Low Exposure and Test Market Exemptions (EPA has received notice of about 10,000 such exempt chemicals) or certain polymers and R&D materials that are exempt under the PMN program’s self-implementing exemptions. The Inventory does not include chemicals when they are solely used for uses that are not subject to TSCA, such as cosmetics, pharmaceuticals, food, food additives, pesticides, tobacco and nuclear materials.

Though the Inventory Update Reporting Rule (IUR), OPPT gathers information on organic chemicals that are produced (manufactured or imported) in quantities of 10,000 pounds or greater in the year preceding the information collection (currently every 4 years). OPPT does not gather information on chemicals which have been withdrawn from commerce.

### **2. How many lower volume chemicals made at over 10,000 pounds per year are in commerce?**

For the 2002 IUR reporting period, the EPA has received notice that 8,318 chemicals on the TSCA Inventory were manufactured at over 10,000 pounds per year per site (only organic chemicals were subject to reporting requirements). Of these, 2,946 were reported in volumes of 1 million pounds or greater. Therefore, EPA was notified of 5,372 “lower volume” chemicals between the reported production volume of 10,000 pounds and 1 million pounds.

The number of chemicals, as well as the specific chemicals themselves, are not the same in successive IUR reports. Industry is required to provide specific information to the Agency on those chemicals which were in commerce the year preceding the IUR reporting cycle which were produced (or imported) in volumes of 10,000 pounds or greater per year per site.

Generally the Agency has noted about a 33% fluctuation in the specific chemicals reported from each IUR cycle (1990, 1994, 1998, and 2002). Approximately 13,800 chemicals, including both lower volume and high volume chemicals, have been reported at least once in the four IUR reporting cycles.

In the 2002 reporting cycle, of the 8,318 chemicals reported, approximately 1,481 had gone through the PMN process (1233 non-HPV, 248 HPV chemicals), which accounted for a total production volume of over 5 billion pounds.

**3. What is the distribution by volume of the non-HPV chemicals reported under the most recent (2002) IUR?**

Production Range pounds	Number of Chemicals	% of Chemicals	Production Volume pounds.*	% of Total Production
< 10K	33**	.4	168,742	<.00
10K – 500K	4,669	56.1	568,006,342	<.00
> 500K – 1M	670	8.1	477,154,042	<.00
> 1M – 10M	1,551	18.6	5,249,843,860	0.03
> 10M – 50M	577	6.9	14,011,670,586	0.09
> 50M – 100M	153	1.8	10,510,499,335	0.07
> 100M – 500M	273	3.3	63,813,760,378	0.42
> 500M – 1B	77	.9	54,890,032,920	0.36
> 1B	315	3.8	15,059,436,582,243	99.02

\* The numbers presented in this table are based on the IUR data base as of October 4, 2005.

\*\* The 33 chemicals at < 10K lbs. figure above represents the number of chemicals with such production volumes reported under the 2002 IUR. Chemicals with production volumes below 10,000 are only subject to IUR reporting if certain conditions are met, such as that they are subject to an order under section 5(e). The Agency believes that the actual number of low volume chemicals (i.e., those with production volumes below 10 K lbs) is significantly greater than 33 but does not have any good information as to the number that are essentially not in production.

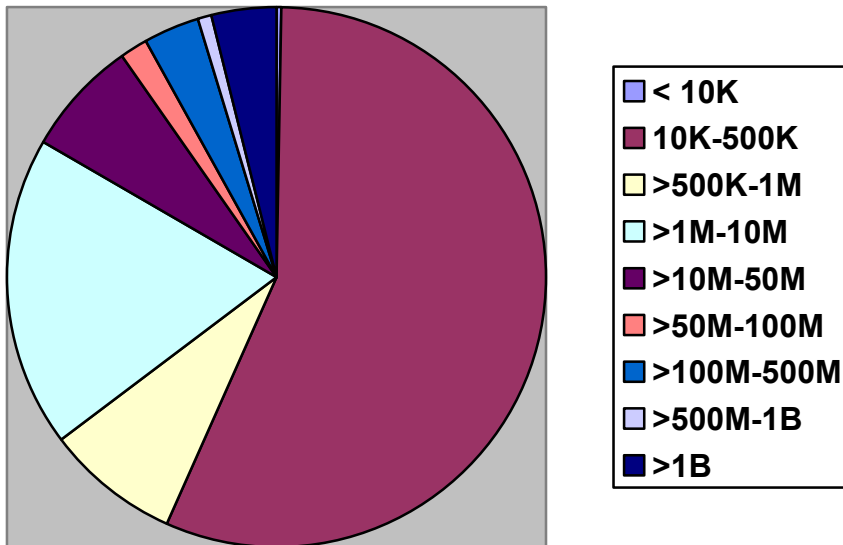


Figure 1: Distribution of chemicals in 2002 IUR by number of chemicals in each production volume category

#### 4. What is the distribution by type of the chemicals on the Inventory?

Based on 82,000 Inventory substances:

Polymer: 28,000

Non-polymer: 54,000

-Organics: 51,500

-Inorganics: 2,500

For original Inventory, based on 62,000 substances:

Polymer: 21,000

Non-polymer: 41,000

-Organic: 39,000

-Inorganic: 2,000

Via PMN review, 20,000 substances:

Polymer: 7,000

Non-polymer: 13,000

-Organic: 12,500

-Inorganic: 500

#### 5. What percentage of the total volume of chemicals in commerce is attributable to HPV chemicals?

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*This is a product of a Work Group of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) and is intended for either Work Group or NPPTAC consideration or review. Nothing herein should be construed as providing Work Group advice to EPA.*

Chemicals Reported Under 2002 IUR		
	Volume	Number of chemicals
All Chemicals	15,208,957,718,448	8318
HPV	15,207,912,389,322	2946
non-HPV	1,045,329,126	5372
% of Total Volume That is HPV - 99.99%		

## 6. How many non-HPV chemicals are in commerce?

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The Inventory does not include chemicals that are exempt from the PMN program under the Low Volume, Low Release, and Low Exposure and Test Market Exemptions (EPA has received notice of about 10,000 such exempt chemicals) or certain polymers and R&D materials that are exempt under the PMN program’s self-implementing exemptions. The Inventory does not include chemicals that are not subject to TSCA, such as cosmetics, pharmaceuticals, food, food additives, pesticides, tobacco and nuclear materials.

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### **III. Non-Regulatory and Regulatory Options for NPPTAC Discussion**

The following non-regulatory and regulatory options were developed to illustrate the issues faced by EPA in addressing the question: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals? The options for discussion include: Option A: Reporting & Database Development; Option B: HPV Challenge-type Program for Non-HPV Chemicals; Option C: Supplement Information Reported Through Section 8(e); Option D: Apply New Chemical Review Process; and Option E: Apply TSCA Sections 4, 5, 6, and 8.

#### **Option A: Reporting & Database Development**

Potential Action: Implement a program to gather and compile into a publicly-accessible database existing information about non-HPV chemicals.

Description of Option A:

EPA would compile into a publicly-accessible database all existing risk-related information on the non-HPV chemicals on the Inventory, or at least a significant subset of those that are known to be in commerce, i.e., those produced above the TSCA Inventory reporting threshold of 10,000 pounds/year/producer. This information is expected to be primarily hazard information, but could also include use and exposure information. This option would represent an effort to reduce the number and extent of data gaps for these chemicals so as to better inform entities attempting to understand potential hazards or risks, or to choose safer, greener chemicals. Many such choices to use safer chemicals might never become publicly known, especially when made by industrial users of chemicals, but may nevertheless be significant for the economy and public health and the environment. This Option would expand on EPA's commitment to enable the many users of chemicals in the industrial economy to make better-informed choices about the chemicals available for use, and complement EPA's more traditional focus on assuming responsibility for making decisions itself about how chemicals should be used.

To begin this project, a subset of the non-HPV chemicals (e.g., those produced between 500,000 and 1 million lbs/yr) could be chosen for initial focus. Alternately, a subset of the non-HPV chemicals could be chosen based on other criteria such as:

- identified as a potential PBT chemical using EPA's PBT profiler;
- used in consumer products (though EPA has almost no information on this);
- inorganic chemicals containing a heavy metal (although the HPV program is not yet handling such chemicals as a priority); or
- non-HPV chemicals from one of the following three current lists of chemicals (note: we do not know how many of the chemicals on these lists are non-HPV chemicals or how many are on the Inventory, which should be determined as an initial matter in exploring this Option):

1. Hazardous Substances Data Bank of the U.S. National Library of Medicine, which contains entries for about 4,700 potentially hazardous chemicals. National Institutes of Health, National Library of Medicine. Hazardous Substances Data Bank at:

<http://www.nlm.nih.gov/pubs/factsheets/hsdbfs.html> (Accessed February 2, 2005).

2. The E.U.'s Harmonized Classification system lists about 5,000 hazardous chemicals. Commission of the European Communities. White Paper: Strategy for a future Chemicals Policy - COM (2001) 88 final, p. 23-24. Brussels, February 27, 2001; Forward to Annex I, p. 2.

[http://ecb.jrc.it/DOCUMENTS/Classification-Labelling/Foreword\\_Annex\\_I\\_28th\\_ATP.pdf](http://ecb.jrc.it/DOCUMENTS/Classification-Labelling/Foreword_Annex_I_28th_ATP.pdf)

Official Journal of the European Communities Annex 1A (August 8, 2001).

3. Norway's List of Hazardous Substances contains about 3,000 chemicals. Norway State of the Environment. List of Dangerous Substances at:

<http://www.environment.no/datasok/stoffliste/stoffliste.asp?topmenuindex=2&leftmenuindex=1&pagename=List+of+Dangerous+Substances>

Any chosen subset of chemicals could be further limited as appropriate to yield a manageable number of chemicals for initial work to test out the approach. Compiling this database could involve any of several complementary approaches:

- Voluntary commitment by manufacturers to submit available information (the full range of information which can be submitted under the HPV Challenge Program (SIDS plus other available data on non-SIDS endpoints) might also be applied here). The submission could be in the form of robust study summaries or full study reports. The voluntary submission might also include available information on uses applying the use categories from the IUR as amended, or be limited to hazard data.
- Use of Section 8 rules to require companies to submit available information. This could be limited to hazard information or extend to include use information. Hazard information could be required to be reported as robust study summaries, full studies, or both.
- The effort could start with a voluntary program and be backstopped by section 8 rulemaking for chemicals not sponsored voluntarily.

All this information would then be made publicly available, in an accessible format, on a website.

#### Benefits of Option A:

The primary benefit of this option would be to reduce data gaps by making existing hazard data on the selected subset of chemicals widely available. This was one of the most useful contributions realized to date under the HPV Challenge program, where almost 7,000 studies were newly made available under this program. The data would enable users of chemicals to make better choices about what chemicals to use and would represent an effort to assist companies and others desiring to do so to choose safer, greener chemicals. This database could also be used by EPA to prioritize non-HPV chemicals and determine which of them need management or further information development.

#### Considerations for Option A:

While it may be necessary to begin this project with a subset of the non-HPV chemicals using an approach such as those noted above to limit the number of chemicals, for this database to be useful for its intended purpose, most or all of the chemicals in commerce would ultimately need to be included. This could represent a major undertaking for the Agency and for industry and would need to be balanced against other, potentially competing, priorities. This option presumes that users of chemicals need to know more than what is currently provided through MSDS's. It

also presumes that they need affirmative information indicating that a chemical they select is safer, at least with respect to a basic data set, than other competing chemicals. It also presumes affirmative data would become available suggesting that certain chemicals are safer than others and that such information might support their continued or expanded use in commerce. This option addresses the concern by some that information only in the possession of a chemical manufacturer or EPA does not assist a user of chemicals or a consumer in making choices.

Several chemical information databases have been compiled as indicated above. The scope of these databases, both with respect to the chemicals included and the information sources used to compile the databases, should be considered and built upon as possible components of or as an alternative approach under this option.

This option has implications for the protection of confidential business information. Because EPA encourages the public disclosure of information under the concept of Right To Know, and because the purpose of the option would be to enable all potential users of chemicals to have access to the available health and environmental data about those chemicals, information on the hazards and fate of chemicals would need to be in the public domain. The protection of CBI is authorized under TSCA, with a long historical precedent of what information and how that information is protected. Health and safety information is not eligible for CBI protection under TSCA, although other elements of information called for under this option could be. These issues would need to be examined closely in considering this option. Also, there could be issues with submission of full studies relating to loss of ability to receive data compensation.

One important consideration will be obtaining consistent and high quality data for compilation into the database. For the data to be useful, there should be some level of confidence in the quality of data collected, without overburdening the system for collecting and checking the data. One could argue that the submitter and/or EPA should assess any data put into such a database, e.g., based on the application of data adequacy understandings developed under the HPV Challenge Program. If data or the reporting are determined to be inadequate, additional information could be sought by EPA, or the submission could be omitted or be flagged as "inadequate." Alternatively, one could argue that such a screening process would be burdensome to the industry and/or the Agency and might not represent the best use of available resources, and that all information submitted on the selected chemicals should be included in the database. One could argue that there are many sophisticated users of chemicals in industry and in the public health fields that are capable of evaluating and using such diverse data (and may even prefer unfiltered data) in order to choose and recommend safer chemicals for industrial users, purchasing organizations, consumers and others.

Finally, some limited efforts of this nature are underway already, particularly focused on the HPV chemicals data. The OECD's "Global Portal" and the EPA's HPV Information System are examples, but these are not expected to include substantial numbers of non-HPV chemicals in the next few years. The experience and technology being developed for these systems should be utilized and built upon. Also, efforts to collect and make available data on lower volume non-HPV chemicals might open the door to further cooperation with EU authorities as they design their IT tools for making the REACH data publicly available.

## **Option B: HPV Challenge-type Program for Non-HPV Chemicals**

Potential Action: Develop an approach modeled on the HPV Challenge Program for a subset of the non-HPV chemicals.

### Description of Option B:

A subset of non-HPV chemicals would be selected for an HPV-like voluntary challenge program involving voluntary collection of available data and voluntary testing as needed to complete an appropriate set of data. The larger goal of this option would be to make publicly available a consistent set of health and environmental effects data for those chemicals. The base data set could be the SIDS data set, or some lesser subset of the SIDS data elements based on the lower production volumes involved. Alternatively it could be based on an updated dataset since some say the SIDS data is outdated; such a step would need to be approached in a way that encouraged international agreement/cooperation (e.g., OECD has not undertaken to define an alternative to the SIDS and securing international agreement would be a valuable step to include). The subset of chemicals could be based on a tonnage tier which would be identified as the appropriate next one down from the 1 million pounds per year of the High Production Volume threshold. Alternatively, the subset also could be based on criteria such as positive results in EPA's PBT profiler; use in consumer products; etc. Under this latter approach, the chosen subset of chemicals could be further limited, e.g., to those manufactured at above a selected tonnage level, such as the current IUR threshold of 10,000 pounds per site per year.

### Benefits of Option B:

The primary benefit would be to compile and provide to the public and EPA a consistent set of basic information about a cohort of important chemicals, in addition to the HPV chemicals. This information would be used by EPA to determine which of these chemicals need management or further information development, but would also be used by users of chemicals in making their own risk management decisions and choices of which chemicals to use. The project would also require evaluation of how much data is currently available for the chosen subset of chemicals, which EPA does not currently know.

### Considerations for Option B:

The ITC may have done some type of study along these lines, and the Work Group needs to explore this. The selected subset of chemicals should be recognized as one that may present unknown risks, as was done with the HPV set of chemicals. Although depending on the approach selected, EPA may not now have enough information to adequately identify the subset of chemicals meeting the selection factors chosen. Thus, EPA may have to run a large number of chemicals through a selection screen or issue a request for identification of chemicals that meet the chosen criteria.

## **Option C: Supplement Information Reported through Section 8(e) Substantial Risk Reporting**

Potential Action: Supplement the information available on non-HPV chemicals that have been the subject of Section 8(e) reporting by industry. This additional information could involve other information useful in further assessing the chemical to determine potential risks of chemicals, or to prioritize chemicals for other potential actions (e.g., information gathering or testing).

#### Description of Option C:

TSCA Section 8(e) requires:

- Any person who **manufactures (including imports), processes or distributes** in commerce
- **A chemical substance or mixture** and
- Who obtains information which **reasonably supports** the conclusion that such substances or mixture presents a **substantial risk** of injury to health or the environment
- Shall **immediately inform the Administrator** of such information
- **Unless** such person has **actual knowledge** that the **Administrator has been adequately informed** of such information.

This provision of TSCA places a statutory obligation on the chemical industry (including users of chemicals) to give EPA immediate notice of information that reasonably indicates a substantial risk. In addition to 8(e), EPA receives information pertaining to hazards and exposure through various existing TSCA elements, such as:

- Interagency Testing Committee (ITC), made up of representatives from numerous federal agencies, which reviews chemicals to identify priorities for testing among TSCA chemical based on suspicions of toxicity or exposure.
- Section 8(c) allegations of significant adverse reactions. EPA can inspect or require submission of 8(c) files at any time, but there is no specific format for recordkeeping under 8(c). EPA might design a form to make the data more usable to EPA in the risk assessment process.
- Section 8(d) reporting has been done on several hundred chemicals for which all health and safety studies on the chemical were to be submitted during the effective period of the rule. It includes formal studies and aggregations of data.

Scientific literature on chemicals is also publicly available and can be accessed by EPA through various sources.

TSCA 8(e) provisions suggest that there is efficiency in having those who manufacture and use chemicals every day be responsible for timely notification to EPA of significant risk from chemicals. As noted in EPA's presentation to NPPTAC, ~ 10% of the Section 8(e) submissions are considered to present a sufficient hazard to warrant further review by the agency. Industry regularly provides data to EPA under Section 8(e) (as indicated by EPA during the presentation at NPPTAC's May 2004 meeting

Section 8(e) notices are an efficient means to identify potential risk, particularly when combined with substances identified by ITC as meriting further scrutiny and with information submitted under Section 8(d). Analysis of substances listed or identified by these three methods, coupled with use of the scientific literature, will enable the agency to efficiently identify substances with potential risk. EPA could then prioritize the 8(c) data for review and use other tools, such as searching the FYI studies, to obtain additional information.

Section 8(e) or any other means of identifying a potential risk also requires analysis of the data as part of a risk assessment process, which necessarily will require some exposure information (data or modeling) to determine if there really is a risk. EPA does that now under Section 8(e), but may wish to consider, as part of this option, development of a process by which EPA could prioritize the data for this in depth analysis (perhaps similar to the NPPTAC advice on prioritizing HPV data). Risk analysis with a weight of the evidence approach could then be used by EPA to make “risk reduction decisions”.

#### Benefits of Option C:

Efficiency in identification of risk involves both timely identification and return on investment of resources. A process that requires review of volumes of data may not be efficient, if very few risks are identified in a labor-intensive, time consuming process.

The option proposed would be very efficient. It would employ the current 8(e) process in conjunction with information submitted to the Interagency Testing Committee, and be used to identify substances with need for testing, as well as other information in EPA’s FYI database and information gathered through Section 8(c). As part of EPA’s examination of the potential risk, this option would add to what EPA has previously described to the NPPTAC as the Section 8(e) process review of other sources of information such as scientific literature data bases and relevant information gathered under the recordkeeping requirements of Section 8(c). As noted in EPA’s presentation on Section 8(e), that process has resulted in a number of actions:

- Advisories
  - 2,4-dichlorophenol
  - Metal catalysts
  - Polystyrene production process
- Risk assessments
  - PFOS
  - PFOA
- Risk management
  - Formaldehyde
  - Acrylamide

If, after review of data submitted under Section 8(e) and information that was publicly available or available to EPA under 8(c), the EPA determined that there was an unreasonable risk, it would

have all of its regulatory and voluntary tools to employ to further examine the substance and develop appropriate risk management.

This option, as currently articulated, generally describes EPA's current handling of Section 8 submissions. It may be possible to put more resources into this program, to place more emphasis on some elements than others, to better integrate it with EPA's other efforts to regulate toxic chemicals, or to otherwise extend and strengthen the existing program.

#### **Option D: Risk Assessment – Apply New Chemical Review Process**

Potential Action: Review non-HPV chemicals using the New Chemicals Program's hazard screening tools.

##### Description of Option D:

This option would entail EPA using the New Chemicals Program's (NCP's) (Q)SAR and other assessment tools to screen a subset of non-HPV chemicals for potential hazards, as a means of prioritizing among them for further scrutiny. EPA would utilize only the tools/screens it uses to identify chemicals with potential hazards, not the full hazard plus exposure panoply. The reason for this limit is that, for the chemicals in question, EPA is unlikely to have access on a routine basis to even the rudimentary exposure-related information that it receives for new chemicals via premanufacture notices (PMNs). A hazard-only focus would be analogous to the HPV Challenge, and might also reduce the EPA resources required. However, because the same EPA staff that conduct PMN, as well as other, reviews would be involved, absent additional resources, EPA staff would be stretched thinner. In addition, applying these screening tools still requires the preparation of a chemistry analysis. No specific TSCA authority would be needed. Results of the screen should be made publicly available.

In combination with Option A, EPA could apply its (Q)SAR tools to extend the available data where possible to endpoints for which information was not submitted. A model for this approach is the Flame Retardancy Partnership, wherein industry submitted available data and EPA added (Q)SAR analyses as needed and possible. The TSCA Section 8(e) approach under Option C could also be complemented with (Q)SAR analyses, as appropriate.

EPA could then utilize the screen results to identify and prioritize chemicals for which further voluntary or regulatory activities are warranted, potentially including: collection or generation of hazard, use, exposure or risk management-related information to support more in-depth characterization or assessment; hazard communication or referrals within EPA, to other agencies and levels of government, and to industry and the public; and consideration of risk management and pollution prevention needs and opportunities.

The BIWG was interested in the amount of resources devoted to the (Q)SAR/chemistry report component of the NCP, in order to assess the potential of proceeding with the utility of using this element of the PMN process to evaluate the non-HPV chemicals. EPA reports that the staff resources associated with implementation of these NCP activities are also involved in international activities, supporting other, non-TSCA activities (e.g., supporting FIFRA or

other groups), and supporting the review of emerging chemicals of concern, such as PFOA. Time spent on any one PMN (parts of these same resources are used for different New Chemicals Program activities) vary widely, depending on the specifics of the case. For example, depending on what is required for a standard review, a range of possible time devoted to a case might be 16-20 hours up to 120-160 hours. EPA estimates that after the first levels of review are completed in the PMN review, staff time to complete the PMN review is approximately 10 hours per chemical. Time required to develop a consent order might range from 40 to 80 hours. These estimates are for a full PMN review, not the (Q)SAR/chemistry report component of that review. Unlike the PMN process, however, where EPA starts with a notice containing information on chemical structure, etc. (although typically quite limited with respect to hazard data), under this approach for non-HPVs, EPA would need to build a dossier largely from scratch. To work for large numbers of chemicals, EPA believes this approach needs to be integrated, as often as possible, into some other approach where the starting dossier already exists, and the (Q)SAR approach builds upon it.

#### Benefits of Option D:

Because there is clear public, consumer and business interest in having assurance that chemicals in commerce are safe as used in their actual and potential applications, this option offers benefits. The lack of public access to even basic hazard data precludes EPA and other stakeholders from assessing safety of, or identifying safer alternatives to, most such chemicals. The HPV Challenge Program has helped to close the hazard data gap for those HPV chemicals that have been sponsored, and such chemicals represent the large majority by tonnage of chemicals in use today. However, a far larger number of chemicals are in actual use, many of them in applications that could lead to human or environmental exposure. Because the great majority of them have never been assessed for safety, there is at present no basis for knowing whether or not they are safe as used. This “legacy problem” impedes industry and EPA from building public confidence on the potential hazards of the chemicals made and used and in their ability to safely manage any potential risks. It also precludes the ability of a range of stakeholders from making more informed choices about chemicals they purchase or use or to which they may be exposed.

Hence, the challenge is how to rationally address this enormous backlog, given obvious resource constraints. This option would apply knowledge and tools at hand to begin the process of sorting through the large number of non-HPV chemicals to find those that merit further scrutiny. The option would take advantage of the huge investment and expertise EPA has in developing robust tools for screening chemicals in the absence of measured data for endpoints of concern. The new chemicals review process and associated tools already enjoy broad support among a variety of stakeholders. Based on the screen, the other more time-consuming and labor-intensive options available to EPA could then be more efficiently applied to those chemicals identified through screening as most likely to warrant concern.

#### Considerations for Option D:

EPA, through its Sustainable Futures program, is essentially urging companies to take this approach for their own new chemicals, and a number have not only done so, but have applied such tools to their existing chemicals, as well. It should be noted that Denmark completed a

similar exercise a few years ago -- for some 55,000 chemicals. And, Canada is nearing completion of a screening-level analysis (based on both hazard and exposure considerations) for the some 23,000 chemicals on its Domestic Substances List.

The group of chemicals proposed to be screened in such a manner, at least initially, would NOT be all non-HPV inventory chemicals, but a far more manageable number: the ca. 5,400 chemicals known to be in commerce with aggregate production/import volumes between 10,000 and 1,000,000 lbs/year (i.e., those reported in the 2002 cycle of the TSCA Inventory Update). Chemicals already exempted from or sponsored under the HPV Challenge (HPVC) would not be included, but the so-called “orphan” HPV chemicals, those not exempt or sponsored, could be included. (As an option, the ca. 570 chemicals proposed for inclusion in the Extended HPV Program – which addresses chemicals that have reached HPV production levels since the original HPV Challenge was launched -- could be included or excluded.)

### **Option E: Regulatory Actions – Apply TSCA Sections 4, 5, 6 and 8**

Potential Actions: Issue Test Rules or Solicit Enforceable Consent Agreements, Information Gathering Rules, Significant New Use Rules, and Chemical Restrictions, as appropriate.

#### Description of Option E:

Several regulatory options exist for data collection and risk management regarding non-HPV chemicals that could be used to collect and generate the data needed to identify potential risks and facilitate risk reduction decisions. EPA’s ability to use regulatory powers (sometimes as a last resort) is critical to the agency’s ability to rapidly identify chemicals of concern and initiate risk management options. Without such powers, the Agency’s ability to encourage voluntary actions is hindered, as there is no clear incentive to participate. Many companies welcome these regulatory options as they provide clear signals and help protect competitive advantages they might have developed. Some TSCA regulatory options (and non-regulatory ones) for non-HPVs include (divided by data collection and risk management):

#### Data Collection

Section 4 Test Rules for non-HPVs of concern. Initiating a S. 4 rule would require some evidence of hazard/risk or high use/exposure and a determination that data are insufficient and testing is necessary. It would appear that such an option would only be possible for chemicals that have fairly known concerns or that have passed through a “non-HPV” type challenge or review such as the proposed new chemicals-type review for non-HPVs.

Theoretically, a Section 4 Enforceable Consent Agreement could be developed for some sub-set of these chemicals (a class of chemicals, use category - electronics etching, cleaning solvents – etc.) to develop key test data

Section 8(a) and 8(d) information gathering. EPA could issue a section 8(a) such as an updated PAIR (preliminary assessment and information reporting) rule to gather critical background information on non-HPV chemicals including uses, exposures, and available toxicity data. EPA

could also issue section 8(d) Health and Safety Data Reporting rules for a group of non-HPV chemicals to support the existing chemicals program and prioritization.

Using its Section 8(a) authority, EPA could also do a systematic assessment of the new use/exposure data coming in the 2006 IUR, especially the more extensive information to be required for chemicals >300,000 lbs/yr, to identify chemicals with use patterns/exposure potential of possible concern, cross-referenced to any hazard information for those chemicals developed via new chemical screening approaches or the other options listed above.

### Risk Management

Section 5(e) and Non-5(e) SNURs. EPA could place a volume or anticipated uses SNUR on new chemical PMNs to gather important additional data, once a new chemical reaches a set production level or when new unenvisioned uses occur. EPA could also identify existing non-HPV chemicals of concern and issue SNURs to ensure review when new uses for these arise. However, to use TSCA Section 5(a)(2) EPA must be able to identify potential new uses; project manufacturing and processing volume; determine the extent to which the uses change the type or form of exposure, etc.

Section 6 restrictions. Generally, this regulatory option would not be a viable option for non-HPV chemicals for which data is sparse. To use Section 6, a significant body of data to establish a significant risk would be required which would in turn require testing and exposure assessment. This could only be done once chemicals have undergone other screens, as detailed in other options. Once data were available to establish a significant risk, the determination of unreasonable risk would require cost-benefit analysis and examination of various options to reduce the risk.

Alternatively, Section 6 discretionary powers could be used through an advanced notice of rule making to create an information incentive for some risk reduction activity to occur. Further, EPA could enter into voluntary agreements with key companies or sectors to undertake risk reduction actions, as was the case with the agreement with Great Lakes Chemicals to phase-out its production of the penta- and octa- brominated diphenyl ethers.

For those chemicals identified as being of concern in the data collection screens, there could be a direct link to P2 programs as outlined in the P2 recommendations – a non-regulatory option.

### Benefits and Considerations for Option E:

Most of the above regulatory actions are relatively resource intensive, though using consent agreements and other non-regulatory tools that take advantage of EPA's discretionary powers can help overcome some of these limitations. The Section 8 options seem to be the least intensive in terms of preparation resources and gains for the resource investment. Most of the options pertain to obtaining basic data that can serve to help facilitate risk management decisions, though only Section 6 specifically addresses risk management. Given the lack of data and need to initially collect data for Section 6 actions for most non-HPVs, using this section is not an option. Similarly Section 4 test rules are costly and consent agreements only work to the extent that affected industry is willing to cooperate. It is unclear how burdensome initiating

Section 8(a) or 8(d) information gathering authorities for non-HPVs would be. In all cases, if data are collected and screened in an efficient way – through means discussed in other options – this could provide a rapid screen for further test actions and risk management activities.

In any case, ideally EPA could link any initial data collection and identification of chemicals of concern to information dissemination and voluntary action, for example, through the Design for the Environment program, or other challenges. All data collected through these regulatory tools could be appropriately placed on the web, and EPA could develop some kind of risk profile/prioritization as it has in the past for TRI chemicals so that adequate signals are sent to manufacturers and users of identified chemicals of concern.

#### **IV. Conclusion**

EPA, other state and federal agencies, and users of chemicals throughout our society (including industrial users and consumers) face information gathering, risk assessment and risk management decisions every day. In order to prioritize activities, the Agency seeks efficient methods for addressing issues of concern. This thought-starter offers a description of an area of unknown risk and potential concern, non-HPV chemicals, and provides options to more efficiently identify potential risks and facilitate risk reduction decisions for these chemicals.