Discussion Forum: Identifying Priority Chemicals for Review and Assessment

Office of Pollution Prevention and Toxics

Step 1(b) Topic: Data Sources for Prioritization Factors »

Step 1(a) Topic: Prioritization Factors

Posted on August 5th, 2011 - 12:07 PM

EPA is planning a two-step process to identify priority chemicals for review and assessment. In Step 1, EPA plans to use a specific set of data sources to identify candidate chemicals that meet one or more of these priority factors:

- Chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects).
- Chemicals identified as persistent, bioaccumulative, and toxic (PBT).
- Chemicals identified as probable or known carcinogens.
- Chemicals used in children's products.
- Chemicals used in consumer products.
- Chemicals detected in biomonitoring programs.

EPA invites your thoughts on these prioritization factors, including:

- What other factors, if any, should the Agency add, and why?
- Please discuss which prioritization factors, if any, should receive greater consideration than others.

Read the Discussion Guide, comment policy, leave a comment.
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23 Responses to "Step 1(a) Topic: Prioritization Factors"

1. *Rob* Says:
   August 23rd, 2011 at 10:56 am

   Canada has gone through a similar prioritization process and is moving through screening level hazard and exposure assessments for a number of substances. While our two economies are different, we are not so different that their high priority substances should not be considered as potential high priority substances for consideration under the US project. Those which have finished the Canadian process and

have entered into a Risk Management phase should be among the first substances considered for the US program unless special circumstances in Canada place their citizens at a substantially different risk than US citizens.

2. *Christina Franz* Says:
   September 6th, 2011 at 3:17 pm

   ACC applauds EPA for initiating the Prioritization Stakeholder Dialogue. Prioritization is the first critical step in establishing a systematic and transparent process for assessing the safety of chemicals for their intended uses. EPA has taken a good first step in developing an approach for prioritizing chemicals. ACC has developed a prioritization tool that we hope EPA will use to augment its published approach so that the prioritization process may be more robust, comprehensive, and science based. ACC welcomes the ideas of others to help improve the tool that we have developed. ACC's tool can be accessed at this link: http://www.americanchemistry.com/Prioritization-Document

3. *Mike Strong* Says:
   September 7th, 2011 at 3:47 pm

   You should be wary of relying on data obtained by modeling. Canada relied heavily on monitoring data even when there was real world data available which differed from the values generated by the mondeling software.
   Any models used should be vailidated by comparing the output of the model against known (i.e. measured) data from a wide variety of chemicals, always keeping in mind that the real world behavior of the chemical may not match a "standard" model.

4. *Scott Braithwaite* Says:
   September 7th, 2011 at 4:15 pm

   The webinar hosted on Sept 7 shed important light on EPA's chemical prioritization program. Specifically, the goal of Step 1 is to identify a couple hundred candidate chemicals (not thousands) and the goal of Step 2 is to prioritize those couple hundred chemicals into batches, with chemicals in the highest priority batches meriting action plans during FY12. The program is risk-based – i.e., identify exposures that exceed hazard benchmarks and then take action to reduce such exposures.

   These program goals are best met by focusing Step 1 solely on the substances detected during the various editions of the CDC's human biomonitoring program (NHANES, a few hundred chemicals detected) and removing from consideration all other data sources. Robust biomonitoring data no only end the dispute whether exposure has occurred bu also can be risk-prioritized in Step 2 by comparing the detected concentrations to hazard benchmarks. Those substances exceeding their hazard benchmarks would receive highest priority, and those approaching their hazard benchmarks the next highest priority. Because internal, biologically equivalent hazard benchmarks only exist for around 60 substances, EPA will need to quickly derive rough estimates for the remaining detected substances. These hazard benchmarks can be refined in the future as part of the action plans.

   In summary, because this EPA program is relatively small in scope – limited to a couple hundred chemicals and then only a couple dozen or so for action – focusing on human data rather than ecological and on proven rather than theoretical exposures makes sense. The CDC biomonitoring data provide such, are unparalleled in the world (even Canada and the EU don't have as much), and are available today as low hanging fruit ready to be picked and prioritized.

5. *Georjean Adams* Says:
   September 7th, 2011 at 4:32 pm

   Given limited resources for both EPA and industry, it is appropriate to quickly narrow the number of

candidate chemicals for management under TSCA to those with known high risks. "Known high risk" means that both the toxicity and exposure is well-characterized by quality data to be high. Chemicals for which either toxicity or exposure is unknown should be candidates for information collection via section 4 or 8(a) under a separate prioritization scheme. (Re ACC's offered tool: I support the focus on highest scoring chemicals, but not the inclusion of "unknown" as a default to high exposure or toxicity.)

The prioritization of known chemical risks should identify the highest scoring risks to health (or the environment). Further, there should be focus on a series of subsets of risks of concern based on populations and endpoints. EPA's initial focus on children's health (e.g., developmental) and exposure in children's products would be an appropriate starting point. Other specific population exposures (e.g., consumer products, workers or fish) and endpoints (e.g., cancer, reproductive toxicity or neurotoxicity) can be covered in subsequent iterations of the scheme after management of the previous subset is underway. What EPA needs to do is achieve a steady stream of risk reduction and not to bog down once again in trying to attack every conceivable risk.

Separately, EPA should have a prioritization and rulemaking process in place to address information collection under sections 4 and 8 to address chemicals with unknown exposure or toxicity where a default assumption of high risk is reasonable. This too needs to be paced at a manageable rate for both industry and EPA. E.g., chemicals that are both very persistent and very bioaccumulative would be excellent candidates for section 4 rules; chemicals that are known to be very persistent, bioaccumulative and toxic would be candidates for a risk management iteration.

In both kinds of prioritization EPA's proposal to solicit information on proposed candidates is welcome.

Achieving risk management of widespread exposure chemicals that are embedded in the economy is not easy. EPA should be prudent in selecting a relatively small but steady stream of chemicals to tackle through a prioritization scheme that focuses on the worst first.

6. *Derek Swick* Says:
September 8th, 2011 at 2:18 pm

The American Petroleum Institute (API) welcomes EPA work on prioritization to identify chemicals for government action. We feel that prioritization is a crucial and necessary first step in any modern chemical management program.

EPA has listed six factors—three related primarily to hazard and three somewhat related to exposure. EPA states, "Chemicals meeting one or more of these Action Plan prioritization factors would become part of the initial group of priority chemicals for review." We agree with the inclusion of both hazard and exposure factors for prioritization. It is important that any prioritization of a chemical be based on at least one hazard factor and one exposure factor (i.e., not on a single factor). There is essentially no risk if there is no exposure or no hazard, so it would not be appropriate to designate a chemical as warranting priority based on hazard or exposure alone.

API agrees with EPA's not including production volume as a prioritization factor, and we would not support using production volume as a surrogate for exposure. It is important that any prioritization approach be based on true exposure—i.e., information about scenarios in which actual exposures occur—rather than an incorrect assumption that volume is highly correlated with exposure.

API agrees with the factor "chemicals used in children's products" and supports a prioritization scheme that gives relatively high priority to chemicals used in children's products where there are realistic scenarios of exposure. On the other hand, we think that the factor "chemicals used in consumer products" is too broad to be effective or appropriate for prioritization, especially since one of the key

data sources EPA is proposing (2006 IUR data) uses a data field that includes commercial as well as consumer uses. If use in consumer products is a factor, it should be in another tier of prioritization, not in the main six factors.

The factor of "chemicals detected in biomonitoring programs" should not be included, and if it is included, it needs to be used with caution. Biomonitoring has been conducted for chemicals already selected based on some previous prioritization, and is biased towards chemicals for which there are well-established analytical methods. Using "chemicals detected in biomonitoring programs" could result in chemicals being prioritized because they were detected, but ignoring that they were detected because they were monitored for when other chemicals were not. EPA also needs to take into account that much biomonitoring information is old enough to have limited relevance to current exposure conditions (particularly children's exposure). Biomonitoring detection does not equate to hazard or health risk. It is an indicator of exposure and should be used as appropriate in formulating, refining, and verifying exposure scenarios. It may be appropriate in a further tier or as supporting information, but not as one of the main prioritization factors.

We recommend existing regulatory controls as a prioritization factor. Chemicals or mixtures for which risks are already managed under existing regulatory schemes should have relatively low priority. An example is gasoline. API is happy to provide detailed information describing the cradle-to-grave regulatory scheme for risk management during the full lifecycle of gasoline.

EPA should consider which chemicals could be assigned low priority up front, based on existing knowledge of their intrinsic properties and/or risk. These would include polymers, and the low interest substances and petroleum process streams that are designated as partially exempt from IUR reporting.

API has established principles for reform of the U.S. chemical management system which suggest the following overarching comments:
• Criteria for prioritization must be clear and transparent.
• Prioritization schemes should be science-based and risk-based, should use hazard information and representative exposure scenarios, and should take into account all phases of the chemical lifecycle.
• The prioritization process should be based on reasonable screening assessments, using available hazard and exposure information.
• Complex mixtures, including petroleum streams, may require screening methods that vary from those for other chemicals. For instance, in many cases it is not scientifically accurate to assess such mixtures based strictly on the hazards of their components.
• EPA should leverage reputable science-based work from the work of other countries.

7. *Pamela Schwingl* Says:
September 13th, 2011 at 5:14 pm

We applaud the efforts of EPA to develop a process for prioritization of chemicals for regulatory action. We agree that the two step process proposed by EPA is appropriate and timely.

We are Fellows in the UCSF's Reach the Decision Makers (Reach) Program on Reproductive Health and the Environment, an innovative science and policy training program that works to increase the number of scientists, community-based leaders, public health and health care professionals who are actively involved in informing the US Environmental Protection Agency (USEPA) of current and relevant scientific findings to impact policy decisions.

Our team is working to address the need for chemical prioritization guidance from EPA in the absence of comprehensive TSCA reform. In particular our team is concerned with protecting the reproductive health of our population from unwarranted exposure to environmental chemicals, and we are focused on how the EPA can move forward to prioritize chemicals for assessment and regulation.

In particular, we are concerned about EPA adhering to the proposed timeline for this process. We believe that the proposed process can move forward at a brisk pace and to support this, we would encourage EPA to look closely at the work that has already been accomplished in the prioritization of chemicals by the REACH program of the European Union; the Safe Environments Program, Health Canada; the State of Minnesota Department of Health; the State of Washington Department of Ecology; the State of Maine Department of Environmental Protection; The State of California Office of Environmental Health Hazard Assessment Proposition 65; as well as the Endocrine Disruption Exchange (TEDEx).

We briefly summarize the work already accomplished that EPA can draw on during the next few months.

● Under authority of the Children's Safe Product Act (CPSA), the State of Washington Department of Ecology identified a list of chemicals of high concern for children. They created a process to build an all-inclusive list of high priority chemicals (HPCs) by reviewing existing lists from governmental and other "authoritative" sources (e.g., EPA, California, Europe, Canada, and others). Next they developed a prioritization scheme that used a qualitative approach to assess the toxicity and exposure potential for children for each chemical on the list. Lastly, Ecology finalized the list by reviewing toxicological and exposure data for each chemical identified, ensuring that each meets the criteria for CSPA listing (including a check for errors and additional investigation of the weight of evidence for each listing); and recommending levels for each chemical that could trigger the reporting requirement.

● Under authority of the Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65 the State of California employs four ways for a chemical to be identified and placed on the list of chemicals of concern: 1) if it is identified as a carcinogen or teratogen by an "authoritative body," such as the U.S. Environmental Protection Agency, U.S. Food and Drug Administration (U.S. FDA), National Institute for Occupational Safety and Health, National Toxicology Program, or International Agency for Research on Cancer; 2) if committees reporting to the OEHHA Scientific Advisory Board finds that the suggested chemical causes cancer or birth defects or/ reproductive harm, based on the most current scientific information available; 3) if it has been mandated by FDA that the chemical effects (carcinogen/teratogen) be reported on the commercial packaging; and 4) if the scientific criteria set by the California Labor Code also holds true for chemicals reported by Proposition 65. These four scenarios are all based on peer-reviewed published, accessible studies that demonstrate chemicals can initiate cancer or reproductive or developmental harm. Currently there are over 850 chemicals currently listed on the Proposition 65 List of Chemicals; state law requires this list to be updated at least once a year.

● Under the authority of the Toxic Free Kids Act (TFKA), the State of Minnesota Department of Health lists criteria for a two stage process for compiling a Chemicals of High Concern (CHC) list and a smaller Priority Chemicals (PC) list. These are listed in the TFKA statute and consider, among other factors, how persistent, bioaccumulative, and toxic the chemical is. To determine whether a chemical meets the criteria, lists from various international, national and state agencies are consulted. If a chemical has not been tested and does not appear on one of those lists, it is unlikely to appear on the CHC list. A chemical can only be included on the PC list. If it is a high production volume (HPV) chemical, and meets certain exposure criteria indicated it is detected in human biomonitoring programs, detected in environmental media such as dust and drinking water, or detected in wildlife. To determine if chemicals fit these criteria, Minnesota used a template created by the State of Maine under similar legislation. Exceptions unique to Minnesota have led to subtractions from the list. Also, some chemicals were added to the list and the decision to do so was based on guidance and data from a variety of sources including EPA's now defunct ChAMP program, the IRIS database, and the Inventory Update Reporting (IUR) list. Both of these lists (CHC and the PC lists) are published by dates specified in TFKA with the CHC list required by law to be updated every 3 years. Additions to the PC list are ongoing. Unlike Proposition 65, additions to the PC list are not mandated, but ongoing efforts are

hoped to spur moves to reduce CHCs and identify green alternatives.

● Safe Environments Program, Health Canada. In 1999 Environment Canada and Health Canada set out successful procedures for assessing toxic substances with mandated timelines for managing exposures to toxins. By law, the legacy chemicals – 23,000 chemicals coming onto the market between 1984 and 1986 – had to be categorized and assessed within 7 years. The goal was to identify chemicals that had potential for human exposure in the general population, and those which are persistent and inherently toxic to humans or non-humans. This resulted in identifying 4300 substances; 500 of these were categorized as highly prevalent or inherently toxic. The government and industry together targeted the very top 200 substances for evaluation. Further, approximately 2600 medium priority chemicals have been identified as lacking strong hazard and exposure data, but a goal was set to evaluate these regardless of the missing data by 2020. The process is led by government scientists who review and prepare screening assessments in 6 month periods; drafts go for public comment; toxic chemicals have a risk management scope document; public comments on this document are sought, modified, and then a final conclusion is reached. These screening assessments are science based documents and built on a weight-of-evidence approach and precautionary principles. Canada's policy objectives have included setting clear priorities, integrating chemical management across federal agencies, enhancing health monitoring and surveillance of chemicals, and informing the population of potential risks.

● The REACH process (Registration, Evaluation, Authorization, and Restriction of Chemicals) is guided by a series of documents developed under the mandate of the REACH EU legislation. In general, substances of very high concern (SVHC) include chemicals that meet the criteria of teratogens; those with wide dispersive uses or manufactured or imported in high volumes; substances having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties for which there is scientific evidence of probable serious effects to human health or the environment; and substances meeting classification as carcinogenic category 1 or 2, and mutagenic category 1 or 2.
To date twenty substances have recently been proposed to be added to a list of 53 existing SVHCs. Inclusion on the list imposes new information requirements on suppliers of preparations and articles containing the substances because of their potentially serious effects on human health. Recently, in August, nineteen of the additional substances have been classified as carcinogenic and/or toxic for reproduction. In addition, one substance is proposed to be identified as a substance of equivalent concern in accordance with Article 57(f) of the REACH Regulation because of its endocrine disrupting properties and potential for serious effects to the environment.

● TEDEx: TEDEx has identified approximately 800 chemicals that are endocrine disruptors, and have been listed on the Endocrine Disruption Exchange List (TEDEx). These substances have verified citations to published, accessible, primary scientific research demonstrating effects on the endocrine system.

In addition to our concern about the need to rely on the important work already done, we ask EPA to consider chemicals with good data on either hazard OR exposure. The availability of information and data is constantly changing. Consideration of high hazard and high volume chemicals that are biopersistent, for example, is critical, even in the absence of solid exposure data. As we begin to understand more about epigenetics and the intergenerational impact of exposures, it is imperative that the EPA work within a framework of "exposure potential." In light of the precautionary principle, removal of a chemical from a list of chemicals of concern should take place when there is adequate data to demonstrate an acceptable level of risk to human health, not in the absence of data needed to evaluate risk.

8. *Richard Denison* Says:
September 13th, 2011 at 7:14 pm

Avoiding paralysis by analysis: EPA proposes a sensible approach to identifying chemicals of concern

Last week, the Environmental Protection Agency (EPA) held stakeholder meetings to get public input into the criteria it will use to identify additional chemicals of concern beyond the 11 chemicals or chemical classes it has already identified. EPA used these meetings (as well as this online forum open until September 14) as an opportunity for the public to respond to a "discussion guide" it issued in August that sets forth draft criteria and identifies data sources it intends to use to look for chemicals that meet the criteria.

EDF and the Safer Chemicals Healthy Families coalition strongly support EPA in this endeavor – both for what it is, and for what it is not.

The word "action" was for many years virtually missing from the EPA chemicals program's vocabulary. (I guess you could say the program was kinda "missing in action.") Of the more than 60,000 chemicals on the market at the time TSCA was adopted in 1976, fewer than two percent have received any substantive, data-informed review. So it is a welcome development that EPA is actually looking at chemicals in commerce – despite the lack of a mandate to do so under the Toxic Substances Control Act (TSCA) – and, for those posing concerns, initiating at least those limited actions allowed by TSCA.

For the chemicals of concern EPA identifies, it expects to develop "chemical action plans" similar to those it has developed for the first 11 noted above. These plans identify "a range of actions … from voluntary phase-outs and alternatives assessments in cooperation with industry and other stakeholders, to the development of test rules to require the development of additional data under section 4 of TSCA, to controls or use restrictions under sections 5 or 6 of TSCA."

That's the purpose of the criteria EPA is now proposing to formalize. Equally important is what EPA's purpose is not. As EPA states on its website:

"EPA's goal is to identify priority chemicals for near-term evaluation, not to screen and prioritize the entire TSCA Inventory of approximately 84,000 chemicals." (emphasis added)

EPA has been clear that the latter task – a comprehensive review and ranking of all chemicals in commerce – is beyond its current authority and resources, and that any such effort – to the extent it is desired – must await TSCA reform.

Clarity as to the more limited purpose of EPA's current initiative is important to note for two reasons. First, it means that EPA is not claiming that chemicals it identifies as priorities are necessarily those that have somehow been shown to pose the greatest risk in comparison to all other chemicals. Rather, they are chemicals for which there is sufficient evidence or reason for concern that they warrant further scrutiny. And, of course, in order to actually regulate the production or use of such chemicals, EPA would have to meet the very high burdens imposed on it under TSCA.

Second, some in industry have been arguing that EPA cannot even name a chemical of concern unless it first shows it is at the top of the list, identified though some kind of comprehensive ranking system that is applied to all chemicals in commerce. That approach is indeed awfully close to what ACC has proposed as its "comprehensive" prioritization tool, about which I'll have more to say in my next post.

This impression is amplified by ACC's invoking of the Canadian approach to prioritization to support its tool. What ACC fails to mention is that Canada's approach – which entailed a review of all 23,000 chemicals on Canada's equivalent to the TSCA Inventory – was mandated by statute in amendments to the Canadian Environmental Protection Act (CEPA) adopted in 1999.

Moreover, Canadian agencies were given seven years and a major infusion of new resources to complete just the first phase of its process. With 84,000 chemicals on the TSCA Inventory … well, I'll

let you do the math to guesstimate how long and how many resources it would take for EPA to carry out the same approach. Without the authority and the resources, well, that's just a recipe for paralysis by analysis.

So, what is EPA's proposal?

While the EPA description of its proposal is merely a "discussion guide" and more detail will be needed to fully comprehend it, the agency proposes to utilize a basic set of criteria about which there is little controversy at least at the 30,000-foot level. We are pleased to see an emphasis on chemicals that can adversely affect children's health, on PBTs (persistent, bioaccumulative and toxic chemicals), and on chemicals detected in biomonitoring.

EPA also identifies a list of sources of information it would use initially to identify chemicals meeting each of the criteria, and then additional sources it would use to refine the list, conduct reviews of the selected chemicals and initiate risk assessment and risk management actions as warranted. Again, the sources EPA identifies are pretty straightforward.

The idea, according to EPA, is to generate and make public an additional list of chemicals of concern this fall, and then to proceed on to identify more chemicals over time using the same criteria. Release of that list would provide all parties with an opportunity to provide more information to the agency.

What else is needed?

We generally support EPA's approach and believe it strikes the right balance between clarity and transparency and avoiding paralysis by analysis. Nonetheless, we offer the following 10 additional suggestions for improvement:

1. Cast a wide net in Step 1: EPA need not and should not limit the sources it relies on in Step 1 to a small number, as it suggests it will do, especially if those sources are intended to identify the longer list from which a subset will be selected for further review and action.
o Many of the sources EPA plans to use in Step 2 could identify chemicals that might otherwise be missed in Step 1. For example, databases of chemical releases to or presence in air, water, fish, sediment, etc. should supplement the human biomonitoring data sources identified for use in Step 1.
o While an exhaustive search of all possible data sources is not warranted especially to develop a "starter list," EPA should be able to efficiently conduct searches of multiple data sources by relying on its own and others' integrated databases and portals, such as:
 ToxRefDB: EPA's own Toxicity Reference Database captures thousands of in vivo animal toxicity studies on hundreds of chemicals.
 ExpoCastDB: EPA's Exposure Database includes studies where chemicals were measured in environmental and biological media, including air, house dust and food, and human biological fluids and tissues.
 The OECD's eChem Portal: The Portal consolidates chemical data from many different international and national programs across OECD member countries.
 European Union classification databases and lists, including ESIS (the European chemical Substances Information System), which includes lists of chemicals classified using criteria developed under the Globally Harmonized System (GHS) for Classification and Labeling as carcinogens, mutagens, reproductive toxicants, aquatic toxicants, PBTs, etc.

2. EPA should not preclude using published, peer-reviewed literature as a primary source of information to identify priority chemicals: While reliability and data quality always need to be considered in any weight-of-the-evidence approach, there is no a priori reason to exclude such information, any more than to exclude industry-generated data that populate many of the databases just noted.

3. Add criteria for environmental hazard and exposure: EPA's proposed criteria are heavily weighted toward human health and need to be balanced by adding criteria that address both hazards to wildlife and ecosystems and environmental release and exposures.

4. Expand health effects of prenatal and postnatal concern for children's health: Reproductive and developmental toxicity are appropriate focuses, but need to be supplemented with an additional explicit focus on neurodevelopmental effects, a major concern for many chemicals for which early life exposure may occur.

5. Expand the scope of exposure considerations for children: While EPA articulates a broad concern for children's health, its main focus on products intended for use by children is far too limited. Children may be directly exposed to products used in the home whether or not they use them. And exposures that occur in utero via transfer of chemicals from pregnant women or through breast feeding may be just as or more important than children's product exposures.

6. Consider a broader range of vulnerable subpopulations: While a focus on children's health is warranted, EPA also needs to consider chemical exposures of workers and other subpopulations (e.g., environmental justice communities) who may be more susceptible or disproportionately exposed relative to the general population. For workers, this focus should extend beyond chemical or product manufacturing workplaces to include exposures to chemicals in industrial or commercial products or materials they use (e.g., building materials, automotive products) or manage after their use (e.g., product and material recycling, disposal).

7. Consider aggregate exposure to chemicals: In making prioritization decisions, EPA should factor in the range of sources and uses of a chemical that contribute to overall exposure, not just those uses that fall under its TSCA jurisdiction. While legal issues would need to be addressed if and when EPA decided that regulatory action would be needed, it makes no sense for EPA to ignore at this stage uses or sources of a chemical that may contribute substantially to overall exposure. Just as EPA's proposed reliance on biomonitoring data represents a measure of exposure integrated across all sources, so too should its consideration of other exposure information sources.

8. Don't exclude chemicals with high hazard or high exposure for which data gaps leave uncertainty as to risk: Where strong evidence of high hazard or pervasive or high exposures exists, EPA should be able to prioritize such a chemical. This is critical if the limited data gaps are to be addressed – otherwise, EPA will simply continue to look at the same data-rich chemicals over and over again. Chemicals with high hazard or high exposure for which there is concern about the other parameter need to be prioritized at a minimum for data development to determine the level of risk they pose. (I'll have more to say about ACC's insistence that only chemicals with affirmative evidence of both high hazard and high exposure should be identified as priorities.)

9. Go beyond the TSCA Inventory Update Reporting (IUR) data on use and exposure wherever possible: As we've blogged about repeatedly in the past, and as EPA has forthrightly acknowledged in finalizing major enhancements to its chemical information reporting system, chemical use information available to EPA through the IUR are woefully incomplete and limited. To the extent possible, EPA should look for other sources of such information to identify priority chemicals, and certainly should not exclude high hazard chemicals on the basis of such information. That was a common mistake EPA made in its earlier, ill-fated ChAMP initiative.

10. Provide more clarity as to how EPA intends to proceed from Step 1 to Step 2: This is an area where EPA discussion guide is particularly lacking in detail and needs to be clarified.

9. *Jane Wishneff* Says:
September 13th, 2011 at 10:09 pm

The International Fragrance Association North America (IFRA North America) commends EPA in takings steps to establish a prioritization system for further assessment of chemicals in commerce. Prioritization is a crucial and necessary first step in any modern chemical management program. It is imperative that EPA establish a risk-based approach to prioritization, which considers both hazard and exposure together in identifying priority chemicals for further assessment. A chemical with high hazard but with no exposure is not a concern, nor is a chemical with high exposure but with no hazard. Chemical priorities should be those substances with the highest hazards and potential risk to human health based on exposure assessment, that warrant further evaluation to ensure meaningful protection of human health and the environment.

IFRA North America recommends that EPA include production and/or use volume as one of the factors for prioritization. There does not seem to be any consideration for low level use in EPA's proposal (irrespective of overall volume) and while we support the use of "chemicals used in consumer products" as a factor in its prioritization, EPA needs to also consider the use level of those chemicals in such products. For example, if a chemical with identified issues is only used below the No Observed Effect Level, then there is no risk to the population and this should be taken into account in EPA's prioritization.

IFRA North America is concerned with the inclusion of "chemicals detected in biomonitoring programs" as a factor EPA will use for prioritization. Biomonitoring detection does not equate to hazard or health risk, but is simply an indicator of exposure and should be used as appropriate in formulating, refining, and verifying exposure scenarios. Additionally, biomonitoring studies are difficult to perform, and the protocol and results need to be scrutinized closely. IFRA North America would also suggest that the factor, if it remains a factor, be clarified to read "chemicals not endogenous to humans that are detected in human biomonitoring programs."

IFRA North America would recommend that EPA consider whether a "chemical is subject to existing regulatory controls" as an additional prioritization factor. Chemicals for which risks are already managed under existing regulatory schemes should have relatively low priority. For example, the Research Institute for Fragrance Safety (RIFM), which is the international scientific authority on the safety of fragrance ingredients, conducts studies and reviews all available data on fragrance materials used in perfumery. Based on the scientific research and findings as established by RIFM, IFRA then sets Standards, set forth in IFRA's Code of Practice, for the safe use of fragrance materials. The Code applies to the manufacture and handling of all fragrance materials, for all types of applications. Abiding by the IFRA Code of Practice, and the Standards set forth within it, is a prerequisite for all fragrance supplier companies that are members of IFRA, who collectively create more than ninety percent (90%) of all scents worldwide. Additionally, IFRA Standards are frequently adopted or referenced by regulatory bodies, including regulatory bodies in the European Union (EU), Brazil, ASEAN Member Countries, Australia and New Zealand. IFRA North America recommends that EPA consider regulatory controls such as those IFRA places upon its members as a factor in its prioritization process.

10. *Andy Igrejas* Says:
September 14th, 2011 at 9:06 am

Safer Chemicals, Healthy Families supports EPA's prioritization initiative and appreciates the process it has undertaken to solicit input. We especially appreciate that EPA has acknowledged the limitations of existing TSCA – and the need for reform- even as it works to address chemical risks with the tools TSCA provides.

We generally support the criteria that have been proposed for the common sense reason that with such a backlog of inaction on chemicals it makes sense to for EPA to begin with those for which there is a lot a data that suggest potential health hazards. Chemicals that are pinged by the proposed data sources for hazard and for exposure clearly fit the bill and the point of this effort is to get started in a timely and

sensible manner. However, as we mentioned at last week's stakeholder meeting, we're concerned that if EPA interprets the criteria as being strictly limited to chemicals on those established lists it could deny EPA the flexibility to prioritize a chemical that the science would otherwise push to the top.

EPA should be able to use credible peer-reviewed studies to decide if a chemical meets the criteria and the criteria should be slightly expanded. The "concern for children" criteria, for example, should not be limited in practice – by the list of data sources- to chemicals that appear on the NTP list, but flexible enough to respond to evidence of neuro toxicity, for example, or other children's health endpoints. We appreciate that there appeared to be a point of commonality among industry and environmental advocates at the meeting to add environmental toxicity criteria. At a more macro level, we would agree with commenters who advocate flexibility to prioritize a chemical that is shown to be extremely hazardous or to which exposure is widespread, but for which there are data gaps on the other side.

Generally, we think EPA is right to come up with a system that allows it to scan existing data sources and "get started" on the next batch of chemicals that rise to the top, rather than creating on overly elaborate scheme that would become a barrier to action. We just propose a little more flexibility so EPA can prioritize something that is "blinking red" in the science or health literature, but has not yet made it's way through the slow grind of being added to the official lists described in the proposed data sources.

11. *ECHA* Says:
September 14th, 2011 at 9:53 am

'We are pleased to provide a few remarks as input to the discussion forum on identifying priority chemicals for review & assessment by the EPA.

Priory setting is inherent in various REACH & CLP processes. However it should be noted that prioritisation is context dependent, i.e. it is used for different proposes & hence how to do it will vary between cases. Within REACH & CLP prioritisation takes place as follows:

• Select registration dossiers for Compliance Check (at least 5%): random, legal criteria, concern-driven related to likelihood of potential incompliance or relevance to safe use

• All Testing Proposals have to be evaluated but prioritise based on deadlines, legal criteria & supplementary criteria

• Substance evaluation: annual update of the Community Rolling Action Plan to chose substances from the pre-selection pool of candidates identified by ECHA & Member States

• Listing of SVHCs in the Candidate List

• Transfer of Candidate List substance onto the Authorisation List

• Selection of substances for proposed Restriction

• Selection of substances for harmonised Classification

• Interaction between the different processes & co-ordination of activities & actors

Some of the criteria used originate from the text of the Regulations, albeit with interpretation how to implement them in practice, & others are developed to help target our work. The prioritisation criteria for the various processes are generally in a state of development so that we can learn by doing and update them as necessary based on our experience.

In addition it is important to remember that there will certainly be useful information on substance properties published by ECHA that would be useful to EPA in selecting substances, notably harmonised classifications as CMR & SVHCs.

For further information please see ECHA Website:
http://echa.europa.eu/home_en.asp

12. *Kathleen Roberts* Says:
September 14th, 2011 at 2:54 pm

The North American Metals Council (NAMC) is pleased to submit input to Step 1(a) — Prioritization Factors in the U.S. Environmental Protection Agency's (EPA) "Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment" (Discussion Guide). We note that our concerns regarding prioritization processes and factors would apply to other prioritization proposals put forward under this discussion forum.

The Prioritization Process Should Reflect EPA's Metal Risk Assessment Framework

EPA recognizes that metals present unique risk assessment issues, and sees the need to develop a framework document that puts forth key scientific principles for metals risk assessments to help ensure consistency in metals assessments across EPA programs and regional offices. (EPA Fact Sheet on Framework for Metals Risk Assessment)

By volume, metals and metal compounds represent the vast majority of marketed substances and to disregard metals in a prioritization process would be wholly inappropriate. To develop a prioritization process that is suitable for all substances, including metal materials, EPA will need to revise its proposed process to reflect the fact that metals exhibit unique characteristics that make it inappropriate to evaluate and prioritize metal substances using the general hazard evaluation principles applied to organic chemicals.

Risk factors for a metal depend on — among other things — the specific metal, the form of the metal and/or metal compound, the bioavailability of the metal to particular organisms, and the organism's ability to regulate and/or store the metal. Certain traits used to screen, assess, or prioritize organic compounds, such as bioaccumulation and persistence, are not appropriate for assessing the hazard of metals. As indicated in the quote above, EPA itself has recognized this point in its Framework for Metals Risk Assessment, noting that metals and metal substances must be assessed differently than organic chemicals. We urge EPA to modify the draft process for identifying priority chemicals to reflect the process outlined in its own Framework for Metals Risk Assessment and to provide specific reference to the guidance contained in that document.

Persistent, Bioaccumulative, and Toxic (PBT) As a Prioritization Factor Is Not Appropriate for Metals and Metal Substances

While organic compounds, for example, undergo bioaccumulation, there are unique properties, issues, and processes within these principles that assessors need to consider when evaluating metal compounds. Furthermore, the latest scientific data on bioaccumulation do not currently support the use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals. (EPA Fact Sheet on Framework for Metals Risk Assessment)

The Discussion Guide includes "chemicals identified as persistent, bioaccumulative, and toxic" as a prioritization factor to identify candidate chemicals for review. This may work when applied to organic chemicals — for which PBT criteria were developed — but it is not a suitable basis for evaluating the hazards of metals.

Persistence is problematic for metals because all metals and other elements on the periodic table are conserved and hence, persistent — although the form and availability of the metal can change (thereby affecting its potential bioavailability and toxicity) depending on the environmental conditions. Applying persistence criteria designed for organics to metals, therefore, can result in misleading assessments of potential hazard. A more discriminating approach is needed.

The same is true of bioaccumulation. Unlike organic substances, the bioaccumulation potential of metals cannot be estimated using octanol-water partition coefficients (Kow). For metals, bioconcentration and bioaccumulation factors (BCF and BAF) are inversely related to the concentration of the metal in the surrounding environmental medium and are not reliable predictors of chronic toxicity, food chain accumulation, or hazard. The inverse relationship between exposure concentration and BCF means that organisms from the cleanest environments (i.e., background) have the largest BCF or BAF values, even though they are least at risk of toxic insult. This inverse relationship does not exist for organic substances. Thus, it is counterintuitive to use BCF/BAF and log Kow — which were originally derived for hazard evaluation of organic substances — to evaluate hazard and risk for metals. EPA recognizes this point explicitly in its Framework for Metals Risk Assessment, which states that "the latest scientific data on bioaccumulation do not currently support the use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals." The Discussion Guide should acknowledge this point as well.

The Presence of Metals in Consumer Products Should Not Be Presumed To Present a Health Risk

NAMC is concerned that the proposed prioritization factors "Chemicals used in consumer products" and "Chemicals used in children's products" can be misapplied in the case of metals. Clearly, many metals will be used in consumer and children's products. In many cases, the metals, however, will be present in a chemical or physical form that does not allow for exposure via a pathway (e.g., inhalation) that could potentially present a health risk (e.g., lung cancer). It would be inappropriate for EPA to identify metals as candidate chemicals for review merely because of their presence in consumer products when those metals are not accessible for biological impacts through a relevant route of exposure.

In addition, NAMC notes that many metals have been classified as "generally recognized as safe" by the U.S. Food and Drug Administration (FDA) and are used in food, vitamins, and cosmetic products.

13. *Paul Dugard* Says:
September 14th, 2011 at 3:03 pm

General:
The Halogenated Solvents Industry Alliance, Inc. (HSIA) recognizes the importance of a rational prioritization process in selecting chemicals for consideration of risk management under TSCA. However, there are many EPA regulatory programs outside TSCA that take into account known properties of chemicals in relation to their applications, human exposures and disposal. One concern is that the proposed prioritization criteria would lead to listing of well-tested materials that are already comprehensively regulated under, for example, the Clean Air Act (e.g. NESHAPs), Safe Drinking Water Act (with established MCLs), and RCRA. Thus, the prioritization process should focus on identifying chemicals that are less well tested and not already adequately regulated. In addition to a selection process, there should be criteria established for deselecting well-tested, fully regulated chemicals.

Prioritization Factors:
The guide suggests that "one or more" of the prioritization factors would be sufficient for inclusion for Step 2. It is more rational to select chemicals where two or more factors apply. Moreover, if only two factors are used, one should be from "hazard" and one should be from exposure or use. For example,

even if a hazard has been identified, if exposure is extremely low or non-existent, no action under TSCA is likely to be necessary.
"Chemicals detected in biomonitoring" should not be employed as a factor. One reason is that most materials that have been subject to biomonitoring have been well-tested and are comprehensively regulated on their known properties. Action under TSCA would be redundant. Since analytical methods are able to detect extremely low levels in biomonitoring, the mere presence of a chemical is not a true indicator of concern. Biomonitoring values may be of most use in Step 2. The greatest concern, thus highest priority, should be for chemicals where the uses point to a probable but uncharacterized exposure, and, in particular, where the chemical has undergone only limited toxicity testing.

14. *Barbara Losey* Says:
September 14th, 2011 at 4:29 pm

The Alkylphenols & Ethoxylates Research Council (APERC) is composed of manufacturers, processors and raw material suppliers of alkylphenols and alkylphenol ethoxylates, including nonylphenol (NP) and nonylphenol ethoxylates (NPEs), which have already been prioritized and are the subject of an EPA action plan. APERC offers the following comments with the expectation that EPA will develop a prioritization process for the assessment of chemicals that is systematic, transparent and founded on uniform risk-based criteria.

The prioritization approach proposed by EPA in the Discussion Guide is fundamentally a list-based approach that provides no context regarding the relevance of these factors and their respective data sources to prioritizing potential candidate chemicals. EPA should instead develop a chemical prioritization scheme that has clear and quantifiable risk-based criteria for what constitutes a priority chemical of interest to the Agency. These criteria should be applied to both Step 1 and 2 in order to have a consistent policy basis for selecting and evaluating chemicals.

The current proposal relies on lists that represent potential hazard and exposure factors that in some cases are defined by other authorities. In addition, the source lists rely on criteria that are variable and, in some cases, have been subjectively developed or based other lists themselves. For example, the Washington State Children's Safe Product Act list is identified as a source of data for chemicals used in children's products. The Washington State list is itself based on other lists, and is therefore not based on objective criteria or on a review of original information on the chemicals. In addition, the Washington State Children's Safe Product Act Reporting Rule only seeks information about whether a listed compound is used in children's products. Since initial reporting is not due until 2012, it is premature to assume that compounds on the Washington State list are actually used in children's products.

Rather than a list-based prioritization approach, the development of clear risk-based criteria is recommended. Furthermore, the selection of priority compounds should be based on the underlying studies that supported listing of compounds on the currently proposed source lists, and other credible studies published since the listing. To raise a chemical to a level of national concern based on existing lists, rather than on defined criteria and supporting data, leaves open the possibility that chemicals will be prioritized based on the inherent biases in the source lists and highly variable approaches that were used in developing these lists.

Since the lists of chemicals that would arise from either Step 1 or Step 2 in the currently proposed prioritization process are likely to yield a de facto "chemicals of concern" with adverse implications for the market place, EPA should develop clear communications to emphasize that these chemicals have not yet been fully assessed for their risks to human health or the environment.

APERC has direct experience with EPA's recent activities on the chemical action plans, specifically the EPA Chemical Action Plan document for nonylphenol and nonylphenol ethoxylates. It is APERC's

opinion that this particular action plan was lacking in scientific rigor in its review. It is APERC's hope that this new prioritization process be held to a higher standard of science, thoroughness, and objectivity.

15. *Jason Rano* Says:
September 14th, 2011 at 4:39 pm

EWG applauds and is encouraged by the Environmental Protection Agency's effort to use its limited authority under the Toxic Substances Control Act to identify priority chemicals for review. In the face of continued inaction by Congress to reform this broken, failed law, the EPA has shown increased leadership to identify and take action on chemicals that threaten public health.

EPA launched the High Production Volume Challenge in the late 1990s as an attempt to assess chemical risks posed by widely used industrial chemicals. A decade's investment in chemical screening and voluntary cooperation with industry has resulted in very few chemical assessments, and even fewer policy actions to reduce human exposure to toxic chemicals. EPA's current approach, focusing on data gaps and policy initiatives for a smaller set of priority chemicals, is a useful next step, as there are numerous chemicals, which pose health risks requiring immediate action.

We fully support the agency's effort to develop a framework for identifying another round of high priority chemicals. We recommend that EPA make a public commitment to a timeframe for prioritization and risk reduction action similar to the timeframe established in Canada. We offer these comments in an effort to improve the proposed process.

EPA Should Prioritize Unstudied Chemicals
EPA should rely on available information on chemical exposures and hazards to ensure that efforts are focused on chemicals posing the greatest risks. Chemicals that lack hazard information should by default be prioritized as "high concern" until studies prove otherwise. Chemicals that are highly hazardous but for which exposure information is unavailable should also be included in the Step 1 screening for further review.

Biomonitoring is an Important Prioritization Factor
EPA's stated goals for this chemical prioritization proposal include identifying chemicals that pose a significant risk to health, and particular those to which children are exposed. EPA has listed chemicals detected in biomonitoring programs as a primary factor for prioritization. Biomonitoring, which tests human blood, urine and other media for the presence of chemicals, is a key way to determine what chemicals people are exposed to.

However, to make this as effective a factor as possible EPA should include biomonitoring data from sources other than the federal government. Federal biomonitoring efforts to date have been limited, especially with respect to exposures during pregnancy and early childhood, periods of great vulnerability to environmental contaminants.

We encourage EPA to establish criteria and protocols that allow the agency to consider biomonitoring data from a wide range of sources, including non-governmental organizations and industry. EWG's search of the publicly available, peer-reviewed literature reveals that more than 280 contaminants have been detected in umbilical cord blood. Many of these studies are funded by the US government, or published in the federally overseen journal Environmental Health Perspectives. EWG's own biomonitoring efforts have detected nearly 500 chemicals in people, including more than 200 chemicals in two studies of umbilical cord blood.

EPA should also establish criteria that allow the agency to consider a wide range of data sources for environmental monitoring data, including studies from NGOs, industry, other countries and states and

localities.

EPA Should Take Proactive Steps to Require Industry to Submit Data and Use Existing Data
Under TSCA, EPA is severely limited in its ability to require industry to conduct and submit health and safety data. However, during the discussion around identifying priority chemicals on September 7th, several industry representatives offered to submit studies and data that they already have. EPA should capitalize on those offers and request that industry submit all existing data relevant for step 1 criteria including; carcinogenicity, developmental/reproductive toxicity, biomonitoring or use in children's or consumer products, to enable the most scientifically accurate prioritization. Though limited, EPA should also use what authority the agency has under TSCA, including in Section 8(d), to submit health and safety data for potential high priority chemicals.

EPA Should Broaden the Factors It Uses to Indicate Children's Exposures
We agree with EPA's idea to consider early-life exposures in prioritizing chemicals for assessment and risk reduction. However, the data sources EPA proposes are far too narrow to be meaningful:

• Children are exposed to many more chemicals than only those in "children's products," the constraint proposed by EPA;
• The industry-submitted information proposed to define chemicals in children's products, the Information Update Rule data, is remarkably incomplete, listing only 267 chemicals used in children's products according to EWG's latest review;
• Critical and sensitive windows of susceptibility begin at conception; exposures during pregnancy would also be of critical concern.

To capture the range of chemicals posing risks during early life, EWG recommends that EPA broaden its proposed factors to include chemicals produced in relatively high volumes, chemicals in consumer products (not just children's products), and chemical pollutants or additives in food and tap water.

Reference:
EWG. 2009. Pollution in People: Cord Blood Contaminants in Minority Newborns.
http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf

16. *Barbara J. Warren, RN, MS* Says:
September 15th, 2011 at 11:03 am

Step 1(a) Topic: Prioritization Factors
EPA has identified a fairly good list of prioritization factors. We wish to make additional recommendations and provide our rationale.
PBTs
High priority should be given to newer chemicals that are persistent and bioaccumulative, not just an old PBT or POPs list. In general, high priority should be given to chemicals that do not degrade in the environment and are toxic, even if full hazard information is limited. While there are a host of legacy PBTs still present at unacceptable levels, there are newer chemicals on the market that can be classified by their persistence and bioaccumulation potential. It is critically important to quickly identify such chemicals and remove their uses to the greatest extent possible. As a class PBTs have a wide range of health effects—carcinogenic, mutagenic, toxic to various organ systems, etc. The persistence of these chemicals means that annual production quantities add to the cumulative environmental loading and increase exposure to biota and humans. When we can document the years since the ban of a PBT and still find it in the environment and living organisms, it is clear that newer PBTs must be quickly identified, better characterized and banned or severely restricted.
Neurotoxic substances
A large number of toxins are toxic to the nervous system. Hazard information is often available on neurotoxicity in animals and in adults. Children from before birth to adolescence do not have fully

developed nervous systems, therefore exposure to substances toxic to nervous systems poses an added risk for unknown neurotoxicity, depending on the stage of development. What is toxic to an adult nervous system can be far more toxic to a child, resulting in permanent damage to developing pathways. This understanding coupled with the number of different neurotoxins that children are currently exposed to completes a picture that demands concerted, deliberate attention from our government.
While I have talked about developmental effects above, I am trying to stay away from that being a required element of the hazard assessment. I am saying neurotoxicity is enough information to act to protect children, even where we do not have good studies that show developmental effects. Simply the fact of a developing nervous system tells us we need to be concerned about chemicals that are neurotoxic.
Endocrine Disruptors
Despite considerable attention by government related to screening and identifying these chemicals, insufficient risk management has been the outcome. We need the Agency to move toward identifying why chemicals in this category need special attention and the development of action plans. We describe the unique biological effects of endocrine disruptors as "a small signal triggering large, even system wide effects."
Additional Information is needed in Step 1a.
We support moving away from attempting to characterize exposure precisely. There are several reasons for this: 1) This has never been done well for a single chemical by including all pathways. Usually one chemical and one pathway is the norm. As a result we have no idea of total exposure to humans for a single chemical. 2) We have even worse information on typical exposures to chemical mixtures. Therefore we support using gross numbers like production and import quantities and use information in consumer products. We also believe there is some good environmental data from federal and state environmental programs, that point to the prevalence of certain chemicals and their degradation products in the environment. This information can be used as a surrogate for studies focused on human exposure. We would also like to add that there are limits to biomonitoring data—some may characterize only one biological pathway representing 10-20% of exposure, while other pathways remain unknown. Prevalence of a chemical in the environment is an important surrogate for exposure. We support moving up data sources from Step 2 to accomplish this—such as the High Production volume information.
Nanomaterials
We support the Agency's efforts to consider the special issues surrounding nanomaterials. While there was little time to fully discuss the evaluation of nanomaterials, we hope that we can engage the EPA in a more detailed discussion on this topic.
Preference for a Large List of Priority Chemicals coming out of Step 1
We prefer the identification of a large list of priority chemicals as a first step as other countries and states have done. We understand this is being done under TSCA, however, it should be possible to include some categories of chemicals that are non-TSCA subjects in the first step, based on your criteria. Then they could be set aside for other kinds of reviews. Since TSCA reform is actively being considered, this would provide important information.

17. *Franklin E. Mirer, PhD, CIH* Says:
September 15th, 2011 at 5:37 pm

Chemicals with substantial occupational exposures should be a priority. EPA is responsible for test rules and may regulate products and processes pursuant to TSCA. Existing chemicals are a major problem. There is a distinct difference between OSHA's authority for setting permissible exposure limits and EPA's authority for regulating products and processes.

Often the clearest and most present danger of a chemical or mixture is in the occupational environment. Frequently, human health effects can be directly observed in the occupational environment, and these data can be used to protect the general population and vulnerable populations.

EPA should conduct this prioritization in conjunction with OSHA, MSHA and NIOSH.

18. *Dan Newton* Says:
September 20th, 2011 at 12:28 pm

SOCMA is pleased that EPA is pursuing dialogue on the important issue of prioritization of chemicals and appreciates its outreach to stakeholders. The logic for EPA's prioritization of chemicals for its Chemical Action Plans has never been clear.

We believe the first step is to revive the Inventory Reset, in some shape or fashion, especially since the prospects of TSCA reform legislation are not imminent. Clearly the large majority of the 80,000+ chemicals on the Inventory are not currently being manufactured. The single greatest way to prioritize among existing chemicals is to remove all those we no longer need to worry about. Certainly the agency should not waste time and resources collecting or analyzing hazard data for chemicals no longer in commerce. If EPA really wants to address this fundamental criticism of its current TSCA program, it needs to prioritize all existing chemicals in the same step. The agency has made great strides by making the Inventory easily accessible to the public, but more work needs to be done to make it a more useful list.

The key next step is for the agency to come up with some sort of risk-based algorithm or screen whose logic is laid out clearly. That way:

- There will be transparency about the prioritization process – both the inputs and the rationale that takes those inputs and produces the results.

- Stakeholders will be able to supply data to EPA, replicate the screen calculations themselves, and point out any errors.

- EPA will be then able to address the highest risks first.

EPA has done this sort of thing before; e.g., the Hazard Ranking System used to decide what sites go onto the Superfund National Priorities List. EPA can look to Canada's CEPA categorization process as a directly relevant model, though Canada's actual screens can be updated and improved. We can also support ACC's proposal, in principle.

There may be others, but ultimately the screen has to be objective and rigorous. This would involve an explanation of how the agency will apply prioritization factors, and how it will choose among the priority chemicals for further action. It would not simply lump together exposure and hazard factors. SOCMA suggests EPA get on board with a system based on risk that uses numbers.

The screen should produce at least three categories (e.g., high, medium, low). Priority or not is too simple.

Data Sources for Prioritization Factors:

For production and exposure information the screen could use the 2006 IUR data. EPA could also use the results of the new Chemical Data Reporting (CDR) rule, if it wants to wait that long. More targeted Preliminary Assessment and Information Reporting (PAIR) rules can be done to capture chemicals that may have not been reported via the IUR/CDR. SOCMA supports the IUR's division of uses (intermediates, industrial, commercial, consumer). Presence in biomonitoring studies and use in children's products, while understandably prioritization factors of interest, should not be separate categories. "Presence in biomonitoring studies" principally means "included in list of chemicals analyzed for." "Use in children's products" is unreliable — it is difficult for manufacturers to determine

all the possible routes of exposure and they will not have knowledge of all the end uses all the time. There are inherent challenges involved in gathering exposure information throughout supply chains. These should therefore be secondary considerations.

Should the agency decide to factor in production volumes, ranges should not be overly broad. A medium volume tier could be 25,000 – 100,000 lbs or even up to 500,000 lbs, for example. This is consistent with what EPA has done in the past.

Hazard Information:

The key is to keep it simple, so that EPA can complete its work in a reasonable time.

If considering GHS we would like to note that these data are not universally available, since many U.S. companies do not export (in some cases they stopped because of REACH burdens). This is especially true for small batch/specialty chemical companies, like SOCMA members.

The New Chemicals Program office is the world's center of excellence in using QSARs and similar approaches — use these liberally where data does not exist.

EPA's hazard categories are too broad: Don't lump together known carcinogens with probable or possible ones (i.e., put IRIS A and B1 in separate categories or treat as separate weighting factors.) Similarly the same should apply with the IARC 1 and 2A, NTP "known" and "reasonably anticipated" categories.

National Toxicology Program (NTP) "serious concern," "concern" and "some concern" span too wide a range. The latter at least should be a separate category or weighting factor.

EPA should be able to leverage REACH data as it becomes available.

19. *Filipa Rio* Says:
September 20th, 2011 at 2:12 pm

We support EPA for initiating the Prioritization Stakeholder Dialog and proposing a process to identify priority chemicals for review and assessment. Further, we support EPA in recognizing the need for a systematic process for prioritizing chemicals, as prioritization is a critical and necessary first step in any chemical management program. In light of EPA's goal to increase transparency, we encourage EPA to invite a public notice and comment period when the initial list of priority chemicals is determined later this Fall. Doing so would provide the public with an opportunity to better-inform EPA's decisions on chemical prioritization and its process.

EPA has not yet explained how it is going to use the prioritization factors and data sources (e.g., what models, assumptions, analysis, etc. it will use) outlined in steps 1 and 2 of the discussion document. How the factors and data sources are used is as important as what the data sources are, particularly in Step 2, which EPA says will be used to select specific chemicals for further assessment, including possible risk assessment and risk management actions. It is critical that EPA establish a solid framework for the analysis up front, and then use it to assess chemicals in batches on a well-communicated schedule with opportunity for public input. The methodology used must be scientifically sound, transparent, properly documented, and consistent.

Along those lines, we support EPA for this important first step, and recommend continued stakeholder dialog and transparency as this process moves forward.

20. *Laura Madden* Says:

September 21st, 2011 at 11:51 am

The American Cleaning Institute®, Consumer Specialty Products Association and Grocery Manufacturers Association (hereinafter referred to as the Downstream Coalition) are the leading trade associations representing downstream users of chemical substances used in household and commercial products. Our member companies are committed to manufacturing and marketing safe, innovative and sustainable products that provide essential benefits to consumers while protecting human health and the environment.

The Downstream Coalition appreciates being a part of EPA's discussion regarding prioritization factors and data sources it plans to use to identify candidate chemicals for review and assessment under the Toxic Substances Control Act (TSCA). We are committed to providing substantive comments and continuing to assist EPA in strengthening its current chemicals management program.

General Comments

Prioritization must be a risk-based screening level process.
We fully support EPA's goal of prioritization, which is to employ a screening-level process to identify chemicals requiring further review and possible risk management actions under TSCA. As we have stated previously, any screening-level priority setting must be risk-based, taking into consideration both a chemical's hazards and potential exposures. Chemicals identified as high priorities for assessment should be those substances with both the highest hazards and the highest potential exposure. EPA has a number of available data sources from which to obtain information on chemical hazards and indicators of exposure to swiftly identify the subset of chemicals in need of priority assessment. The Downstream Coalition remains committed to working with the Agency to develop a longer-term, practical approach by which downstream formulated companies can provide more complete use information to better inform EPA's prioritization decisions in the years ahead.

We also agree with EPA that the mere identification of a chemical for further review does not, in and of itself, constitute a finding that the chemical poses a risk to human health or the environment; rather, it signals that the chemical needs further study and assessment.

To that end, we strongly recommend that EPA adopt nomenclature in this process to more clearly describe the chemicals under consideration in Step 1. Referring to them as "priority chemicals" would seem to infer that the chemical has already been identified as a priority for review and assessment, when, in fact, EPA needs to first complete the Step 2 process of gathering additional information prior to identifying which are priority chemicals. We suggest using the language EPA used in the Discussion Guide of "candidate chemicals for review" for chemicals identified in Step 1 to remove confusion about the status of the substance in question, and remove any prejudice that might come with such a label. We believe that the label "priority chemicals" should be reserved for substances that have been selected to move to the risk assessment process.

Step 1: Identifying Candidate Chemicals for Review

Prioritization Factors:
Step 1 outlines the "risk-based prioritization factors" to identify candidate chemicals for review. The Discussion Guide lists six prioritization factors that EPA will consider and notes that chemicals for review will be identified by meeting "one or more" of the priority factors. EPA would have amassed an overwhelming universe of chemicals by using just one prioritization factor to identify candidate chemicals for review. We appreciate the Agency's clarification during the webinar that chemicals should meet at least one hazard and one exposure factor to become part of the initial group of candidate chemicals for review. We agree that the six factors listed by the Agency are appropriate to identify an initial group of candidate chemicals for review; however, we believe the prioritization factors set forth

by EPA need further refinement .

Chemicals in Consumer Products: The factor, "Chemicals used in consumer products," should be refined to recognize the broad range of chemical uses in consumer products in order to more effectively distinguish those chemicals that warrant further assessment. We recognize that applying this refinement may be challenging in the timeframe EPA has set for an initial set of substances to be selected this Fall for assessment. However, we urge the Agency to develop comprehensive approaches to refine the universe of chemicals used in consumer products that are of interest for further assessment in future rounds of prioritization. The Downstream Coalition welcomes the opportunity to work with EPA to develop improved tools for EPA for using indicators of consumer product exposure to refine the categorization of those chemicals for further assessment, recognizing that the approach needs to be practical, objective, and predictable in order to quickly and efficiently narrow the large chemical universe to a smaller, more meaningful, subset of chemicals that would receive further assessment.

Biomonitoring Factor: The factor, "chemicals detected in biomonitoring programs," should also be refined to clarify, consistent with Center for Disease Control statements, that biomonitoring information alone is not sufficient to indicate a risk. Rather, it is an indicator of exposure and additional information must be considered that compares the exposure information to the chemical's hazard to determine whether there is a potential for harm. This is also true for environmental monitoring information. Biomonitoring as well as environmental monitoring information that is reliable should be used as appropriate in formulating, refining, and verifying exposure scenarios and potential for risk.

We support the six prioritization factors identified by EPA to make the first cut for candidate chemicals for review; however, EPA must still develop criteria for refining the list to a workable number of chemicals for further assessment. While the Agency has identified some data sources it plans to use to further analyze and select the chemicals, additional transparency is needed with regard to the criteria the Agency will use to narrow the collection of candidate chemicals for review that progress to risk assessment.

Lastly, once candidate chemicals are identified, there should be opportunity for stakeholder input to ensure EPA has sufficient information to make well-informed decisions. We would like to reaffirm the downstream commitment to provide additional information on proposed candidate chemicals and respond to questions EPA has on specific chemicals prior to finalization of a list of candidate or priority chemicals. This approach would allow a better informed selection of chemicals that would warrant further review and safety assessment.

21. *Fred Corey* Says:
September 21st, 2011 at 2:37 pm

Thank you for the opportunity to comment on EPA's plans to identify priority chemicals for review and assessment. We are pleased that EPA intends to consider possible risk management actions under TSCA for chemicals that are identified as presenting a risk to human health and the environment.

Background
EPA Administrator Lisa Jackson has identified children's health issues, persistent bioaccumulative and toxic chemicals, and carcinogens as among the Agency's highest hazard based priorities.

EPA intends to identify priority chemicals for review and possible risk management under the Toxic Substances Control Act (TSCA).
EPA has developed a list of factors (such as chemicals used in consumer products, and chemicals used in children's products) to assist with prioritizing chemicals for review.

Prioritization Factors

The list of factors that EPA has developed does not represent significant chemical exposures experienced by subsistence practitioners (as used here, the term subsistence refers to all cultural and traditional uses of natural resources, including use for food, medicine, spiritual practices, occupational activities, and traditional arts and crafts).

Therefore, EPA should add an additional factor for "chemicals detected in subsistence or traditional use natural resources (environmental exposures)." This factor will capture potential exposures to those who may be most exposed and potentially most vulnerable to risks (in subsistence communities, EPA's typical exposure factors are not indicative of actual contaminant pathways). As an example, Alaskan Natives are among those with the highest toxics burden, yet have perhaps the lowest exposure to children's products and consumer products.

According to a group of U.S. states seeking TSCA reform:
"The Arctic is a hemispheric sink for PBTs, which are transported long distances via atmospheric and oceanic currents. Arctic Indigenous peoples reliant on traditional diets of fish and marine mammals are among the most highly exposed people on earth. A study of the Yupik people of St. Lawrence Island in Alaska found that they carry PCBs in their blood at levels that are 6-9 times higher than the general population in the lower-48 states."

Since access to typical consumer products and children's products is limited in remote villages, these exposure factors are obviously not the primary factors affecting Native Alaskan's exposure to chemicals. Furthermore, for most Alaskan Natives, there are few alternatives to consuming traditional foods and using local natural resources for medicinal, spiritual, and other cultural uses.

22. *James Cooper* Says:
September 21st, 2011 at 4:09 pm

Comments on Step 1(a): Prioritization Factors

NPRA generally supports the prioritization factors identified by EPA. NPRA recommends that the agency also consider significant environmental hazards. NPRA also suggests adding concentration for mixtures and total quantity produced or imported in the initial tier to assist in focusing on the highest potential exposures. This information is available from the IUR database.

While some stakeholders view biomonitoring data as evidence of exposure, EPA should give more weight to general uses, total volume and concentrations in formulated mixtures. Appropriate weighting should be developed for each of the factors, as well as the data used, and made publicly available for comment. This would not necessarily need to be published in the Federal Register, as long as the development, proposal and comment gathering are conducted in a transparent manner.

23. *James Cooper* Says:
September 21st, 2011 at 4:15 pm

General Comments on Priority-setting:

The National Petrochemical and Refiners Association, NPRA, appreciates the opportunity to comment on EPA's proposed chemical prioritization plan. NPRA commends EPA on its interest in establishing a risk-based priority process. First and foremost, any priority process should be fully transparent and viewed holistically in the context of tiered and targeted risk assessment and risk management. Transparency can be accomplished by developing thorough guidance, complete with full descriptions of each step in the priority-setting process, potential outcomes of each step, criteria used in decision-making and appropriate weighting for decision factors.

NPRA agrees with several other stakeholders that EPA has been slow and, in some cases, reluctant to use certain regulatory authorities granted under TSCA. EPA is moving in the right direction by establishing a priority-setting process and needs to use a tiered, targeted and risk-based approach to ensure that resources are utilized in an effective and efficient manner. Both hazard and exposure should be considered during each tier in the process. The ultimate goal of priority-setting is to allow EPA to focus its resources; therefore, casting a wide net and considering an abundance of different factors too early in the process will only make achieving the agency's objectives more challenging. Considering all the factors proposed under this blog would result in an initial cut that includes most chemicals subject to IUR reporting, which would put EPA right back at the starting point. NPRA recommends that EPA keep it simple in the first and second tiers, consider the factors that the agency has proposed to develop a "quick-start" list of chemicals for immediate review and movement through the tiers, and move forward in a deliberate and transparent manner. Other factors could be added in subsequent tiers to help refine screening-level assessments and look at a fuller array of potential hazards and exposure pathways.

The first tier in the process should address all chemicals in commerce that are produced or imported at quantities greater than 25,000 pounds per year – i.e., chemicals reported to the agency under the Inventory Update Reporting (IUR) rule. EPA should develop a software-based sieve to enable it to quickly screen the IUR chemicals. All chemicals in the first tier should be judged using the same tools and criteria to avoid penalizing data-rich chemicals. EPA should use its predictive models, structure-activity-relationship (SAR) analysis and internal databases for the first tier. While some have questioned the accuracy of models and SAR, the intent is not to use an academic risk assessment approach to screen chemicals; rather, the intent is to use conservative assumptions that are protective of health and the environment initially, and refine the assessment using measured data in subsequent tiers. This approach is consistent with current risk assessment processes used by EPA. Each subsequent tier in the process should allow for stakeholders to submit information that could help refine the assessment of the chemical. Additional factors could also be added in subsequent tiers to ensure that chemicals with uncontrolled risks are not set aside as low priorities.

NPRA supports the concept of a sieve as proposed by the American Chemistry Council and suggests that EPA convene a multi-stakeholder task group to assist in refining the sieve and developing an outline for appropriate guidance. The stakeholder meeting held on September 7 revealed interest in the ACC sieve from a variety of stakeholders. EPA should take advantage of that interest.

Another important component of the overall risk assessment process is the employment of a weight-of-the-evidence approach, which can only be accomplished by weighting data according to scientific certainty, clarity and quality. An appropriate weighting scheme should be developed and made publicly available for comment to assist in refining assessments and priorities in the overall process.

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