ASEAN PRIORITY SCREENING TOOL

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AMERICAN CHEMISTRY COUNCIL
Regulatory and Advocacy Information Network

Prioritization Screening Approach

I. Introduction

This document provides background on a suggested approach to chemical substance prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify chemical 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 a Prioritization Approach

The first step in this prioritization approach is to apply a ranking criteria based on the chemical substance's human health and environmental toxicity potential. Numeric values will be assigned to both toxicities, and the highest value (score) will determine the hazard rank score.

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 various ASEAN Member States.

The GHS system applies to both human health and environmental 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 environmental endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all chemical substances.

To classify a chemical substance in a hazard based priority ranking where there is not direct data on the chemical substance, an Agency can employ the full range of approaches, such as QSAR, SAR, read-across and other credible modeling tools. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical substance would be classified as "medium 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 substance management prioritization.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental*	Ranking	Environmental Rank Score
Acute 1 or Chronic 1	High	4
Acute 2 or Chronic 2, or Insufficient Information to Classify**	Medium High	3
Acute 3, or Chronic 3/4, or Not acutely toxic and no Chronic data	Medium	2
Not classified	Low	1

* *Hazardous to the Ozone Layer is not included in the table because all ASEAN MS have ratified the Montreal Protocol and should address these chemical substances separately*

** *Refer to ASEAN Regulatory Concept, Regulatory Element: Baseline Data of Chemicals in Commerce, Point 5*

2. ***Human Health Ranking***

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	Ranking	Human Health Rank Score
CMR 1a, 1b	High	4
Acute Toxicity 1; or CMR 2; or Effects on/via lactation; or STOT RE 1; or Insufficient information to classify*	Medium High	3
Acute Toxicity 2; or Respiratory/Skin Sensitization 1; or Skin corrosion; or Serious eye damage; or STOT RE 2; or Aspiration hazard	Medium	2
Acute Toxicity 3, 4 or 5; or Skin irritantion; or Eye irritation; or STOT SE; or Not classified	Low	1

* *Refer to ASEAN Regulatory Concept, Regulatory Element: Baseline Data of Chemicals in Commerce, Point 5*

- 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).
- 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 chemical substance to affect reproduction; and 4) evaluation of the potential of a chemical substance to damage DNA.

Integration of Hazard Elements:
Each of the environmental and human health classifications is assigned a numeric value (score), with 1 being the lowest value and 4 the highest. The greatest score (highest hazard potential score) of either Environmental or Human Health is drives the overall hazard ranking score for the chemical substnace. This 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 3 elements:

1. The chemical substance's uses and use pattern(s).
2. Production/importation 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 chemical substances.
3. Persistence and bioaccumulation characteristics of the chemical substance.

Each element will be assigned a numerical value (score), then together the 3 numerical values (scores) will be used to rank the exposure potential.

1. Use Patterns

To keep the initial prioritization simple and transparent, the approach classifies different use patterns based on general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are adopted from the TSCA Inventory Update Reporting (IUR) rule in the USA, but 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. 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/Non Isolated Intermediates	Low	1

The definitions of these terms are (as adopted from the US 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 chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the chemical substance is stored after its manufacture.

2. Production/Importation Volume

Recognizing that detailed exposure information will not be available for all chemical substances to be screened, the proposed approach uses production/importation volume as an indicator of exposure, which is widely used in many prioritization schemes. As production/importation volume is just a rough surrogate of emissions, it is suggested to only use 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. Annual Production/Importation Volume as Emission Surrogate - Exposure Ranking

Production/Importation Volume as Emission Surrogate	Ranking	Volume Score
>= 1000 tons/yr national aggregate	High	4
100 MT to < 1000 tons/yr national aggregate	Medium – High	3
>= 10 MT to < 100 tons/yr national aggregate	Medium	2
< 10 tons/yr national aggregate	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 chemical substance that is emitted to the environment at the same rate as a non-persistent chemical 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 chemical substance partitions is a good indicator of human exposure potential). Similarly, chemical 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.

The regulatory criteria for persistence and bioaccumulation (P&B) are not harmonized around the world. Therefore, the following recommendations are best practices reflecting industry's experience with criteria & requirements of multiple regulatory regimes. Data used to determine P&B should be evaluated based on the Weight of Evidence[1] of available data.The proposed approach is targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals

[1] *When evaluating the hazard or potential exposure of a chemical (e.g. PBT determination) it is not uncommon to have a rich dataset from which a research can consult. The larger the dataset, the more likely there may be conflicting data points. This is due to the inherent variability when working with biological systems and limitations of statistics. Any time a single experiment is performed there is a statistical chance a false positive, or false negative will be encountered. For this reason when many data points for a single chemical exist, it is necessary to look at them collectively. The European Chemicals Agency defines weight of evidence as using a combination of information from several independent sources to give sufficient evidence to fulfil an information requirement. Therefore "weight of evidence" is simply a method for assessing all data collectively and making a decision using best professional judgment. The weight given to the available evidence depends on factors such as the quality of the data, consistency of results, nature and severity of effects, and relevance of the information.*

The proposed best practice for assessing persistence distinguishes persistent from non-persistent chemicals using the following criteria (listed in order of preference where options are provided):

- For volatile chemical substances (defined using a vapour pressure cut-off, i.e. >1000 Pa)
  - Persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a chemical substance is not persistent if air half life is < 2 days).
- For non-volatile chemicals,
  - Non-persistent chemical substances can be defined as chemical 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 chemical 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 (Epi Suite v 4.11)
  - Non-volatile chemical 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. To determine if a chemical substance has the potential to biomagnify the following metrics have been agreed (also listed in order of preference):

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000.

This approach allows all organics to be addressed.

Table 5. Summary of Persistence and Bioaccumulation for Organic Chemicals (listed in order of preference for decision making)

Persistence	Non-volatile substance (VP ≤ 1000Pa)	Not Persistent IF: • Readily biodegradable (OECD 301) [1] • Inherently biodegradable (OECD 301, 302, 306)[2] • Read-across from measure data on a related substance[3] • Equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111) [3] OR: • Evaluation of simulation data from transformation in soil, marine water/ sediment, brackish water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days[4] OR, if data are lacking: • Evaluation via BIOWIN model (Epi Suite v 4.11)[5]
	Volatile substance (VP > 1000Pa)	Not persistent: $t_{1/2}$ < 2days[6]
Bioaccumulation		Not Bioaccumulative IF • Measured TMF < 1 (field suty)[7] • Measured fish BMF < 1 (lab study)[7] • Measured fish BCF < 5000 (lab study)[8] • Predicted BCF < 5000 using BCFBAF model included in Epi Suite v 4.11[9]

References

1: *ECHA guidance document "R.11: PBT/vPvB assessment", v. 3.0, June 2017*
2: *ECHA guidance document "R.11: PBT/vPvB assessment", v. 3.0, June 2017 if accompanied with supporting data (e.g. abiotic degradation, QSARS, monitoring data)*
3: *Read-across is allowed under weight of evidence evaluation as per Introductory Section of Annex XIII to REACH*
4: *Based on Toxic Substances Management Policy of Canadian Environmental Protection Act*
5: *Allowed as per ECHA guidance document "R.11: PBT/vPvB assessment", v. 3.0, June 2017*
6: *US EPA Premanufacture Notices in the Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances under TSCA*
7: *Gobas et al. 2009*
8: *Based on Toxic Substances Management Policy of Canadian Environmental Protection Act*
9: *Allowed as per ECHA guidance document "R.11: PBT/vPvB assessment", v. 3.0, June 2017*

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

Table 6. 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 element (use pattern, production volume, and P&B) would be assigned a numeric score based upon its ranking. All 3 scores are added to arrive at the Total Score. These Total Scores are then grouped into categories from low to high Exposure Rank that have been assigned corresponding Exposure Ranking Scores as demonstrated in Table 7.

Table 7. Integration of Exposure Rankings

Total Score – All 3 elements (Use Pattern Score, Volume Score, P&B Score)	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

C. Overall Priority Grouping

In the overall approach, both hazard and exposure elements are considered when placing a chemical substance in a risk-based prioritization ranking (grouping). The overall Prioritization Grouping is achieved by combining both the hazard (human health and environment) and exposure eleremnts in the matrix :
Priority Group = Hazard Score + Exposure Ranking Score
(The highest hazard score from either the human health rank or environmental rank will drive the Priority Group for the chemical substance)

Subsequently the Priority Groups that are designated as High, Medium or Low Priority can be defined by the Agency based on the outcome of prioritizing all chemical substances in their scope against resources available to further assess and manage high priority chemical substances. Resources such as funds, time commitment, number of employees/expertise available are key considerations in setting these targets. As a starting point, it is suggested to designate 5-10% of all chemical substances assessed as high priority as a manageable number.

Exposure Ranking Score		1 *Combined scores 3-4*	2 *Combined scores 5-6*	3 *Combined scores 7-8*	4 *Combined scores 9-10*	5 *Combined scores 11-13*
Human Health Rank Score	Environmental Rank Score					
1	1	2	3	4	5	6
2	2	3	4	5	6	7
3	3	4	5	6	7	8
4	4	5	6	7	8	9

Example of Priority Setting

Table 8 provides an illustration of priority setting by applying the following criteria:

High Priority = Priority Groups 7, 8, and 9
Medium Priority = Priority Groups 4, 5, and 6
Low Priority = Priority Groups 2 and 3

Table 8. Example of Prioritization Grouping Matrix

Exposure Ranking Score Human Health or Environmental Rank Score	1 *Combined scores 3-4*	2 *Combined scores 5-6*	3 *Combined scores 7-8*	4 *Combined scores 9-10*	5 *Combined scores 11-13*
1	2	3	4	5	6
2	3	4	5	6	7
3	4	5	6	7	8
4	5	6	7	8	9

A further example can be found in Appendix 1.

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 chemical substances, the Agency 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 chemical substances within individual priority groupings may require further rank ordering, particularly where a large number of chemical substances 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 chemical substances in humans or the environment, for example, found in biomonitoring in the US Center for Disease Control (CDC) program, or found in water, or 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 substance 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).

Emissions Data:
Production/importation volume, which is readily available for chemical 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. Under many regulatory regimes estimates of environmental emissions will be available for some chemical substances. In other cases, emissions estimates can be developed as a percentage of production/importation 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 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 chemical 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 chemical substances. For initial screening purposes, the same science-based criteria should be used to rank all chemical 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

The suggested 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 chemical substances 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 chemical substances, the Agency may not have access to all available information. An open and iterative process that includes an opportunity for industry to participate as well as to 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.

Proposed Prioritization Approach

EXPOSURE ELEMENTS					
Use Pattern	Intermediates	Industrial	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	<10 t/yr	10 to <100 t/yr	100 to <1000 t/yr	≥ 1000 t/yr	
Tonnage Score	1	2	3	4	
SUM (Use + PB + Tonnage Scores)	**Range 3 – 13**				

Exposure Ranking Score			1 *Combined scores 3-4* **Low**	2 *Combined scores 5-6* **Medium Low**	3 *Combined scores 7-8* **Medium**	4 *Combined scores 9-10* **Medium High**	5 *Combined scores 11-13* **High**
Hazard Ranking Score							
	Human Health	Environmental					
1	Acute Tox 3, 4, 5 Skin corrosion/irritant Serious eye damage/irritation STOT SE Aspiration hazard Not CMR, not STOT RE	Not classified	2	3	4	5	6
2	Acute Tox 2 Not CMR STOT RE 2	Acute Tox 3 Chronic Tox 3 or 4 Not acutely toxic and no chronic data	3	4	5	6	7
3	Acute Tox 1 Respiratory/Skin Sensitization 1 CMR 2/Effects via lactation STOT RE 1 Insufficient information to classify	Acute Tox 2 Chronic Tox 2 Insufficient information to classify	4	5	6	7	8
4	CMR 1A, 1B	Acute Tox 1 Chronic Tox 1	5	6	7	8	9

Hazard and Exposure Criteria for Prioritization Approach

HAZARD

Environment and Human Health Classification based upon GHS

Human Health:

As above, based upon GHS

Environmental:

From GHS classification guidance document

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

Classification categories			
Short-term (acute) hazard (*Note 1*)	**Long-term (chronic) 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 ≥ 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 ≥ 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 ≥ 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 ≥ 500 or, if absent log Kow ≥ 4, unless NOECs > 1 mg/l		

EXPOSURE

Use Patterns (based on US TSCA IUR)

Intermediates	Consumed during industrial processing
Industrial (not intermediate)	Used in an industrial setting
Commercial	Occupational use in non-industrial setting
Consumer	General population residential use

Persistence

Volatile substance (VP > 1000 Pa): Not persistent if air half life < 2 days

Non-volatile (VP < 1000 Pa): Not Persistent if:

a) Readily biodegradable (OECD 301)
b) Inherently biodegradable (OECD 301, 302, 306)
c) Read-across from measure 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, 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 (Epi Suite v 4.11)

Bioaccumulation:

A substance is not bioaccumulative if:

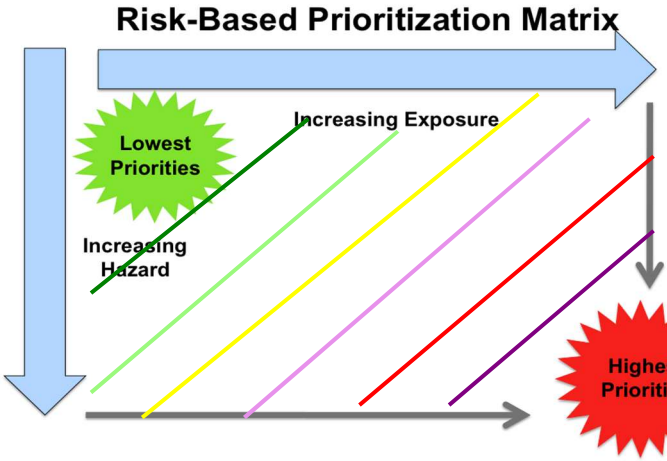
a) Measured TMF < 1 (field suty)
b) Measured fish BMF < 1 (lab study)
c) Measured fish BCF < 5000 (lab study)
d) Predicted BCF < 5000 using BCFBAF model included in Epi Suite v 4.11

The above order reflects the preference for use in decision-making

NOTE – P&B CRITERIA ARE FOR ORGANICS

Tonnage

<10 t/yr
10 to <100 t/yr
100 to <1000 t/yr
≥ 1000 t/yr



Two-Step Prioritization Process

Second Tier

Rank Ordering within Priority Groups

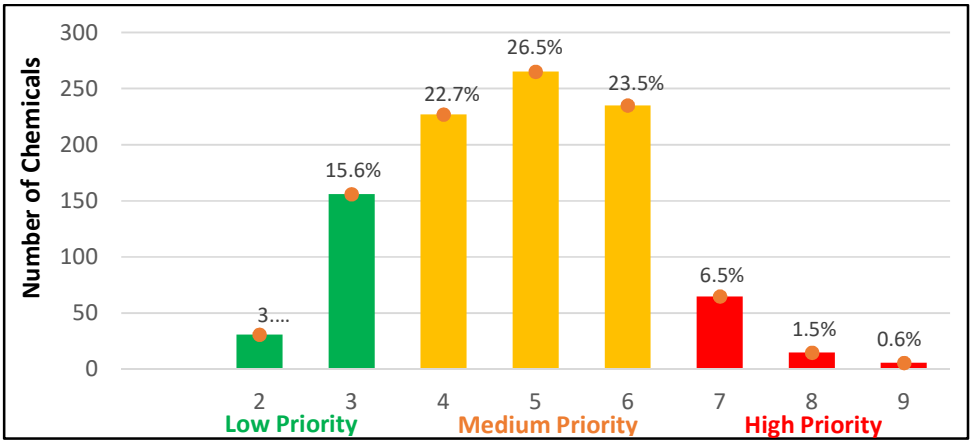
- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions

Appendix 1 – Example of Priority Setting

In this example of prioritization, the number of chemical substances in scope for prioritization is 1000 and the outcome of prioritization exercise is illustrated in the table below.

Priority Group	Number of Chemicals	Percentage
9	6	0.6%
8	15	1.5%
7	65	6.5%
6	235	23.5%
5	265	26.5%
4	227	22.7%
3	156	15.6%
2	31	3.1%
	Total = 1000	Total = 100%

If the policy decision is to set the 5-10% of all chemical substance assessed as high priority, and the next 40-80% of chemical substances as medium priority, the priority groups can be designated as follows:



Exposure Ranking Score / Human Health or Environmental Rank Score	1 *Combined scores 3-4*	2 *Combined scores 5-6*	3 *Combined scores 7-8*	4 *Combined scores 9-10*	5 *Combined scores 11-13*
1	2	3	4	5	6
2	3	4	5	6	7
3	4	5	6	7	8
4	5	6	7	8	9

Change Log

Date	Change Description
31 July 2019	Final Draft
22 Nov 2019	Editorial changes (minor)
21 Jan 2020	Editorial changes
8 Mar 2021	Rename from ASEAN Prioritization Tool to *ASEAN Priority Screening Tool*