

Testimony of
The Honorable Cal Dooley
President and CEO
American Chemistry Council
700 Second Street NE
Washington, DC 20002

Before the
Senate Committee on Environment and Public Works and the
Subcommittee on Superfund, Toxics & Environmental Health

"Legislative Hearing on the Safe Chemicals Act"

November 17, 2011

Thank you for the opportunity to testify on behalf of the American Chemistry Council, our member companies and their nearly 800,000 employees. We appreciate the efforts of Senators Lautenberg, Inhofe and other Members of this committee, and we appreciate the chance to discuss our views about S. 847, the "*Safe Chemicals Act of 2011*."

ACC strongly supports efforts to reform the 35-year old Toxic Substances Control Act (TSCA). Over the years, public confidence in TSCA has diminished, contributing to misperceptions about the safety of chemicals, ill-conceived state laws, unnecessary product de-selection, and baseless litigation.

Safety is the top priority of our member companies. We need an effective and reliable chemical regulatory system that will instill in policymakers, our business partners and the public the same level of confidence in our products that we have.

Over two years ago, ACC released *10 Principles for Modernizing TSCA*. These principles create a roadmap to a modern chemical regulatory system that will protect public health and the environment, while preserving the ability of American chemical companies to drive innovation, grow jobs, and compete in the global marketplace.

In recent months, ACC and other stakeholders have engaged with bipartisan committee staff to discuss our respective positions about legislation to update TSCA. We have appreciated the opportunity for our views to be heard and would like to commend Ben Dunham from Senator Lautenberg's staff and Dimitri Karakitsos from Senator Inhofe's staff for their professional management of the discussions. Unfortunately, though, today we are discussing a bill that remains very similar to the bill introduced in 2010, which we consider unworkable.

There are fundamental flaws in the legislation, including:

Safety Standard: The bill's standard of "reasonable certainty of no harm… from aggregate exposure" for all chemicals would be virtually impossible to meet. If the U.S. Environmental Protection Agency (EPA) were required by TSCA to consider the aggregate exposures to a substance from every industrial, commercial, and consumer product use of a chemical substance, regulatory paralysis would ensue.

New Chemicals: There is broad consensus, even among TSCA critics, that the current program to evaluate new chemicals is working. In spite of this, the legislation would prescribe significant new data requirements before new chemicals could come to market, as well as extend EPA's time to evaluate this data, potentially keeping these chemistries in a state of limbo. Manufacturers are certain to seek more manageable regulatory environments and produce new chemicals, including "green" chemistry developments and potentially revolutionary new products, in other countries to avoid prohibitive costs and uncertainty.

Minimum Data Set: The bill would create an enormous burden on EPA and on manufacturers with little benefit by requiring a minimum data set for all chemicals. Instead, EPA should take advantage of the massive amounts of data and information that the Agency already has access to.

Prioritization: The bill's prioritization proposal lacks rigorous criteria and makes no mention of integrating current knowledge about hazard, use, and exposure – three factors that are critical to an informed regulatory decision. ACC recently proposed a transparent and scientifically-sound prioritization process to determine which chemicals should receive full safety assessments so EPA can focus its resources where they are most needed. We believe our prioritization proposal would be more effective than what has been proposed in S. 847, and have attached the details for your review.

We also believe that S. 847 would compromise the protection of confidential business information, inappropriately expand EPA's authority into the jurisdiction of other federal agencies such as the U.S. Food and Drug Administration (FDA), further complicate issues surrounding national uniformity of standards, and fail to adequately consider animal welfare.

Reform of TSCA is an important priority, but one that must be done right. Chemistry will be the source of clean energy, improved infrastructure, efficient transportation, medical advancements, and of a strong national defense. An ill-conceived regulatory system, like that which would be created by S. 847, would undermine America's ability to develop and produce these transformational technologies and would put jobs of today and of tomorrow at risk.

Even though S. 847 is not the answer, we remain fully committed to TSCA reform. We believe we can develop legislation that will give consumers confidence, learns from the success and missteps of reforms undertaken by other countries, and fosters innovation and job creation.

Thank you for the chance to express our views on this critical subject, and I look forward to answering your questions.

10 Principles for Modernizing TSCA

The American Chemistry Council and its members support Congress' effort to modernize our nation's chemical management system. Such a system should place protecting the public health as its highest priority, and should include strict government oversight. It should also preserve America's role as the world's leading innovator and employer in the creation of safe and environmentally sound technologies and products of the business of chemistry.

The current chemical management law, the Toxic Substances Control Act (TSCA), is more than 30 years old. It should be modernized to keep pace with advances in science and technology. Moreover, the law must provide the Environmental Protection Agency with the resources and the authority to do its job effectively.

We have previously offered general concepts on which to base a modern chemical management system. This document expands upon those concepts and begins to provide more detail, which we hope will be useful to policy makers. We will continue to refine the details of our principles for modernizing TSCA and are committed to working with all stakeholders toward enactment of effective legislation.

1. Chemicals should be safe for their intended use.

    - Ensuring chemical safety is a shared responsibility of industry and EPA.

    - Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety.

    - EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.

    - Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.

    - Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision making, but should not be part of its safe use determinations.

    - Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.

2. EPA should systematically prioritize chemicals for purposes of safe use determinations.

    - Government and industry resources should be focused on chemicals of highest concern.

- The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.

3. EPA should act expeditiously and efficiently in making safe use determinations.

   - Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.

4. EPA should complete safe use determinations within set timeframes. Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.

   - Companies throughout the chain of commerce should be responsible for providing necessary hazard, use, and exposure information.

   - EPA should be authorized to require companies, as appropriate, to generate relevant new data and information to the extent reasonably necessary to make safe use determinations without having to prove risk as a prerequisite or engaging in protracted rulemaking.

   - Testing of chemicals should progress to more complex and expensive tests through a tiered approach as needed to identify hazards and exposures of specific concern.

   - To minimize animal testing, existing data should be considered prior to new testing, and validated alternatives to animal testing should be used wherever feasible.

   - Existing data and information should be leveraged in EPA's safe use determinations, including data and information from other mandatory and voluntary programs such as REACH and the U.S. High Production Volume challenge.

5. Potential risks faced by children should be an important factor in safe use determinations.

   - Safe use determinations should consider the effects of a chemical on children and their exposure to the chemical.

   - Safe use determinations should consider whether an extra margin of safety is needed to protect children.

6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.

   - The controls could range from actions such as labeling, handling instructions, exposure limits and engineering controls to use restrictions and product bans.

- The controls should be appropriate for managing the risk, taking into account alternatives, benefits, costs, and uncertainty.

7. Companies and EPA should work together to enhance public access to chemical health and safety information.

   - EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.

   - Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.

   - Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.

   - Reasonable protections for confidential as well as proprietary information should be provided.

8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.

   - EPA should establish transparent and scientifically sound criteria for evaluating all of the information on which it makes decisions to ensure that it is valid, using a framework that addresses the strengths and limitations of the study design, the reliability of the test methods, and the quality of the data.

   - EPA should encourage use of good laboratory practices, peer review, standardized protocols, and other methods to ensure scientific quality.

9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.

   - EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.

10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.

    - A new chemical management system should preserve and enhance the jobs and innovative products and technologies contributed by the business of American chemistry.

    - Implementation of TSCA should encourage product and technology innovation by providing industry certainty about the use of chemicals.

700 Second St., NE | Washington, DC 20002 | (202) 249.7000

ACC Prioritization Screening Approach

I. Introduction

This document provides background on ACC's approach to chemical prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures.
- Apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Include criteria applicable to the range of chemicals being screened. Apply this principle through a two-step process rather than just those information elements available only for subsets of chemicals.
- Leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
- Incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. improvements in how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- Adopt a simple, transparent screening method.
- Include opportunity for public review and comment to ensure the best available data and information is used in prioritization decisions.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.

II. Applying Initial Screening Step in ACC's Prioritization Approach

The first step in applying ACC's prioritization approach is to apply criteria on human health and environmental toxicity potential to chemical substances.

A. Hazard Potential

The U.N. Globally Harmonized System of Classification and Labeling (GHS) was developed and internationally agreed to by many governments to provide criteria and a consistent approach for hazard classification of chemicals. It can also provide a recognized and generally accepted method for sorting chemicals in a prioritization process. The GHS framework has been used by international bodies, such as the OECD and WHO, and was endorsed by EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to support prioritization.

The GHS system applies to both human health and ecological endpoints. It includes criteria for both human and ecological health. For human health, criteria are available for both acute and chronic classifications, as well as CMR categorization. For ecological

endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all substances. GHS classification information is readily available for all substances, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements.

ACC's support of the GHS criteria for purposes of this prioritization tool is not a categorical endorsement of the GHS criteria for any other purpose. ACC has been an active participant in the development of GHS and supports the system in principle. The GHS has not been broadly implemented to date in the U.S., although the Occupational Safety and Health Administration (OSHA) has indicated an intent to publish a regulation applying GHS in the workplace. ACC's December 29, 2009, comments on OSHA's proposed rule to modify the existing Hazard Communication Standard (HCS) to reflect the GHS urged that implementation of the GHS adhere to certain principles (e.g., continued application of the "Building Block Approach" of the Purple Book). ACC made specific recommendations concerning details of the Hazard Classification definitions, cut-off values, among others. ACC stands behind those comments. In ACC's view, the use of GHS criteria in a screening-level prioritization of chemicals can materially assist in determining which chemicals receive additional evaluation by the Environmental Protection Agency, but does not necessarily preclude the use of other appropriate, applicable criteria developed under other systems.

To classify a chemical in a hazard based priority ranking where there is not direct data on the chemical, EPA can employ the full range of approaches, such as QSAR, SAR, read-across and other modeling tools in which EPA has confidence based on molecular structure. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical would be classified as "high" for its environmental or health ranking.

1. Environmental Ranking

Table 1 provides a summary of how GHS criteria could be logically used for chemical management prioritization.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental	Ranking	Environmental Rank Score
Acute I or Chronic I or Insufficient Information to Classify	High	4
Acute II or Chronic II	Medium High	3
Acute III or Chronic III/IV or none	Medium	2
Not classified	Low	1

2. ***Human Health Ranking***

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	**Ranking**	**Health Rank Score**
GHS CMR Cat 1a, 1b; OR Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	High	4
GHS CMR Cat 2; OR Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	Medium High	3
Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	Medium	2
Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	Low	1

It is important to note that specific concerns about children's health (specifically potential hazards and adverse effects on the nervous system) and those caused by endocrine disruption mechanisms are addressed in this prioritization process:

- The GHS CMR "R" classification includes specific evaluation of effects on development in utero and upon growth, maturation and reproduction. ("R" stands for reproductive toxicity and includes adverse effects on sexual function and fertility, as well as developmental toxicity in offspring).
- Endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a compound's ability to interact with components of the endocrine system. The prioritization process evaluates data and information on relevant apical tests, including tests for reproduction and developmental toxicity (potential

effects, which can be mediated by endocrine pathways). Thus, even if specific screening for potential endocrine activity has not yet been conducted on certain compounds, hazard identification based on observable outcomes from apical toxicity tests (e.g., outcomes such as pathologic states indicative of disease conditions) covers all modes of action, including endocrine pathways.

- The toxicity information evaluated (CMR and repeat dose toxicity) is directly relevant to evaluating potential hazards to all individuals, including children. Such data typically includes: 1) identification and definition of possible hazards upon all major organ systems from both acute and repeated exposures, including the nervous system; 2) detection of potential hazards arising from in utero exposures, including possible effects on the nervous system; 3) evaluation of potential of a substance to affect reproduction; and 4) evaluation of the potential of a substance to damage DNA.

Integration of Hazard Elements:
Each of the environmental and human health classifications is assigned a numeric value based upon its ranking, with 1 being the lowest value and 4 the highest. The greatest ranking (highest hazard potential score) of either Environmental or Human Health is used in a substance-specific priority ranking. The numeric value does not imply relative weighting, but rather a numerical order of priority.

B. Exposure Potential Ranking

The screening method allows for an initial indication of the extent of exposure potential by considering:

1. The chemical's uses and use pattern(s).
2. Production volume as a first pass indicator of relative emission/release potential since magnitude and route (i.e. air, water, soil) of emissions is not available for all substances.
3. Persistence and bioaccumulation characteristics of the substance.

Together the 3 elements are used to rank exposure potential.

1. Use Patterns

The proposed approach applies the most current 2006 TSCA Inventory Update Reporting rule (IUR, now called the Chemical Data Reporting rule (CDR) data. To keep the initial prioritization simple and transparent, the approach "bins" different use patterns to align with general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are the same as those reported in the IUR and are consistent with REACH exposure categories (intermediates, worker, professional, consumer). Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. For the initial prioritization approach, child specific products are captured under general consumer products and all consumer products are weighted equally (see additional

discussion below under Second Tier Considerations). Intermediates will have low general population exposures, since these substances are consumed, by definition, within the workplace. Therefore, they are given the lowest priority ranking within the approach. In the context of the proposed approach, the intermediates category includes both intermediates and non-isolated intermediates. A chemical used in multiple use patterns is assigned the priority of the highest use, e.g., a chemical in both industrial and commercial uses would be assigned the commercial Medium-High rank.

Table 3. Use Patterns - Exposure Ranking

Use Pattern	Ranking	Use Pattern Score
Consumer	High	4
Commercial	Medium-High	3
Industrial	Medium	2
Intermediates	Low	1

The IUR Definitions of these terms are (40 CFR 710.3, 710.43):

- "consumer use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of article) when sold to or made available to consumers for their use.
- "commercial use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "industrial use" means use at a site at which one or more chemical substances or mixtures are manufactured (including imported).
- "intermediate" means any chemical substance:
    - which is intentionally removed from the equipment in which it is manufactured, and
    - which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)
- "non-isolated intermediate" means any intermediate that is not intentionally removed from the equipment in which is it manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

2. Production Volume

Recognizing that detailed exposure information will not be available for all substances to be screened, the proposed approach uses production volume as an indicator of exposure, which is widely used in many prioritization schemes. As production volume is just a rough surrogate of emissions, ACC suggests only very broad categories, covering about

two orders of magnitude each. It may be useful to consider how additional exposure estimates may be applied in the second tier assessment.

Table 4. Production Volume as Emission Surrogate - Exposure Ranking

Production Volume as Emission Surrogate	Ranking	Volume Score
>= 100,000,000 lbs national aggregate	High	4
1,000,000 lbs to < 100,000,000 lbs national aggregate	Medium – High	3
>= 25,000 lbs to < 1,000,000 lbs national aggregate	Medium	2
< 25,000 lbs (below IUR site reporting limit)	Low	1

3. Persistence and Bioaccumulation

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the approach. A persistent substance that is emitted to the environment at the same rate as a non-persistent substance with similar partitioning properties will result in higher exposure to humans and the environment. In fact, multimedia modeling clearly indicates that environmental persistence in the compartment to which a substance partitions is a good indicator of human exposure potential (MacLeod & McKone et al. 2004). Similarly, substances that are not subject to biotransformation by higher organisms will exhibit a high bioaccumulation potential that results in higher exposures via the food chain (Arnot et al. 2010). Therefore, it is recommended to apply the proposed persistence and bioaccumulation criteria in assessment of exposure potential as described below.

The persistent and bioaccumulative (P&B) criteria of the proposed approach are targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals, as in the approach taken by Canada's Chemical Management Program (CMP).

For assessing persistence, based upon recent expert consensus (Boethling et al., 2009) it is recommended to distinguish persistent from non-persistent chemicals using the following criteria:

- Volatile chemicals can be defined using a vapor pressure cut-off (i.e., > 1000 Pa)
    - For volatile chemicals, persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a substance is not persistent if air half life is < 2 days).
    - For non-volatile chemicals, non-persistent substances can be defined as substances that are deemed:
        - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) or SAR or read across from measured data on a related substance,
        - show an equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111),

        - evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days, OR
        - if data are lacking, evaluation via BIOWIN model (EPIWEB 4)
    - Non-volatile substances that are not biodegradable or subject to abiotic losses based on the above criteria would be considered persistent.

For assessing bioaccumulation, the key question for screening is the potential for biomagnification based on recent expert consensus (Gobas et al. 2009). To determine if a substance has the potential to biomagnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000. These metrics can be derived using lab or field measurements (where available) or recently improved computational models that are included in EPA's EPIWEB model that can be freely downloaded at www.epa.gov/oppt/exposure/pubs/episuite.htm.

This approach allows all organics to be addressed and is a scientifically updated version of the approach used in Canada's CMP.

Based on the above recommendations, substances can be grouped with regard to persistence and bioaccumulation as follows:

Table 5. Persistence and Bioaccumulation - Exposure Ranking

Persistence and Bioaccumulation	**P&B Ranking**	**P&B Score**
Persistent and Bioaccumulative	High	5
Persistent and Not Bioaccumulative OR Not Persistent and Bioaccumulative	Medium	3
Not Persistent and Not Bioaccumulative	Low	1

Integration of Exposure Elements:

As demonstrated in the tables, each factor (use pattern, P&B, and production volume) would be assigned a numeric score based upon its ranking. All 3 factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential. A proposed "banding" approach is illustrated in Table 6.

Table 6. Integration of Exposure Rankings

Combined Score – All 3 elements	Exposure Rank	Exposure Ranking Score
11 – 13	High	5
9 – 10	Medium High	4
7 – 8	Medium	3
5 – 6	Medium Low	2
3 – 4	Low	1

Overall Priority Grouping:
In the overall approach, both hazard and exposure elements are considered when placing a substance in a risk-based prioritization ranking. The overall prioritization score for priority grouping and risk evaluation is based on the combined consideration of the hazard and exposure rankings. Priority Groups 7, 8, and 9 are deemed High Priority; Priority Groups 4, 5, and 6 are Medium Priority; and Priority Groups 2 and 3 are Low Priority.

Review and Comment:
It is important that screening be done in an open and transparent way and that the best available information be used. When screening for thousands of chemicals, EPA may not have access to all available information. The process should provide an opportunity for review and comment on initial rankings and an opportunity to submit additional relevant data and information to update proposed rankings with improved information.

III. Second Tier Considerations:

After the initial screening, some substances within individual priority groupings may require further rank ordering, particularly where a large number of chemicals are in the same priority group. Listed below are the types of information that will be useful to consider in this Second Tier rank ordering:

Biomonitoring/Environmental Monitoring Data:
Mere detection of chemicals in humans or the environment, i.e.,"found in biomonitoring (CDC), found in water (NCOD), and found in air", while providing an indication of exposure, does not provide a useful criterion for exposure potential because almost any industrial or commercial chemical could be detected at trace levels, given increasingly sensitive analytical methods. Therefore, detection alone primarily reflects only the fact that a specific chemical was included in a measurement program. This criterion will also tend to bias the prioritization of chemicals for which well-established analytical methods are available. Consequently, this criterion is not used in the initial prioritization scheme. However, within a particular priority grouping, reliable monitoring information should be considered for Second Tier rank ordering within a quantitative process that assesses if the data is above a level of concern (i.e., places it in a risk context).

Use in Children's Products:
Protection of childrens' health is a top priority and, in the initial ranking, child-specific products are captured under general consumer products and all consumer products are weighted equally. The specific IUR reporting of information on chemical use in products intended for children would be considered further within a particular priority grouping for Second Tier rank ordering, noting the following points:

- the IUR definition is based upon use in a child specific product rather than child specific exposure potential[1] (see below). Without knowing a specific product type, it is difficult to understand if potential child exposure is greater than for a non-child specific product. For example, how does child exposure to a general use cleaner compare to exposure from use in a child's raincoat. In the VCCEP assessments, there are examples for inhalation exposures where estimates of passive child exposure during adult product use exceeded conservative estimates of child exposure during active use of a child-specific product (such as a hobby product) – differences were related to the amount of product used and substance concentration within the product (MEK VCCEP Submission).
- the IUR definition targets children age 14 and younger. Younger children may be exposed to a variety of non-child specific products that are in general household use. Older children may be exposed to a variety of additional products.
- the IUR information request is targeted to manufacturers, which may not have direct knowledge of all uses, particularly the presence in products for specific subpopulations, such as children. Therefore, it is not clear that the information requested for the IUR information would be consistently available across all substances being screened. Ideally, this information should be requested from formulators of child-specific products.

Therefore, for the initial prioritization approach, which represents a broad, unrefined categorization, child specific products are captured under general consumer products and all consumer products are weighted equally. The IUR information on child specific use would be utilized within a particular priority grouping for Second Tier rank ordering. If the IUR information is utilized, it is important that the limitations above be considered in its application.

[1] IUR definition (Federal Register Volume 75, Number 156, Friday August 30, 2010, p. 49686): Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least on of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:
(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?
(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?
(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

Emissions Data:
Production volume, which is readily available for substances, is used in this proposed approach, but only serves as a surrogate for environmental emissions. For further prioritization, data or estimates of environmental emissions can be used to refine prioritization. Estimates of environmental emissions will be available for some substances (e.g., TRI data). When TRI data are utilized it should be recognized that it addresses only emissions that result from industrial and not wide dispersive uses. In other cases, emissions estimates can be developed as a percentage of production volume based upon consideration of use categories. Within a particular priority grouping, available emissions information can be considered for Second Tier rank ordering, with the understanding that emissions information is not an indicator of actual exposure.

Similarly, non-isolated system intermediates, by definition, would have de minimis exposure potential. Therefore, this IUR information could be considered within a particular priority grouping for Second Tier rank ordering.

International Risk Management Actions:
An initial screening approach for chemical prioritization should be based upon consistent application of specific hazard and exposure science elements that define risk potential. The hazard and exposure elements should be applicable across all substances being evaluated. For initial screening, existence of international risk management action plans should not be a factor that determines priority grouping. Risk management plans may be based upon many factors, including political drivers. It is unclear how factors, their relative weighting, and the rigor of the evaluation may vary across agencies and substances. For initial screening purposes, the same science-based criteria should be used to rank all substances. Consideration of existing international risk management plans could be utilized to check the functioning of the approach and could be considered within a particular priority grouping for Second Tier rank ordering with the possible effect of moving a chemical up in a grouping if actions are being taken internationally.

IV. Summary

ACC's prioritization approach is an example of a risk-based screening prioritization process that implements the general principles outlined at the outset of this document. It is based upon widely available information that can be utilized to understand the relative priority of chemicals for further evaluation from a risk perspective, i.e., integrating both hazard and exposure elements. Implementation of the screening framework will be most effective when utilizing the best available information. When conducting screening for thousands of chemicals, EPA may not have access to all available information. An open and iterative process that includes an opportunity for review and comment on initial rankings, together with the information that led to the result, and an opportunity to update the ranking with improved information will create a transparent and scientifically sound process.

V. References

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Proposed Prioritization Approach

DRAFT May 6, 2011

Exposure Elements				
Use Pattern	Intermediate	Industrial - not Intermediate	commercial	consumer
Use Score	1	2	3	4
Persistence / Bioaccumulation (PB)	not P, not B		P & not B OR B & not P	P&B
PB Score	1		3	5
Tonnage	<25,000 lbs (below IUR site reporting limit)	25,000 - <1MM lbs IUR aggregate	1MM- <100MM lbs IUR aggregate	≥ 100MM lbs IUR aggregate
Tonnage Score	1	2	3	4
SUM (Use + PB + Tonnage Scores)	**range 3 -13**			

PRIORITY GROUPING = Hazard + Exposure Rankings				Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores)				
				3-4	5-6	7-8	9-10	11-13
				low	med-low	medium	med-high	high
Hazard Ranking = Higher Score from Environmental and Human Health Hazards				1	2	3	4	5
		Environmental Hazard	Human Health Hazard					
1	low	not classified	Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	2	3	4	5	6
2	medium	Acute III OR Chronic III/IV ; [not acutely toxic and no chronic data]	Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	3	4	5	6	7
3	med-high	Acute II or Chronic II	GHS CMR Cat 2; OR GHS Repeat Dose Cat 2: Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	4	5	6	7	8
4	high	Acute I OR Chronic I OR Insufficient information to classify	GHS CMR Cat 1a, 1b; OR GHS Repeat Dose Cat 1: Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR Insufficient information to classify	5	6	7	8	9

Hazard and Exposure Criteria for Prioritization Approach

HAZARD

Environment and Human Health Classifications based upon GHS

Environmental:

From GHS classification guidance document:

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Acute hazard *(Note 1)*	**Long-term hazard** *(Note 2)*		
	Adequate chronic toxicity data available		**Adequate chronic toxicity data not available** *(Note 1)*
	Non-rapidly degradable substances *(Note 3)*	**Rapidly degradable substances** *(Note 3)*	
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$	**Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$	**Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 *(Note 4)* Example: *(Note 5)* No acute toxicity and lack of rapid degradability and BCF $\geq$ 500 or, if absent log Kow $\geq$ 4, unless NOECs > 1 mg/l		

Human Health:

As above, based upon GHS

EXPOSURE

Use Elements - based upon IUR

intermediate — consumed during industrial processing
industrial (not intermediate) - used in an industrial setting
commercial — occupational use in nonindustrial setting
consumer — general population residential use

Persistence:

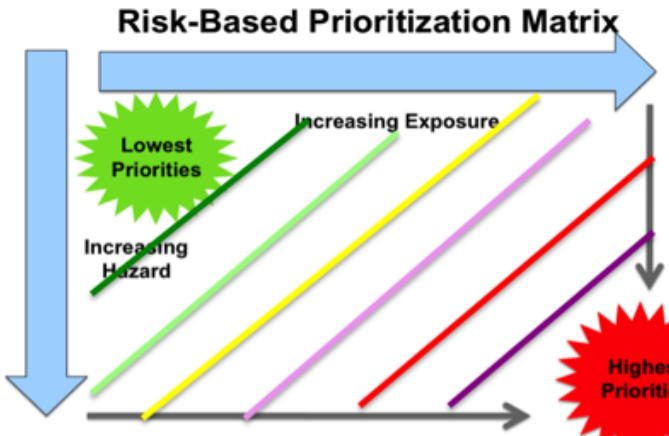
Volatile substance (VP > 1000 Pa): Not Persistent if air half life < 2 days
Nonvolatile (VP < 1000 Pa): Not Persistent if:
a) ready biodegradability (OECD 301)
b) inherent biodegradability (OECD 301, 302, 306)
c) read across from measured data on a related substance.
d) equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111)
OR, a substance is Not Persistent if:
e) evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g., OECD 308/309) have half lives below 180 days.
OR, if data are lacking:
f) evaluation via BIOWIN model (EPIWEB 4)

Bioaccumulation:

A substance is not bioaccumulative if:
a) measured TMF < 1 (field study)
b) measured fish BMF < 1 (lab study)
c) measured fish BCF < 5000 (lab study)
d) predicted BCF < 5000 using the BCFBAF model included in EPIWIN 4
The above order reflects the preference for use in decision-making
NOTE -- P&B CRITERIA ARE FOR ORGANICS

Tonnage - based upon IUR reporting ranges

< 25,000 lbs (below IUR site reporting limit)
25,000 - <1 MM lbs national aggregate
1MM - <100 MM lbs national aggregate
≥100 MM lbs national aggregate



Two-Step Prioritization Process

Second Tier

Rank Ordering within Priority Groups

- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions