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, readacross 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 -	Ranking	Environmental Rank	
Environmental		Score	
Acute I or Chronic I or			
Insufficient Information to	High	4	
Classify			
Acute II or Chronic II	Medium High	3	
Acute III or Chronic III/IV or	Medium	2	
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);</td <td></td> <td></td>		
<= 20 mg/kg/day (dermal);	TT: 1	4
= 50 ppm/6hr/day (gas inhalation);</td <td>High</td> <td>4</td>	High	4
<= 0.2 mg/l/6h/day (vapour inhalation);		
= 0.02 mg/l/6h/day</math (dust mist fume inhal).		
OR insufficient information to classify		
GHS CMR Cat 2; OR		
Repeat Dose 10 - 100 mg/kg/day (oral);		
20 - 200 mg/kg/day (dermal);	Medium High	3
50 - 250 ppm/6hr/day (gas inhalation);	_	3
0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).		
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);	Medium	2
1.0 - 5.0 mg/l/6h/day (vapour inhalation);		2
0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).		
Not carcinogen/mutagen/repro/develop; OR		
Repeat Dose >1000 mg/kg/day (oral);		
> 2000 mg/kg/day (dermal);	Low	
> 1000 ppm/6hr/day (gas inhalation);	Low	1
>5.0 mg/l/6h/day (vapour inhalation);		
> 1.0 mg/l/6h/day (dust mist fume inhal).		

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	Medium – High	2	
aggregate	Medium – mgn	3	
>= 25,000 lbs to < 1,000,000 lbs national	Medium	2	
aggregate	McGruin	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	P&B Ranking	P&B Score
Bioaccumulation	_	
Persistent and	High	5
Bioaccumulative		
Persistent and Not	Medium	3
Bioaccumulative OR		
Not Persistent and		
Bioaccumulative		
Not Persistent and Not	Low	1
Bioaccumulative		

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	Exposure Rank	Exposure Ranking
elements		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 (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.

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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

- Arnot, J.A., D. Mackay, T. F. Parkerton, R. T. Zaleski, C. S. Warren (2010), Multimedia modeling of human exposure to chemical substances: The roles of food web biomagnification and biotransformation, Environmental Toxicology and Chemistry 29(1):45–55.
- Boethling, R., K. Fenner, P. Howard, G. Klecka, T. Madsen, J.R. Snape, M.J. Whelan (2009). Environmental persistence of organic pollutants: guidance for development and review of POP risk profiles. Integrated Environmental Assessment and Management 5(4): 539 556.
- Gobas, F.A.P.C, W. de Wolf, L. P Burkhard, E. Verbruggen, K. Plotzke (2009). Revisiting Bioaccumulation Criteria for POPs and PBT Assessments Integrated Environmental Assessment and Management, 5(4):624–637.
- MacLeod, M., T. E. McKone (2004). Multimedia persistence as an indicator of potential for population-level intake of environmental contaminants, Environmental Toxicology and Chemistry 23(10):2465–2472.
- van Wijk,D., R. Chénier, T. Henry, M. D Hernando, C. Schulte (2009). Integrated Approach to PBT and POP Prioritization and Risk Assessment Integrated Environmental Assessment and Management, 5(4):697–711.

Proposed Prioritization Approach

DRAFT May 6, 2011

Exposure Elements					
Use Pattern Use Score	Intermediate	Industrial - not Intermediate 2	commercial 3	consumer 4	
Persistence / Bioaccumulation (PB) PB Score	not P, not B		P & not B OR B & not P 3	P&B 5	
Tonnage	<25,000 lbs (below IUR site reporting limit)	25,000 - <1MM lbs IUR aggregate	1MM- <100MM lb6 IUR aggregate	≥ 100MM lbs IUR aggregate	
Tonnage Score	1	2	3	4	
SUM (Use + PB + Tonnage Scores)	range 3 -13				

poventry engineries in the party		Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores)						
1	PRIORITY GROUPING = Hazard + Exposure Rankings		3-4	5-6	7-8	9-10	11-13	
				low	med-low	medlum	med-high	high
	Hazar	d Ranking = Higher Score from Enviro		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	,	/ ,	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 pm//6hr/day (gas Inhalation); 1.0 - 5.0 mg/l/6h/day (vapour Inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist tume Inhal).			,		,
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/shr/day (gas inhalation); 0.2 - 1.0 mg/l/shr/day (vapour inhalation); 0.02 - 0.2 mg/l/sh/day (dust mist fume inhal).		5	,	,	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</td <td>5</td> <td></td> <td>,</td> <td></td> <td>9</td>	5		,		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

<u> </u>	Classification categories				
Acute fiszard (Note I)	Long-term hazard (Note 2)				
	Adequate chronic toxicity data available		Adequate chronic toxicity data not available		
	Non-rapidly degradable substances (Note 3)	Rapidly degradable substances (Note 3)	(Note 1)		
Category: Acute 1	Category: Chronic 1	Category: Chronic 1	Category: Chronic 1		
L(E)C ₅₀ ≤ 1.00	NOEC or EC _x ≤ 0.1	NOEC or EC _x ≤ 0.01	$L(E)C_{50} \le 1.00$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{os} \ge 4$		
Category: Acute 2	Category: Chronic 2	Category: Chronic 2	Category: Chronic 2		
$1.00 < L(E)C_{50} \le 10.0$	0.1 < NOEC or EC _x ≤ 1	0.01 < NOEC or EC _x ≤ 0.1	$1.00 < L(E)C_{10} \le 10.0$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{co} \ge 4$		
Category: Acute 3		Category: Chronic 3	Category: Chronic 3		
$10.0 < L(E)C_{50} \le 100$		$0.1 < NOEC$ or $EC_x \le 1$	$10.0 < L(E)C_{50} \le 100$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{co} \ge 4$		
	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 \geq 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

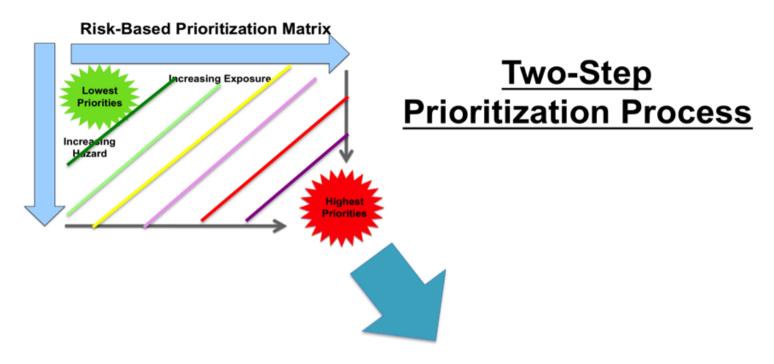
Tonnage - based upon IUR reporting ranges

< 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



Second Tier Rank Ordering within Priority Groups

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