New York State Pollution Prevention Institute (NYSP2I)

Chemical Product Risk Prioritization Framework

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I. Background

SI Group, Inc. is a privately held, global manufacturer of chemical intermediates, and phenolic resins headquartered in Schenectady, New York. Products are categorized into eight market segments for use by its industrial customers including: surfactants, rubber chemicals, plastics additives, engineering plastics, fuels and lubricants, industrial resins, adhesive resins and specialty chemicals. As a member of the American Chemistry Council and a Responsible Care® company, SI Group is interested in evaluating their existing chemical products for potential environmental, health, and safety risks. The New York State Pollution Prevention Institute at Rochester Institute of Technology was asked by SI Group to assist with the development of a tool to systematically evaluate the EHS risks of their products in order to recognize and prioritize top hazardous products at SI Group to inform the business of the current state of the product line.

The resulting Chemical Product Risk Prioritization Framework focuses on the risk of market and regulatory driven product deselection, risk of regulatory scrutiny, and voluntary programs promoting greener products. Anticipating regulatory risk and the risk of deselection is difficult. The tool provides a systematic method to analyze their potential risk associated with chemical products and further quantifies these risks to aid in decision making.

i. About the Chemical Product Risk Prioritization Framework

A number of risk assessment tools and schemes have been developed by leading researchers such as the US Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) chemical summaries and toxicological reviews and National Center for Environmental Assessment (NCEA) Published Assessments, International Council of Chemical Associations (ICCA) Guidance on Chemical Risk Assessment, and the American Chemical Council's (ACC) Prioritization Screening Approach. Traditionally, chemical substances have been evaluated solely on their intrinsic hazard or risk. This typically includes identification of the hazard, an exposure assessment, and a dose response assessment. While traditional risk assessments provide valuable information on the potential environmental and human health effects of the substance, the assessments and their results are somewhat limited.

The goal of the Chemical Product Risk Prioritization Framework is to integrate a substance's intrinsic hazard and business risk into a single risk profile. Business risk looks at those factors which may impact a business' perception of the long term viability and growth potential of a chemical product or product portfolio. This includes factors such as movement of the marketplace away or towards use of the substance, government action toward the substance or similar substances, stakeholder requests for the substance or alternatives, and the availability of greener alternatives which would make a substance more likely to be deselected. It is critical to integrate these factors into the risk profile as business decisions are not typically made purely based upon the intrinsic risk of a substance. Furthermore, in recent history, the marketplace has begun to voluntary deselect substances based on their intrinsic hazard and the use of the substance. For example, polycarbonate was voluntarily deselected by consumers for use in baby bottles due to the presence of bisphenol-A (BPA). It was deselected not only due to the possible endocrine disruption potential of BPA, but also because it was used in a product for

newborns, a sensitive population. In order to predict future usage and deselection of a substance, it is essential to consider the business risk as well as the intrinsic risk of a substance.

The Framework is intended for use by chemical companies to help understand the business and EHS risks of their products in order to assist with internal decision making. Risk Profile results from this Framework are not intended to be disclosed to the public nor are they intended to be used by government agencies to assist with policy making. The tool was developed with the following guiding principles:

- *It is a method to assess and rank products internally.* Because of the subjectivity built into the strategic risk factors, it is not recommended to use the risk profile to compare product lines or products among multiple manufacturers.
- *The structure is adaptable.* The framework consists of three parts: intrinsic hazard, precautionary risk and strategic risk. The framework has been developed with the intention that the chemical substances evaluated are intermediates and are not sold directly to consumers. The structure is adaptable such that users may integrate other factors which may be critical to evaluating the precautionary and intrinsic risk of a substance.
- *Results are replicable internally.* Internal criteria may be required to help define some of the subjective choices in the Framework to ensure risk profiles of the same substance performed by multiple assessors have the same result.
- *Results speak to the sustainability of a product line.* The framework integrates traditional EHS concepts that are easy to measure and have historically been measured internally with metrics that don't normally get measured, such as regulatory and consumer acceptance.
- *Results are predictive.* The intent of the tool is to evaluate a substance's current EHS risk, precautionary risk, and strategic risk in order to understand current and future potential for the substance to be regulated or voluntarily deselected. The goal is to identify whether or not EHS attributes of the substance will be a significant factor in future use of the substance.
- *Results are actionable.* Risk profile results are used to inform the company of the potential risks to the business associated with the substance. Results determine which aspects of the substance produce the most risk which can be used to guide research and development activities to further reduce these risks. The framework further prioritizes chemical substances for action based on their risk and business value.

ii. Framework structure

This Framework is an approach to the assessment and prioritization of pure chemicals, mixtures, and polymers to provide a relative risk ranking. The risk prioritization is two phased. First, a *Risk Profile* consisting of three components, (1) human and environmental health and exposure, (2) precautionary risk, and (3) strategic risk, is developed. *The Risk Profile* numerically presents twelve different components of a substance's risk. Risk Profile results are used to evaluate individual components of a substance's risk or to compare the risks associated with multiple substances.

The *Risk Value* is then calculated by combining the twelve components of the Risk Profile into a single numerical score. The Risk Value is used to rank chemicals according to their perceived risk.

To further prioritize chemicals for action, the Risk value is multiplied by net sales of the substance, normalized to 100% of annual sales to arrive at the *Action Value*.

Risk Profile Structure

A. Intrinsic Hazard
    i. Hazard Potential
        a. Environmental Safety
        b. Human Health
    ii. Exposure Potential
        a. Use Patterns
        b. Production Volume
        c. Persistence and Bioaccumulation
B. Precautionary Risk
    i. Detection
        a. Human Biomonitoring
        b. Environmental Detection
    ii. High Production Volume
C. Strategic Risk
    i. Alternatives Assessment
    ii. Government Marketing & Use Restrictions
    iii. Stakeholder Requests
    iv. Safer Alternative

iii. Multiple Applications

Many substances are used in multiple applications and each application may present unique risks. Five of the Risk Profile attributes are dependent upon the end use application of the substance: use patterns (Intrinsic Risk), alternatives assessment, government marketing & use restrictions, stakeholder requests, and safer alternative (Strategic Risk). The remaining seven attributes do not consider the end use of the substance, and therefore remain the same among applications of the substance. There are many methods available for completing the risk profile and prioritization while considering various applications of one substance. While the options below are not exhaustive, they provide suggestions for completing the Risk Profile.

1. Rank the applications of a substance from high to low sales. The application(s) resulting in the most sales is included in the Risk Profile, while the others are not. Based on the resulting Risk Profile, the user can determine if additional applications should also be evaluated.

2. Rank the applications of a substance from most to least common. The application(s) with the highest manufacturing volume of the substance is included in the Risk Profile, while others are not. Depending on the number of applications for a substance, it may be helpful to categorize the applications to make data more managable. Based on the resulting Risk Profile, the user can determine if additional applications should also be evaluated.

3. Identify all applications (or a significant portion of them) of the chemistry. Evaluate the exposure, user group, and greener alternative attributes for each application, and average the values. The average values are used to calculate the Risk Profile, which will indicate to the user if further investigation of the specific applications is warranted.

iv. Geographic Data

Five of the attributes included in the risk profile are dependent upon the region in which the substance is used and/or produced: production volume (Intrinsic Hazard), environmental detection (Precautionary Risk), alternatives assessment, government marketing & use restrictions, and stakeholder requests (Strategic Risk). The remaining seven attributes remain the same among the geographic region where the substance is manufactured and/or used.

There are multiple methods to complete the risk profile and prioritization while considering geographic location, including:

1. Evaluate the geographic location(s) with the highest volume of sales. This location is important as it will be most impacted by use of the substance.
2. Evaluate the geographic location(s) with the highest production volume. This location is important as it will be most impacted by manufacturing restrictions.
3. Evaluate the geographic location(s) with the most stringent environmental health and safety manufacturing and/or use regulations. Ensuring the chemistry meets the most stringent level of regulatory scrutiny will ensure it meets regulations in other, less stringent, geographies.
4. When evaluating a small number of geographic locations, collect data from all locations and average them. This will give the user an overall picture of use of the chemical. Based on the results, the user can determine if individual Risk Profiles for multiple geographies is necessary.

II. Risk Profile Framework

i. Preparation

As a first step in completing the Risk Profile, it is important to consider the goal and scope of the assessment. Many of the attributes included in the framework are dependent upon the application of the substance and the geographic location in which it is used or manufactured. It is critical to define the scope up front in order to keep the Risk Profile results manageable.

a. Select the application or applications of the substance to be evaluated. Consider if all or a selection of applications will be included. If a selection of applications will be used, consider why those applications are selected. The following factors are dependent upon the application of the substance: use patterns, government marketing & use restrictions, and safer alternative.
b. Select the geographic location or locations to be evaluated. Consider both manufacturing and use locations. Consider why geographic locations are included or excluded from the process. The following factors are dependent upon the geographic location of the substance: environmental detection.

A. Intrinsic Hazard Ranking Procedure

This approach is adapted from the American Chemistry Council's Prioritization Screening Approach[1], a risk based screening prioritization process that integrates the degree of hazards and exposure potential of a chemical substance. The purpose of this approach is to identify substances that have a high intrinsic hazard potential and associated high exposure potential due to high production volume or dispersive end use. A science- and risk-based approach is applied, considering both the degree of hazard as defined by the substances' classification under the Globally Harmonized System for Classification and Labeling (GHS) and extent of exposure potential as defined by the product volume.

The risk of chemical substances is described by the basic equation:

RISK = HAZARD X EXPOSURE

1. 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.

The GHS system applies to both human health and ecological endpoints, and includes criteria for both. For human health, criteria are available for both acute and chronic classifications, as well as Carcinogen, Mutagen, Reproductive Toxicant (CMR) categorization. For ecological endpoints, criteria are similarly available for both acute and chronic classification.

[1] ACC Prioritization Screening Approach, released August 2011, available at http://www.americanchemistry.com/Prioritization-Document

a. Environmental Ranking Table 1 provides a summary of how GHS criteria for environmental hazard is applied to substances.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental	Ranking	Environmental Rank
Acute I or Chronic I	High	4
Acute II or Chronic II	Medium High	3
Acute III or Chronic III/IV	Medium	2
Not classified	Low	1

b. Human Health Ranking Table 2 provides a summary of how GHS criteria for human health hazard is applied to substances.

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	Ranking	Health Rank
GHS Carcinogen, Mutagen, Reproductive Toxin Cat 1a, 1b	High	4
GHS Carcinogen, Mutagen, Reproductive Toxin Cat 2;	Medium High	3
Not carcinogen/mutagen/repro/develop; OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 1.0 - 5.0 mg/l/6h/day (vapor inhalation);	Medium	2
Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); >5.0 mg/l/6h/day (vapor inhalation);	Low	1

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.

2. Exposure Potential

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

1. The substance'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 three elements are used to rank exposure potential.

a. Use Patterns

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, consumer use, and children under the age of 12. Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. 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.

Table 3. Use Patterns - Exposure Ranking

Use Pattern	Ranking	Use Pattern Score
Children under the age of 12	Very high	5
Consumer	High	4
Commercial	Moderate	3
Industrial	Low	2
Intermediates	Very low	1

The definition of terms used in Table 3 are as follows;

- "children under the age of 12" means the use of a chemical substance or a mixture containing a chemical substance (including as part of the article) when sold to or made available specifically to children under the age of 12 for their use.
- "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)

b. 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

c. Persistence and Bioaccumulation

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the risk evaluation model. It is an accepted principal that 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. Similarly, lipid soluble substances that are not rapidly excreted will exhibit a high bioaccumulation potential that results in higher exposures via the food chain. Therefore, the persistence and bioaccumulation criteria have been applied in assessment of exposure potential as described below.

The assessment to distinguish persistent from non-persistent chemicals uses 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:
    - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) 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 bio-magnification based on recent expert consensus. To determine if a substance has the potential to bio-magnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1
- Fish Bio-magnification Factor (BMF)>1
- Fish Bioaccumulation Factor (BAF)/Bio-concentration Factor (BCF) > 5000.

Table 5. Persistence and Bioaccumulation - Exposure Ranking

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

Integration of Exposure Elements

As demonstrated in the Tables, each factor (use pattern, production volume, and persistence and bioaccumulation) is assigned a numeric score based upon its ranking. The three factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential, via the banding approach illustrated in Table 6.

Table 6. Integration of Exposure Rankings

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

3. Overall Priority Grouping

In the overall approach, both hazard and exposure elements are considered when placing substances 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.

Table 7. Integration of Intrinsic Hazard Grouping

Hazard Ranking = higher score from Environmental & Human Health		Exposure Ranking = Use + Production Volume + P&B				
Environmental Hazard	**Human Health Hazard**	**3-4**	**5-6**	**7-8**	**9-10**	**11-12**
1 very low	1 very low	2	3	4	5	6
2 low	2 low	3	4	5	6	7
3 moderate	3 moderate	4	5	6	7	8
4 high	4 high	5	6	7	8	9
5 very high	5 very high	6	7	8	9	10

B. Precautionary Risk Ranking

The precautionary approach states that if a substance is suspected to negatively impact human health or the environment and there is no scientific data proving the substance causes harm, it is assumed the substance is harmful until it can be proven safe. One of the globally accepted definitions of the precautionary principle resulted from the Earth Summit in 1992. Principle 15 of the Rio Declaration on Environment and Development[2] notes

> *In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

In order to better understand the potential for future regulatory action or voluntary deselection of chemistries, additional attributes beyond known environmental and human health risks (as identified in section A1 Hazard Potential) are incorporated in the risk profile.

1. Detection

It is often difficult to know exactly how chemicals are used, the products they are in, who is exposed to them, and the environmental compartments where they ultimately end up. Using human biomonitoring data in combination with environmental detection data considers those chemicals which are measured in the human body and/or in the environment.

a. Human Biomonitoring

Biomonitoring data is considered one of the most effective methods to understand people's exposure to chemicals as it measures actual amounts of substances in the body rather than potential exposure.

Each year, the US Center for Disease Control (CDC) measures a predefined set of chemicals and their metabolites in blood and urine samples from a random sample of about 2,500 participants in the National Health and Nutrition Examination Survey. Participants vary in age, gender, ethnicity, and geography. Data is released via the *National Report on Human Exposure to Environmental Chemicals*[3] and is presented for the population as a whole and subgroups.

It is important to note that the exclusion of a chemical from CDC's biomonitoring program does not imply that the chemical is safe and there is not cause for concern. Chemicals included in the biomonitoring program are determined via a nomination process based on (1) scientific data which suggest the potential for US exposure to the chemical is changing, (2) seriousness of the health effects due to exposure to the chemical, (3) proportion of the US population likely to be exposed to levels of the chemical at a known or potential level significant to health, (4) need to assess public health actions to reduce exposure to a chemical in the US population, (5) existence of an analytical method to measure the chemical or its metabolite in blood or urine, and (6) incremental cost to perform the analysis. Those chemicals nominated by the public are then evaluated and numerically scored by the CDC to determine

[2] Principle 15 of the Rio Declaration on Environment and Development, http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163

[3] CDC National Report on Human Exposure to Environmental Chemicals, http://www.cdc.gov/exposurereport/

those which will be included in the biomonitoring program[4]. While the biomonitoring program does not measure all chemicals in commerce, it is currently the best data available to quantify the amount of a chemical that actually ends up in the US population.

Table 8. Human biomonitoring hazard ranking

Biomonitoring Data	Ranking	Value
Chemical is included in the US CDC National Biomonitoring Program and the geometric mean of the levels detected have INCREASED over previous years results in at least one age group, gender, or ethnicity.	Very High	5
Chemical is included in the US CDC National Biomonitoring Program and the geometric mean of the levels detected have DECREASED or stayed the SAME over previous years results in all age groups, genders, and ethnicities	High	4
Chemical is not included in the US CDC National Biomonitoring Program	Moderate	3
Chemical is included in the US CDC National Biomonitoring Program and the geometric mean level detected is not available due to "proportion of results below limit of detection was too high to provide a valid result"	Very low	1

b. Environmental Detection

Detection in environmental media is important as it is a direct measure of the amount of a chemical that actually ends up in the environment. Because detection in the environment varies among geographic regions, it is the practitioner's responsibility to determine the appropriate region to consider for the analysis.

Environmental media includes:

- Water bodies – lakes, rivers, ponds, shorelines, sediment
- Drinking water
- Outdoor air
- Soil

Table 9. Environmental detection hazard ranking

Environmental Detection Data	Ranking	Value
Detected in environmental media at a level at which the local government is actively trying to reduce the chemical	Very High	5
Detected in environmental media above the threshold level OR detected in environmental media, a threshold level does not exist, and the level detected causes concern	High	4
Detected in environmental media below the threshold level OR detected in environmental media, a threshold level does not exist, and the level detected does not cause concern	Low	2
Not detected in environmental media	Very low	1

Integration of Detection Elements

Human biomonitoring and environmental detection are assigned numerical values, which are averaged to arrive at the Detection score.

[4] Federal Register, Vol 67, No 194, October 7, 2002, Department of Health & Human Services, Centers for Disease Control and Prevention, Final Selection Criteria and Solicitation of Nominations for Chemicals or Categories of Environmental Chemicals for Analytic Development and Inclusion in Future Releases of the National Report on Human Exposure to Environmental Chemicals

2. High production volume

Whereas Production Volume in the Intrinsic Hazard Ranking is based on the mass of chemistries produced by a company, high production volume chemicals are those which are produced industry wide in high volumes. Chemicals produced in high volumes present a higher risk for exposure, and as such, are more likely to be regulated or the focus of non-governmental organization (NGO) activities.

The US EPA and the Organization for Economic Cooperation and Development (OECD) define high production volume (HPV) chemicals differently. US EPA HPV chemicals are ranked higher than those identified by OECD as the EPA has a lower production threshold for identifying chemicals.

US EPA: HPV chemicals are classified as those chemicals produced or imported in the United States in quantities of 1 million pounds or more per year.

Sponsored chemicals list http://www.epa.gov/chemrtk/pubs/update/spnchems.htm

Unsponsored chemicals list http://www.epa.gov/chemrtk/pubs/general/regactions.htm

OECD: HPV chemicals are those produced or imported to any European Union member country in quantities of 1,000 tons (2.2 million pounds) or more per year.

OECD High Production Volume chemicals list http://webnet.oecd.org/hpv/ui/Default.aspx

Table 10. High production volume ranking

High Production Volume	Ranking	Value
Listed by EPA	Very High	5
Listed by OECD	High	4
Not listed by EPA or OECD	Very low	1

3. Overall Priority Grouping

Detection and high production volume are assigned a numerical value based on their rankings and the chart below is used to arrive at the overall Precautionary Risk score.

Table 11. Integration of Precautionary Risk Rankings

	High Production Volume value				
Detection value	**1**	**NA**	**NA**	**4**	**5**
1-2 very low	2	NA	NA	5	6
3-4 low	3	NA	NA	6	7
5-6 moderate	4	NA	NA	7	8
7-8 high	5	NA	NA	8	9
9-10 very high	6	NA	NA	9	10

C. Strategic Risk Ranking

The purpose of the strategic risk assessment is to understand the potential risk of the industry moving away from use of the substance. Motivation can be driven by the environmental health and safety attributes of the substance, actions of competitors, proprietary nature of the substance, and requests by stakeholders.

Key to predicting future use of a substance is understanding existing marketplace restrictions, government action to eliminate use of the substance, and stakeholder request to limit or discontinue use of the substance.

1. Alternatives Assessment

Alternatives assessment is a tool used to compare the environmental health, safety, and performance attributes of substances and their potential replacements to ensure replacements are indeed less toxic and hazardous than the substance they are replacing and that the replacement does not have an unforeseen side effect. Where risk assessment is used to determine safety of substances, alternatives assessment focuses on determining which of a set of chemicals is safer or safest. Alternatives assessment can be used in the product design or redesign phases to evaluate potential alternatives and prioritize them for replacement.

A number of state governments have adopted alternatives assessment processes to support banning or restricting the use of a chemical in order to ensure less toxic counterparts not only exist, but will function the same or better than the toxic chemical. The US EPA Design for Environment (DfE) program helps industries choose safer chemicals for specific applications through alternatives assessments.

A list of current Federal & State level alternatives assessments can be found at http://www.ic2saferalternatives.org/page/Current+Alternatives+Assessment+and+Related+Legislation

Table 12. Alternatives assessment risk ranking

Alternatives assessment	Ranking	Value
State or Federal gov't has completed an alternatives assessment & REQUIRES adoption of an alternative chemical for the application	Very High	5
State or Federal gov't has completed an alternatives assessment & RECOMMENDS adoption of an alternative chemical for the application	High	4
State or Federal gov't has announced plans to conduct or is currently conducting an alternatives assessment for chemical in the application	Moderate	3
State or Federal gov't has conducted, is conducting, or has plans to conduct an alternatives assessment for another application of the chemical	Low	2
State or Federal gov't does not plan to perform an alternatives assessment for the chemical	Very low	1

2. Government Marketing & Use Restrictions

Government marketing and use restrictions of a substance in one application are indicators of future action against the substance in other applications. For example, the banning of BPA in baby bottles by state governments has lead to NGOs and governments reviewing additional applications of BPA in order to determine if further restrictions are warranted to reduce or eliminate exposure.

Table 13. Government Manufacturing & Use Restrictions risk ranking

Government Manufacturing & Use Restrictions	Ranking	Value
State or Federal gov't has restricted the marketing & use of the chemistry in all applications	Very High	5
State or Federal gov't has restricted the marketing & use of the chemistry in the applicable application	High	4
State or Federal gov't has restricted the marketing & use of the chemistry in an application other than the current application	Moderate	3
There are no state or federal gov't marketing & use restrictions on this chemistry	Very low	1

3. Stakeholder Requests

Typically, customers and stakeholders request the reduction of substances in specific applications. Failure to reduce or eliminate requested substances may result in the loss of customers to competitors and through negative action or reaction by consumer groups to use of the substance.

Stakeholders include, but aren't limited to, customers, communities surrounding manufacturing facilities, nongovernmental organizations, and the public.

Table 14. Stakeholder requests risk ranking

Stakeholder requests	Ranking	Value
Stakeholders have requested the substance be reduced or removed from all company specific applications of the substance	Very High	5
Stakeholders have requested the substance be reduced or removed from at least one but not all company specific applications of the substance	High	4
NGOs, consumer groups, or other market pressure is requesting the substance be reduced or removed from the marketplace	Low	2
There has not been a request to remove or reduce the substance in the marketplace	Very low	1

4. Safer Alternative

A global societal trend that impacts the chemical industry is the drive towards sustainable or green chemistry and safer chemical substitutes. Sustainable chemistry aims to reduce or eliminate negative environmental impacts throughout the life cycle of the substance. Trends in sustainable chemistry are reinforced through governmental incentives, industry voluntary programs, product certifications, and demand by customers.

Safer alternatives are dependent upon three factors:

1. An alternatives assessment process which identified a safer alternative.
2. A viable alternative. The price/performance ratio must be at least equivalent or better than the current substance and the alternative must be readily available to meet production demands.
3. The human health and environmental performance of the alternative must be better than the current substance.

Table 15. Safer alternative risk ranking

Stakeholder requests	Ranking	Value
An alternative with higher human health & environmental performance has been identified and the price/performance ration is equal to or lower than the current substance	Very High	5
An alternative with higher human health & environmental performance has been identified but the price/performance ration is higher than the current substance	Moderate	3
An alternative with higher human health & environmental performance has not been identified	Very low	1

Integration of Strategic Risk

To arrive at the Strategic Risk value, the values for alternatives assessment, government marketing & use restrictions, and the stakeholder requests are added. The resulting sum is then compared to the safer alternative value to arrive at the Strategic Risk score.

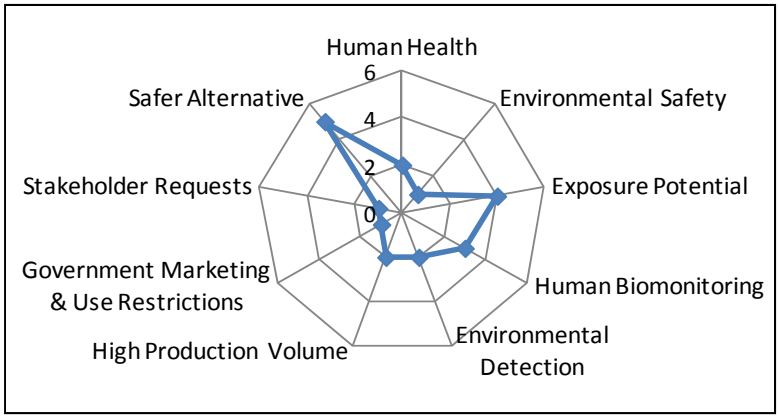
Table 16. Integrating Strategic Risk values

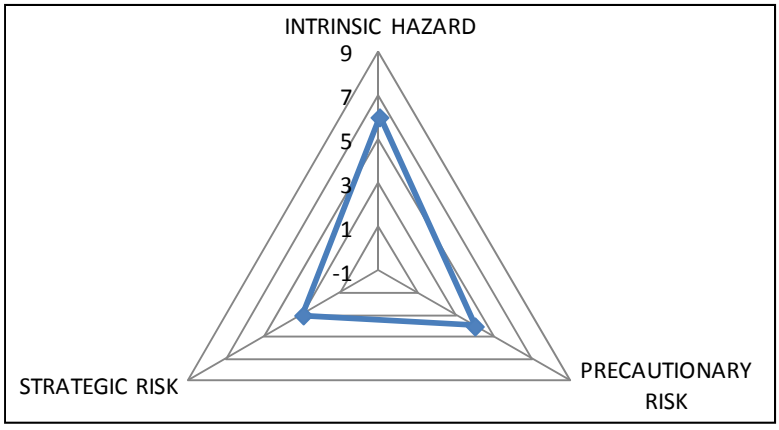
	Alt. Assessment + Gov't Marketing & Use Restrictions + Stakeholder Requests				
Safer Alternative	**4-5 very low**	**6-7 low**	**8-9 moderate**	**10-12 high**	**13-15 very high**
1 very low	2	3	4	5	6
2 low	NA	NA	NA	NA	NA
3 moderate	4	5	6	7	8
4 high	NA	NA	NA	NA	NA
5 very high	6	7	8	9	10

D. Risk Profile Results

Results are presented numerically, allowing them to be presented visually a number of ways. Radar charts displaying results at the individual risk attribute level as well as the higher risk category level allow substances to more easily be compared and the attributes which contribute the most and least risk to be easily identified.

Figure 1. Example radar charts of results





III. Prioritizing Substances for Action

The next step in the Prioritization process is to identify those substances with a high level of risk and further prioritize them for action.

A. Identifying High Risk Substances

While the radar charts allow the relative risk of attributes of chemistries to be identified and compared, they do not provide a method to prioritize chemistries for further action. There are multiple methods to combine the intrinsic, precautionary, and strategic risks into the EHS risk profile. The methods vary by the amount of weight given to each of the three risk components when calculating the profile. Selecting the EHS Risk Profile calculation method is therefore dependent upon needs of the assessor.

Methodologies for identifying high risk substances:

1. Intrinsic risk, precautionary risk, and strategic risks are equally important

    a. Risk Value = Intrinsic hazard + Precautionary risk + Strategic risk
    Results range from 3 to 30

    b. Risk Value = Intrinsic hazard x Precautionary risk x Strategic risk
    Results range from 1 to 1,000

2. Strategic risk is prioritized

    c. Risk Value = ([Intrinsic hazard + Precautionary risk]/2) x Strategic risk
    Results range from 1 to 100

3. Intrinsic risk is prioritized

    d. Risk Value = [(Precautionary risk + Strategic risk)/2] x Intrinsic hazard
    Results range from 1 to 100

B. Prioritize for Action

Based on the results of the Risk Value, the practitioner determines at which value substances will be further prioritized for action. Those chemistries in the selected are prioritized according to their EHS Risk Profile and net sales. The Risk Value is multiplied by the net sales of the substance, normalized to 100% of annual sales.

Action Value = Risk Value x net sales

Substances are then prioritized for action based on the resulting Action Value, with higher values representing those substances with highest risk.

IV. Summary

The Chemical Risk Prioritization Framework has been developed to assist chemical manufacturers with evaluating the environmental health and safety risks of chemical products. Most chemical risk evaluation and prioritization schemes consider the EHS risks only, but business decisions are not typically made on the intrinsic hazards of a chemical alone. By incorporating chemical detection, government action, and marketplace trends along with the intrinsic hazard into one Risk Profile, a chemical's risk can be assessed more completely to further aid in decision making at the company level.

While the Framework has been developed for the chemical manufacturing industry, its structure is flexible and adaptable, allowing it to be refined for use in other industries or sectors. Furthermore, a chemical manufacturer may adapt the model to reflect nuances between product lines or multiple market segments of the same product.

A chemical's risk prioritization score is dynamic and changes over time. The level and type of scientific information available, uses of a chemical, and new and changing external forces both at the chemical and business levels can significantly impact a company's use of the chemical. Over time, studies and test results for human health and environmental effects as well as biomonitoring and environmental monitoring of chemicals increase the amount and type of information available, affecting the intrinsic and precautionary risk of the chemical. In addition, the manufacturer may change the use patterns or production volume of the chemical, further affecting the intrinsic hazard. State and federal governments regularly identify new chemicals of concern targeted for alternatives assessments, stakeholders are constantly shifting attention to new chemicals, and safer alternatives for hazardous chemicals are regularly created. It is important to understand that the Risk Profile and Prioritization results present the current state of a chemical or suite of chemicals and that the results will change – both positively or negatively – over time.

While the Framework incorporates aspects of a chemical's risk to the business, the environmental health and safety risk is just one element of a chemical's total business risk. Additional aspects not included in the Framework, such as worker health and safety and legal liability, are also considered when chemical manufacturers make decisions about the fate of chemicals. The Framework provides support to assist with decision making, but is not the only consideration.

Appendix A. Chemical Product Risk Prioritization Summary Worksheet

The following worksheet can be used to facilitate completing a Risk Profile, calculating Risk Values, and prioritizing substances for action.

Chemical Product Risk Prioritization Framework Summary

Substance: _____

Application: _____

Geographic location: _____

Results Summary:

Intrinsic Hazard Rating: _____

Precautionary Risk Rating: _____

Strategic Risk Rating: _____

_____ a. Risk Value = Intrinsic hazard + Precautionary risk + Strategic risk (min 3, max 30)

_____ b. Risk Value = Intrinsic hazard x Precautionary risk x Strategic risk (min 1, max 1,000)

_____ c. Risk Value = ([Intrinsic hazard + Precautionary risk]/2) x Strategic risk (min 1, max 100)

_____ d. Risk Value = [(Precautionary risk + Strategic risk)/2] x Intrinsic hazard (min 1, max 100)

Notes: _____
_____
_____
_____
_____
_____
_____
_____

A. Intrinsic Hazard Rating: score _____

_____ 1. Human Health

_____ 2. Environmental Safety

_____ 3. Use Patterns

_____ 4. Production Volume

_____ 5. Persistence and Bioaccumulation

_____ Hazard Potential = higher score of Environmental Safety & Human Health

_____ Exposure Potential = Use Patterns + Production Volume + Persistence & Bioaccumulation

Hazard Potential	Exposure Potential				
Value	3-4	5-6	7-8	9-10	11-12
1	2	3	4	5	6
2	3	4	5	6	7
3	4	5	6	7	8
4	5	6	7	8	9

B. Precautionary Risk Rating: score _____

_____ 6. Human Biomonitoring

_____ 7. Environmental Detection

_____ 8. High Production Volume

_____ Detection = average Human Biomonitoring and Environmental Detection

High Production Volume	Detection				
Value	**1-2**	**3-4**	**5-6**	**7-8**	**9-10**
1	2	3	4	5	6
2	3	4	5	6	7
3	4	5	6	7	8
4	5	6	7	8	9
5	6	7	8	9	10

C. Strategic Risk Ranking: score _____

_____ 9. Alternatives Assessment

_____ 10. Government Marketing & Use Restrictions

_____ 11. Stakeholder Requests

_____ 12. Safer Alternative

_____ Market Pressure = Alternatives Assessment + Gov't Restructions + Stakeholder Requests

Safer Alternative	Market Pressure				
Value	**4-5**	**6-7**	**8-9**	**10-12**	**13-15**
1	2	3	4	5	6
2	3	4	5	6	7
3	4	5	6	7	8
4	5	6	7	8	9
5	6	7	8	9	10