This guide necessarily addresses implementation activities of a general nature. Local, state and federal laws and regulations should be reviewed with respect to particular circumstances.

In publishing this work, the American Chemistry Council is not undertaking to meet the duties of employers, manufacturers or suppliers to warn, properly train and equip their employees and others exposed, concerning health and safety risks and precautions.

Information concerning product safety should be obtained from the employer, manufacturer or supplier of that material or equipment or the material safety data sheet.

This Guide provides sample strategies and resources to assist companies in implementation of the Responsible Care Product Safety Code of Management Practices. The sample strategies and implementation resources are intended solely to stimulate thinking and offer helpful ideas on code implementation. They are in no way intended to establish a standard, legal obligation or preferred option for any practice. Other approaches not described in this document may be as effective or even more effective for a particular company. If a company so chooses, it may adopt any of these strategies or may modify them to fit the company's unique situation.

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I. Background

A commitment to the stewardship of chemical products has long been part of the American Chemistry Council’s Responsible Care® program. In 1992 ACC adopted the Responsible Care Product Stewardship Code of Management Practices, which set forth activities that chemical companies committed to take as part of their Responsible Care obligations. Companies implemented these activities over a five year time frame and conducted self-assessments against the Code elements through the year 2000. At that time, ACC began an integration of all Responsible Care Codes into a Responsible Care Management System® (RCMS®) covering all Code elements, including the traditional “product stewardship” discipline. In 2002, the integration was completed, and the new RCMS® and RC14001® were established, creating new certification specifications against which each ACC member was required to achieve third-party certification.

During this same timeframe, ACC and the International Council of Chemical Associations (ICCA) began developing a global articulation of the chemical industry’s commitment to product safety and stewardship: The Global Product Strategy (GPS). The GPS was adopted by ACC and ICCA in 2004 and the GPS requirements for chemical companies were incorporated at a high level into the RCMS and RC14001 specifications.

ACC and its members’ longstanding commitment to product stewardship is evident in the legacy Product Stewardship Code, GPS implementation and the incorporation of these performance requirements into the RCMS and RC14001 specifications. Despite these actions, when ACC undertook a Strategic Review of Responsible Care in 2010-2012, clear feedback received from internal and external stakeholders alike was that ACC and its members must go further and deeper in its articulation of product safety and stewardship management requirements through Responsible Care. In exploring the elements of the expanded focus on product safety and stewardship, ACC and its members determined that a new Code would be the best vehicle to add specificity to Responsible Care requirements in this area as a “bolt-on” to the RCMS and RC14001 requirements. Reference Document 8 is a matrix that shows the interconnectivity of the legacy Product Stewardship Code; GPS; RCMS: RC14001; and new Product Safety Code. A fundamental change as a result of the launch of this Code is that the Responsible Care certification process will include a review of the new Code implementation, with a greater degree of focus on product safety requirements articulated in the Code than ever before.

In determining the name of the new Code, some time was spent discussing the use of the terms “product safety” and “product stewardship”. It was generally agreed that ACC’s view of the term product stewardship is expansive and covers the management of product safety along the value chain. However, it was also agreed that the term was not well-understood with our external audiences, and others had begun using the term and incorporating an altered meaning.

Meanwhile, the public debate around chemicals in products centered around the “safety” of these products, and seemed to have the most resonance externally. In addition, the term “safety” allows us to talk about a determination of the safety of our products for their intended uses, which is the flip side of risk management, an historic pillar of product stewardship. While the industry generally views the term “product safety” as an endpoint and only one component of “product
stewardship", it was chosen as the name of this new Code because that endpoint seems to convey the ultimate goal of the Code itself. Both terms are used throughout the Code in this context.

Chemistry Value Chain

\[1\] Chemistry Industry Association of Canada Responsible Care Stewardship Guide.
II. Responsible Care® Product Safety Code of Management Practices

Purpose and Scope
Chemistry is a source of innovation that creates a healthier, safer and more sustainable future. From solar cells, wind turbines and rechargeable batteries to air filters, water purifiers and disinfectants, chemistry enables us to save energy, reduce pollution and enhance public health.

The American Chemistry Council’s (ACC) Responsible Care companies manufacture a broad array of chemical products, ranging from commodity industrial chemicals used to make other chemical products, to specialty chemicals tailored for unique applications and formulations, to finished goods and consumer products. Product safety and stewardship are shared value chain responsibilities, as each company, depending upon its position in the chemical value chain, has a distinct and essential role to play. At each stage in the value chain, protecting public health, safety, and the environment must be embraced as a core value, as it is by chemical manufacturers.

ACC Responsible Care companies are committed to making innovative chemical products that can be used safely for their intended purposes. As part of this commitment, ACC and its members created this Responsible Care Product Safety Code, which sets forth a set of practices to manage chemical product safety as part of our industry's signature health, safety, security, and environmental management system. The Code reinforces Responsible Care’s legacy of product stewardship that goes beyond regulatory requirements, which has been a central tenet of the program since its inception.

The Responsible Care Product Safety Code provides a comprehensive framework to drive continuous improvement in chemical product safety and stewardship. Implementation of this Product Safety Code is mandatory for all ACC Responsible Care companies.

Management Practices
The Product Safety Code requires that companies include product safety and stewardship as part of their management systems. Product safety management requires an understanding of intended product uses, a science-based assessment of potential risks from products, and consideration of the opportunities to manage product safety along the value chain. A key component of managing product safety by parties in the value chain is exchanging information regarding product hazards, intended uses, handling practices, exposures and risks. Product stewardship is the responsibility to understand, manage and communicate the health and environmental impacts of chemical products.

Taken together, implementation of the following management practices enables chemical manufacturers to systematically evaluate, demonstrate and continuously improve their product safety performance, while also enhancing communication about important factors that can influence product safety throughout the value chain.

Each Responsible Care company's management system will include the following product safety and stewardship management practices:
1. **Leadership Commitment.** Senior leadership commitment to a culture of product safety and stewardship. Each company’s senior leadership demonstrates clear commitment through their words, policies and actions throughout their organization and in external communications.

   Senior leaders drive continuous improvement of product safety and stewardship through published policies, active participation and communication concerning product safety, establishing, tracking/reporting of objectives and goals, and providing sufficient and qualified resources. Senior leadership is charged with evaluating the effectiveness of product safety programs and providing active support to drive improvement.

2. **Accountability and management.** Clearly established organizational accountability for product safety and stewardship. Product safety and stewardship are integral to business processes and employee expectations.

   Product safety and stewardship are core values that permeate each company’s operations and functional responsibilities. Product safety and stewardship responsibilities of employees are understood, including those roles that engage with suppliers, customers, contract manufacturers, carriers, distributors, contractors and third-party logistics providers. Employees assigned these roles are informed and held accountable for their performance.

3. **Prioritization of products.** A risk-based process that considers available hazard and exposure information to prioritize products in need of further evaluation.

   Companies have a process in place to prioritize their products to identify those that require a more detailed evaluation, assessment, and risk management controls, as well as those that require additional data and information gathering. Companies apply a science- and risk-based approach, considering hazard, intended uses and exposure potential when they prioritize their products. Companies include criteria that are applied uniformly to all products screened and that incorporate relevant, credible scientific advances and consider significant new information to ensure that prioritization decisions remain current.

4. **Product information.** A process to develop and maintain information on safety, health and environmental hazards, intended uses and exposures for new and existing products to support risk characterization and product safety management.

   Companies consider the results of their risk-based prioritization process when gathering and developing information that is used in their risk evaluations, characterizations, and consideration of product safety management actions. Companies evaluate existing information and appropriate assessment techniques, such as ACC’s science policies and principles, to determine when additional information on hazards, intended uses, and exposures is needed.

5. **Risk characterization.** A process for the characterization of product risks based on information collected on hazards, intended uses, and exposures associated with the stages of a product’s lifecycle.
Companies characterize the potential risks of their products using an iterative, tiered process that considers prioritization results and may identify needs for additional hazard, use and exposure information. Risk characterizations include consideration of information about downstream uses and reasonably anticipated exposures, including potential exposures to children. Risk characterizations use valid, reliable and relevant scientific studies and information, giving such studies and information appropriate weight, to determine potential risks associated with relevant levels of exposure under expected conditions of use.

6. **Product safety management.** A process to identify, implement, document and communicate health, safety and environmental measures to manage risk so that products can be safely used for their intended purposes.

Companies implement a process to select, implement, document and communicate measures that appropriately manage health, safety and environmental risks of their products. A range of measures may be considered commensurate with the risk characterization, taking into account the feasibility of value chain implementation. Examples of such measures may include labeling, handling instructions, training, engineering and design controls, use restrictions and/or reformulations. Risk management actions may require modifications based on substantive new information on hazards, uses and exposures so that products can continue to be safely used for their intended purposes.

7. **Management of new information.** A process to identify and evaluate new information that may trigger changes to risk characterizations and product safety management actions. Such triggers include significant new product safety and stewardship information, including hazard, use and exposure information.

Companies establish processes that enable new information to be brought to light and establish when and how to elevate product safety and stewardship issues within the company. New information could come from internal and external sources.

8. **Product design and improvement.** A process that considers health, safety and environmental impacts in the innovation, design, development, and improvement of products, their manufacture, and uses.

Companies consider health, safety and environmental impacts when designing and improving their products, including factors such as intended use, expected product lifetime, durability, reuse, recyclability or beneficial disposition.

9. **Value chain communication, cooperation and outreach.** Processes to work with suppliers, customers and other value chain participants to foster product safety management and information exchange along the value chain, commensurate with risk.

Commensurate with risk, companies work with and as appropriate, review customers, suppliers, contract manufacturers, carriers, distributors, contractors and third-party logistics providers based on Responsible Care or other health, safety, security and environmental performance criteria. Processes are in place to communicate, receive and evaluate product safety and
stewardship information and requests from value chain participants. If improper practices involving a product are discovered, corrective measures are taken based upon a company’s independent judgment, ranging from resolving the improper practices to termination of business relationships, if necessary.

10. Information sharing. Publicly available product safety and stewardship information.

Companies make product safety and stewardship information publicly available to enhance public knowledge of and confidence in the safe use of chemical products, while protecting confidential business information. Publicly available information includes relevant health and environmental effects and safety management measures to promote safe handling and use of products throughout their lifecycle.

11. Performance assessment and continuous improvement. Routine monitoring and assessment of product safety and stewardship, with processes in place to drive continuous performance improvement and implement corrective actions when needed.

Companies implement an internal process to monitor and assess product safety and stewardship performance, utilizing appropriate indicators. Companies report their activities associated with implementation of this Code to ACC to facilitate public understanding of the industry’s overall product safety commitment and performance.
III. Implementing the Code in Your Company

Under the Product Safety Code, each Responsible Care company must implement a risk-based product safety management system for its chemical products. This Product Safety management system should be integrated within the company’s overall Responsible Care Management System, taking into account the company’s value chain for its chemical products.

This guidance has been prepared to assist ACC member companies in applying the new Code elements to their company and product-specific activities, recognizing that each company’s activities, processes and system will be tailored to its specific needs based on the organizational structure, a company’s product mix and the markets served by the company’s chemical products.

For each of the 11 management practices, this document presents the following:

- Formal statement of the practice
- Sample strategies
- Implementation resources

The implementation resources are taken from ACC policies and advocacy documents, chemical company policies, procedures, plans, and from other sources, such as ICCA or government documents. Users of this implementation guide may wish to adopt the resources into their own product safety and stewardship programs, changing the language to fit the particular characteristics of their companies and products. Note: it is advisable to examine all the resources and examples given in this implementation guide. Because of the interconnectedness of the 11 management practices, a resource offered for one management practice may be useful in implementing other management practices as well.

The Product Safety Code also complements the Responsible Care Management System® (RCMS® and RC14001®) and other Codes of practice, as well as the ICCA Global Product Strategy. For this reason, many of the practices may already be in place, at least partially, within a company. (See Reference 8 - Matrix)

Measurements, Reporting and Implementation Schedule:
ACC will collect an annual attestation from each member company on its progress in implementing the Code and its individual elements, as was the case with the Responsible Care Security Code. The staged implementation deadlines for Code elements, to be reported on annually by companies through ACC Executive Contact attestations, are as follows:

<table>
<thead>
<tr>
<th>Management Practice</th>
<th>Implementation Deadline</th>
<th>Verification Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>12/31/14</td>
<td>ACC Executive Contact attestation</td>
</tr>
<tr>
<td>4-7</td>
<td>12/31/15</td>
<td>ACC Executive Contact attestation</td>
</tr>
<tr>
<td>8-11</td>
<td>12/31/16</td>
<td>ACC Executive Contact attestation/RCMS certification</td>
</tr>
<tr>
<td>All (1-11)</td>
<td>Beyond 2016</td>
<td>RCMS/RC14001 certification</td>
</tr>
</tbody>
</table>
The Implementation Affirmation Statement will be an attestation that the relevant management practices have been implemented. If companies are moving ahead of the ACC schedule, their attestations could include management practices beyond the minimum requirements. Certifications that are occurring in the 2014-2016 timeframe will include verification that Code elements are in place.

The attestation statement that each company will submit by December 31st in each of the years 2014, 2015 and 2016 is shown below:

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**Executive Contact Attestation Statement of Product Safety Code Implementation**

In 2012, the American Chemistry Council (ACC) Board of Directors adopted the Responsible Care Product Safety Code, a state-of-the-art product safety and stewardship management system. ACC has established an implementation schedule for the Code that each Responsible Care company must meet. In accordance with the implementation schedule, our company attests that the following management practices are in place as part of our processes and systems related to product safety and stewardship performance:

>>insert relevant Management Practices, e.g. #1-3 for 2014<<

_____________________________________

Company Name

_____________________________________

Printed Name and Signature of Responsible Care® Coordinator - Date

_____________________________________

Printed Name and Signature of ACC Executive Contact - Date

---
IV. Management Practice Descriptions and Guidance

The following pages include sample strategies for each of the 11 management practices, and links to several implementation resources contained in the Reference Documents section. Implementation resources provide implementation tips and examples of policies and other company documentation that illustrate how companies can demonstrate their commitment to the effectiveness of product safety and stewardship efforts.

The sample strategies and resources are intended to stimulate ideas and offer helpful suggestions on code implementation. However, other approaches not described here may be as effective or even more effective for a particular company. Companies may adopt any of these sample strategies or may modify them to suit the company's unique situation.
1. Leadership Commitment

Management Practice 1

**Leadership Commitment.** Senior leadership commitment to a culture of product safety and stewardship. Each company's senior leadership demonstrates clear commitment through their words, policies and actions throughout their organization and in external communications.

*Senior leaders drive continuous improvement of product safety and stewardship through published policies, active participation and communication concerning product safety, establishing and tracking/reporting of objectives and goals, and providing sufficient and qualified resources. Senior leadership is charged with evaluating the effectiveness of product safety programs and providing active support to drive improvement.*

Senior leaders must establish a culture of product safety so that it permeates through the organization and manifests itself as a core value of the company. The following are various strategies that senior leadership can consider adopting to fulfill this management practice and support their companies’ product safety and stewardship programs.

**Sample Strategies**
- Approve, oversee, and externally communicate the company’s product safety and stewardship objectives and management approach.
- Include product safety and stewardship as one of the company’s core values.
- Set, approve, and externally communicate company product safety and stewardship policies and specific programs.
- Include product safety performance in the company’s annual performance reports.
- Set and communicate product safety targets and expectations organization-wide.
- Track and monitor progress at regular intervals using established product safety performance indicators.
- Monitor progress and intervene as appropriate.
- Provide and allocate resources necessary to meet established goals.
- Incorporate product safety and stewardship into facility-level strategic plans and objectives.
- Seek opportunities outside the company to communicate the company’s commitment to product safety.

**Management Practice 1: Implementation Resources**

1. Company Responsible Care® and Sustainability Websites and Reports
A number of company websites highlight their Responsible Care and sustainability
commitments to product safety and stewardship.

- Dow Chemical’s 2015 Sustainability Goals
- Dow Chemical’s Responsible Care webpage
- Lanxess HSEQ Policy
- Bayer Responsible Care webpage
- Nova Molecular webpage on product stewardship and Responsible Care
- ExxonMobil Product Stewardship and Product Safety page
- BASF Product Stewardship webpage
- Momentive Product Stewardship webpage

2. Company Goal Statements
Example 1: [Insert Company Name] long range business plans include vision, strategy and goals for EH&S and Sustainability/Product Stewardship as part of its business strategy and vision.

Example 2: By 2020, [Insert Company Name] commits to conduct a risk assessment for all products of which quantities of more than 1 metric ton are sold worldwide per year. Through this new goal, we take our responsibility for our products much further than all existing legal regulations. Risk assessments will be available for all products of which we sell more than 1 metric ton – regardless of the volumes of individual substances used in them. We will provide both our customers and the general public with transparent information about these risk assessments. We will issue annual reports on the processes for assessing substances and products, the way in which substances and products are handled, and our progress in achieving the goals we have set ourselves.

Example 3:
  Short Term:
  - Complete LCAs on product families aligned with our customers’ priorities (equivalent to approximately 60% of products which represents 80% of total revenues)
  - Collaborate with a minimum of six key influencers in our value chain to promote sustainable practices

  Medium Term:
  - Complete LCAs on all new product family launches
  - Expand our value chain engagements to focus on strategic sustainability issues with key influencers such as designers, academia, government and nongovernment organizations

  Long Term:
  - Become an active voice in our industry, sharing leading practices on sustainability throughout our value chains
3. Example Product Safety Senior Leader Bio Descriptions
Mr. Steve Pryor (President of ExxonMobil Chemical Co.) is Chairman of the ACC Global Strategy Committee which in 2011/2012 took ownership for ACC member completion of the GPS Product Safety Summaries. Mr. Pryor is also a member of both the ICCA Global Executive Strategy Group and the ICCA Board.

ExxonMobil Chemical’s SSHE Manager is a member of the ICCA Chemical Policy & Health (CP&H) Leadership Group which focused on industry’s commitment to SAICM (Strategic Approach to International Chemicals Management) which mainly meets these objectives through Responsible Care® and the Global Product Strategy.

MANAGEMENT PRACTICE 1: REFERENCE DOCUMENTS


REFERENCE 15. RCMS IMPLEMENTATION GUIDE 102.02 Element 3.3
2. Accountability and Management

Management Practice 2

**Accountability and management.** Clearly established organizational accountability for product safety and stewardship. Product safety and stewardship are integral to business processes and employee expectations.

*Product safety and stewardship are core values that permeate each company’s operations and functional responsibilities. Product safety and stewardship responsibilities of employees are understood, including those roles that engage with suppliers, customers, contract manufacturers, carriers, distributors, contractors and third-party logistics providers. Employees assigned these roles are informed and held accountable for their performance.*

Specific responsibilities related to the management of the company’s product safety processes and system must be established and understood. Employees assigned these specific roles should be held accountable through their position descriptions, annual goals and objectives, and/or through processes that track product safety performance outcomes. The company’s culture of product safety should be evident as a core company value. The following are various strategies that companies can consider adopting to fulfill this management practice and assign product safety and stewardship accountability and management.

**Sample Strategies**

- Develop corporate product safety and stewardship organizational model and chart illustrating how product safety responsibilities are carried out within the company, businesses units, divisions and/or world regions.
- Define product safety and stewardship roles by position, including business functions.
- Develop product safety and stewardship training for business functions (supply chain, purchasing, marketing, etc.) with roles and responsibilities charting (RACI - R: Responsible, A: Accountable, C: Consulted, I: Informed).
- Have formal governance reviews of product stewardship functions and responsible parties throughout the company.
MANAGEMENT PRACTICE 2: IMPLEMENTATION RESOURCES

1. Product Safety and Stewardship Organizational Models
The organization and assignment of roles within a company to deal with product safety and stewardship can vary from a central corporate support group to a decentralized network of business unit product stewards or a combination of both, depending on the breadth of business and markets for the company's product portfolio or geographic locations. Regardless, active communication across functions in R&D, manufacturing, marketing, sales, logistics and legal affairs is critical for the successful product stewardship program.

- Centralized organizations may be composed of EHS scientific and engineering experts who service all or assigned portions of a company's business units. Smaller companies often will have corporate staff support only.

- Individual business units with fairly unique markets and sets of regulatory and other EHS concerns (e.g., one handles industrial markets, another consumer markets) may benefit from business unit level product stewards who can become familiar with the subset of regulations and EHS issues that impact a business.

- Where common issues or systems cross most businesses, there may be a combination of business stewards who are closely aligned with and knowledgeable of the business products and customers who work with specialized corporate (or contracted) experts (e.g., toxicologists, environmental scientists, industrial hygienists).

2. Product Safety Job Descriptions
Product Stewardship Specialist Job Description and Responsibilities:

- Developing and maintaining documentation relevant to assessment of risk to human health and the environment.

- Performing technical activities leading to regulatory compliance, assessment of safety to human health and the environment, liability avoidance, and product responsibility issues concerning existing or new chemicals, materials, products, or hard-goods.

- Contributing to the timely introduction of new/modified products. This includes building and maintaining product Life Cycle Assessments. Working with suppliers to obtain relevant data for these assessments.

- Maintain and expand in-depth knowledge of global regulatory requirements and develop business processes to ensure assessment and compliance with requirements.
- Support New Product Introduction Teams in the areas of regulatory, life cycle management, and hazard reviews as needed.

- EHS planning corporate scorecard, and audits.

- Complete global filings/registrations and ensure proper product labeling (RoHS, WEEE, China RoHS, state waste recycling programs, eWaste, Mercury, REACH, etc.).

- Provide EHS and Regulatory oversight for the various business units of the division.

- Develop and foster relationships with inside corporate support functions and with outside agencies/groups to influence where possible future regulations or comments to propose regulations.

- Take initiative to proactively encourage cross-functional support and relationships to more effectively resolve regulatory requirements in support of meeting the division’s plans and objectives.

- Responsible for supporting Customer Service, Marketing, Sales and answering questions from internal and external customers on regulatory/safety issues for products and requirements on a global basis in alignment with regional organizations. Works closely with Research and Development, HS&E-RA, Information Technologies, Quality, Legal, Purchasing and the business global team to ensure the effective processing of internal and external product stewardship documentation, formula compliance determinations, process/procedure documentation, raw material management, and systems maintenance.

- Lead assigned projects for raw material coding, technology transfer and site audits which may be international in scope as well as regional focus.

- Interface between regional laboratories and corporate for new raw material and intermediate requests to ensure global initiatives are maintained and implemented.

- Act as consultant and first point of contact for queries regarding product stewardship expertise for the business unit.

- Serve as a resource for acquisition, follow-up, and documentation of raw material data from raw material suppliers.

- Prepare all necessary documentation regarding launching of new product, new mix or import in relation to regulatory requirements.

- Maintain the product file history as required to provide all the product information necessary to demonstrate the products are meeting all pertinent regulations.
Focus on areas of concern and provide priority assignments to resolve product documentation discrepancies in relation to regulations or assignment.

Prepare or oversee preparation of SDS and labels and updates as necessary

Maintain awareness of public EHS concerns that could impact products and contribute to strategic planning to address those concerns

3. Global Product Sustainability Leader Job Description and Responsibilities

The Global Product Sustainability Leader (PSL), under the management of the Director of Product Stewardship and the direction of the Business leadership team, is responsible for ensuring global product regulatory compliance, implementation of the global product stewardship program and strategic product sustainability leadership. This PSL is also responsible for leveraging Environment Health & Safety (EH&S) work processes and corporate as well as business EH&S resources to assure that EH&S vulnerabilities and opportunities are managed within the business consistent with the business strategy and long-term value optimization for the company. Specific responsibilities include:

- Leading the integration of EH&S/product sustainability objectives, plans and goals into the business strategy.

- Assuring product regulatory compliance globally for the business by leveraging (Area) (Business) Product Stewardship Specialists.

- Developing, documenting and implementing business-specific Product Stewardship plans that address Business and Company needs.

- Developing, maintaining and leveraging local resources to ensure implementation of a global product stewardship plan for the business consistent with the Global Product Stewardship Management Standard (GPSMS) for Businesses and commitment to Responsible Care.

- Leverage Sustainability resources to ensure alignment with business, corporate and regional Sustainability objectives.

- Act as Product Sustainability Champion within the business.

- Defining the level of local implementation resources needed to achieve the business' global product stewardship plan.

- Leading the business in the appropriate use of the various EH&S tools (i.e., EH&S Business Risk Reviews, Life-Cycle Assessment, New Product EH&S assessments) to identify and manage risks, vulnerabilities and opportunities.
• Working with the appropriate experts to review and interpret relevant environmental, health and safety data in order to accomplish product stewardship objectives.

• Leveraging (Area) (Business) Product Stewardship Specialists and regulatory and issue management experts to identify and monitor relevant legislation, regulation and emerging short and long-term trends important to the business and assure that potential impacts are analyzed and communicated within the business. Drive appropriate business response.

• Working with Business Leadership to develop business-specific EH&S goals to enable the company to achieve its 20xx goals. Ensures implementation plans for achieving goals are in place. Measures, communicates and is accountable for the results.

• Working with the Global EH&S (Business) Operations Leader to provide a consistent, coordinated and comprehensive EH&S program for the business.

4. Sample Product Stewardship Training Program
Training on product stewardship should be given to business functions other than product stewardship (Supply Chain, Purchasing, Marketing, R&D, Technical/ Customer Service, Manufacturing, Transportation, etc.). This could include general awareness training on product safety and business conduct issues to detailed information related to a specific product’s EH&S considerations. Corporate policies, procedures, legal requirements, resources and appropriate contacts should be covered in the training. Insofar as possible, product stewardship activities should be integrated into existing business processes and training.

Roles and responsibilities should be clearly identified to promote prompt handling of information and follow up. One method is to do a RACI chart (R: Responsible, A: Accountable, C: Consulted, I: Informed). This should apply to all functions across the company and not just to the product stewardship and EHS staff.

MANAGEMENT PRACTICE 2: REFERENCE DOCUMENTS


REFERENCE 15. RCMS IMPLEMENTATION GUIDE 102.02 Element 3.3
3. Prioritization of Products

Management Practice 3

Prioritization of products. A risk-based process that considers available hazard and exposure information to prioritize products in need of further evaluation.

Companies have a process in place to prioritize their products to identify those that require a more detailed evaluation, assessment, and risk management controls, as well as those that require additional data and information gathering. Companies apply a science- and risk-based approach, considering hazard, intended uses and exposure potential when they prioritize their products. Companies include criteria that are applied uniformly to all products screened and that incorporate relevant, credible scientific advances and consider significant new information to ensure that prioritization decisions remain current.

Companies must implement a risk-based process to prioritize their products, using available hazard and exposure information. This is a “screening level” assessment process, using qualitative or quantitative approaches, that will result in an identification of products that require further or more refined evaluation, assessment, risk management measures and/or additional data gathering with respect to their hazards, uses and exposures. The process used by the company should be documented and applied uniformly. The process should also be triggered in the event that relevant and scientifically valid new information about a product comes to light. The following are various strategies that companies can consider adopting to fulfill this management practice and to prioritize their chemical products.

Sample Strategies

- Develop and employ objective scientific criteria that are applied uniformly to all chemical products screened and subsequently prioritized.
- Leverage available data and existing hazard classification frameworks already in use across industry and by regulators.
- Develop systems to identify and incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to enable prioritization decisions to remain current.
- Adopt a transparent screening method for prioritization.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.
MANAGEMENT PRACTICE 3: IMPLEMENTATION RESOURCES

1. Industry Prioritization Models
   - ACC Prioritization Tool (Reference 10)
   - ICCA Guidance on Chemical Risk Assessment factors (excerpt Reference 2)
     - Chemicals with testing or risk evaluation work already completed or under way in response to current or impending regulatory scrutiny (e.g., Canadian DSL, EU Regulation of existing chemical substances, EU REACH);
     - Categories of chemicals of particular concern under national or regional regulatory programs, such as those listed as known carcinogens, mutagens, or substances that are toxic to reproduction;
     - Chemicals listed as candidates under the Stockholm Convention (Persistent Organic Pollutants) or the Rotterdam Convention (Prior Informed Consent);
     - Chemicals restricted by other national or regional regulations or international conventions.
     - Whether the chemical could be classified as Persistent, Bioaccumulative and Toxic (PBT);
     - Whether and to what extent the chemical has potential for (significant) human exposure, especially when children and other sensitive subpopulations could be impacted. For example, such chemicals might include those:
       - used in products used by children;
       - used in consumer products, medical devices, drugs or cosmetics, particularly where such products are not regulated under a separate legal regime;
     - Whether and to what extent the chemical has a potential for significant environmental exposure when these chemicals are not regulated under a specific regime;
     - Whether the chemical presents a significant acute hazard (e.g., highly flammable, corrosive, reactive, etc.);
     - Whether the chemical is a high production volume chemical (1,000 tons production per year);
     - Whether and to what extent the chemical is a focus of broader or increasing societal concern;
     - Whether there are attributes of the value chain for a particular chemical that could raise significant concern (e.g., customers are very numerous or generally lack sophistication and competency in managing chemicals, or they do not have adequate product stewardship practices in place);
     - Whether a company wants to make a chemical “high priority” for business or other purposes (e.g., a new product or an existing product in a new application).

2. Government Prioritization Models
   - EPA ChAMP Prioritization Framework
   - Canadian DSL Prioritization Process
3. **Company tools and work processes for prioritization**
   - Solvay prioritization process
   - Bayer prioritization process
   - Lanxess prioritization process
   - Eastman prioritization process

4. **Taking Public Concerns into Account During Prioritization.**
   Public concerns can be monitored by using the company’s public affairs staff, conducting literature searches, discussion among companies at trade associations, screening agency and NGO data bases and websites, and other social media. Some factors to consider include:
   - Has the product had a high level of media attention? What impacts has the media coverage had on the public’s perception of risk associated with the product?
   - Has the product had a high level of public interest group attention? What impacts has public interest group coverage had on the public’s perception of risk associated with the product?
   - Has the product recently been of concern to users/customers as reflected by customer service or public affairs requests (e.g., volume of calls to an information hotline, requests for MSDS)?
   - Has the product/corporation been the subject of a lawsuit?
   - Is there an incident history associated with the product (e.g., release of the product from a facility)? Does the product have any catastrophic potential?
   - Is the product on any upcoming legislative or regulatory agendas?
   - Has the product been the subject of publicized studies, conducted either by regulatory agencies or national environmental groups?
   - Is the product closely associated with a specific company? What degree of trust does the public have in that company?
   - Is the product known to have “sensitive uses” – e.g., used for infants or pregnant or nursing mothers, or used in medical implants?
   - Does use of the product provide benefits to the same individual(s)/segments of society that would experience potential adverse effects?
   - Are there potential effects on future generations or long-term environmental impacts?

**Management Practice 3: Reference Documents**

**REFERENCE 1.** Recommendation for Developing and Disseminating Hazard and Exposure Data: The Integrated Tiered Testing and Assessment Approach

**REFERENCE 2.** ICCA Guidance on Chemical Risk Assessment
REFERENCE 5. ACC Weight of Evidence

REFERENCE 6. ACC Statement on Principles on Children’s Health

REFERENCE 7. ACC PBT Policy

REFERENCE 10. ACC Prioritization Tool
4. Product Information

**Management Practice 4**

**Product information.** A process to develop and maintain information on safety, health and environmental hazards, intended uses and exposures for new and existing products to support risk characterization and product safety management.

Companies consider the results of their risk-based prioritization process when gathering and developing information that is used in their risk evaluations, characterizations, and consideration of product safety management actions. Companies evaluate existing information and appropriate assessment techniques, such as ACC’s science policies and principles, to determine when additional information on hazards, intended uses, and exposures is needed.

Companies must develop and maintain EH&S information about their products. This information includes the environmental, health and safety hazard characteristics of the chemical product, its intended uses as well as exposures. Product use and exposure information should be based on the knowledge of the markets companies’ products serve, derived from typical business relationships and customer interactions. Companies are not expected to commission investigative exercises to gather specific exposure data from downstream users, but rather, should have a working knowledge of the ways their products are intended to be used.

Exposure and use-related information that companies can consider includes particular applications, use of engineering and administrative controls in those applications, use of personal protective equipment, and other factors affecting potential for human or environmental exposure. The following are various strategies that companies can consider adopting to fulfill this management practice and develop and maintain product safety and stewardship information.

**Sample Strategies**

- Develop a system that records product hazard, toxicology, use, exposure and environmental impact information.
- Use a hazard communication work process so that safety, health and environmental hazard information is updated on safety literature (MSDSs, product literature, product safety summaries, etc.)
- Use a risk-based assessment approach for gathering product information based on prioritization results (e.g., ACC Prioritization Tool - Reference 10)
- Use various read-across methods and third party databases and tools to access, record and develop information. ICCA’s Guidance on Chemical Risk Assessment contains many references to publicly available data sources.
MANAGEMENT PRACTICE 4: IMPLEMENTATION RESOURCES

1. Government Tools, Programs and Databases as Sources of Information

- [http://www.epa.gov/risk_assessment/health-risk.htm](http://www.epa.gov/risk_assessment/health-risk.htm)
- [http://www.epa.gov/opptintr/exposure/index.htm](http://www.epa.gov/opptintr/exposure/index.htm)
- [http://www.epa.gov/risk/guidance.htm](http://www.epa.gov/risk/guidance.htm)
- REACH, IUR/CDR reports, ASTDR Toxicological Profiles, OECD, OSHA

Systems that search and record hazard, toxicology and environmental information on products

- Product safety professionals should maintain currency in their field through attendance at appropriate conferences and readings, aided by relevant scientific literature search agents.
- Public media can also represent sources of information that the product steward needs to address potentially providing new risk information and/or public perceptions of risk.

Obtain downstream use and exposure information, including misuse information, by

- Awareness training for technical service and sales personnel who visit customer sites
- Search agents for news media and agency databases
- Supplier Safety Data Sheets
- Customer websites and other literature.

2. Sample Customer Risk Assessment Survey

Microsoft Excel 2003 Worksheet

3. Sample Company Risk-Based Testing Approach for Products

**Air Products and Chemicals, Inc. Product Testing Prioritization**

As part of our commitment to Product Stewardship and Responsible Care®, Air Products assesses the hazards of company products to provide safe handling information to customers and to comply with regulations such as the OSHA Hazard Communication Standard (29 CFR 1910.1200), EPA’s Right to Know Initiative, and international regulations such as REACH and Canadian Workplace Hazardous Materials Information System (WHMIS). Hazard information is also required for international product registrations and may be required for other country specific regulations.
All chemicals possess hazardous properties. Such properties need to be properly characterized to effectively evaluate and manage the potential risks that may be associated with the production, distribution, use, and disposal of products. For these reasons, basic toxicity data is obtained for all products prior to commercialization. The hazards of established products are assessed on an on-going basis as new information is available.

A minimum amount of product data (or basic information set) is required to prepare SDSs, classify products for labeling and shipping, and complete hazard assessments. Toxicology information from any reliable source may be incorporated into the review of a product’s health hazards provided that the quality standard outlined in Appendix A of 29 CFR 1910.1200 is applied. This data may be obtained through literature searches, structure activity relationships, similar product logic, modeling, or testing. Data references and/or copies of the data are maintained by the Product Safety Department.

If the required data already exist for the product that is being evaluated or its analogues (similar products) then testing would not be required. If testing is needed, related products may be grouped together into a category and a category approach may be used when determining testing requirements. Specialized testing may be required based on the chemical and its intended use.

Wherever possible, Air Products tries to avoid or minimize the use of animals in testing. The company does this by searching for any publicly available health information, using computer models and other predictive techniques, and utilizing novel testing protocols that use fewer animals and minimize discomfort. Air Products also tries to group closely related chemicals into categories for evaluation so that fewer individual chemicals must be tested. In addition, the company employs non-animal (in vitro) tests as often as possible, such as synthetic membranes to screen for skin corrosion potential of our products, which is information required for transportation classification.

**MANAGEMENT PRACTICE 4: REFERENCE DOCUMENTS**

**REFERENCE 1.** Recommendation for Developing and Disseminating Hazard and Exposure Data: The Integrated Tiered Testing and Assessment Approach

**REFERENCE 2.** ICCA Guidance on Chemical Risk Assessment

**REFERENCE 3.** ACC Science Principles on Animal Testing and Alternative Methods

**REFERENCE 4.** ACC Science Principles on Exposure Assessment

**REFERENCE 6.** ACC Statement on Principles on Children’s Health
5. Risk Characterization

**Management Practice 5**

**Risk characterization.** A process for characterization of product risks based on information collected on hazards, intended uses, and exposures associated with the stages of a product’s lifecycle.

*Companies characterize the potential risks of their products using an iterative, tiered process that considers prioritization results and may identify needs for additional hazard, use and exposure information. Risk characterizations include consideration of information about downstream uses and reasonably anticipated exposures, including potential exposures to children. Risk characterizations use valid, reliable and relevant scientific studies and information, giving such studies and information appropriate weight, to determine potential risks associated with relevant levels of exposure under expected conditions of use.*

Companies must characterize the risk of their products, using a process that considers hazards, uses, exposures, emerging new information and potential exposures to children. Risk characterizations can be qualitative and/or quantitative and an iterative, tiered approach will allow for the gathering of additional data as well as more refined assessment processes when needed. Assessments can be conducted for product families, where sufficient hazard, use and exposure scenarios exist.

Product safety is a shared value chain responsibility and this management practice envisions employing information obtained from the value chain in the characterization process pertaining to the use and exposure data in particular. Product use and exposure information should be based on the knowledge of the markets companies’ products serve, derived from typical business relationships and customer interactions. Companies are not expected to commission investigative exercises to gather specific exposure data from downstream users, but rather, should have a working knowledge of the ways their products are intended to be used.

The following are various strategies that companies can consider adopting to fulfill this management practice and characterize the risks of their products.

**Sample Strategies**

- Rely on the set of data gathered in Management Practice 4, considering mammalian and environmental toxicological endpoints and fate information for each risk based prioritization tier.
- Establish a tiered, risk-based assessment program and any required test plans for products using the risk-based program.
• Use a multifunctional team. It is important to conduct risk characterization with input from a team of persons knowledgeable about not only the toxicological hazards, but also the nature of human and environmental exposures throughout the life cycle such as R&D, technical service, marketing, industrial hygiene and environmental engineers and scientists.

• Consider a product’s life stages/lifecycle – product development, raw material acquisition, manufacturing, distribution, processing, use and disposal of the chemical product. Organizations involved in these life stages/lifecycle are considered part of the value chain. End use and disposal by consumers is also included in the lifecycle.

**MANAGEMENT PRACTICE 5: IMPLEMENTATION RESOURCES**

1. **Company Risk Characterization and Management Processes**
   - Shell risk characterization and management process
   - Dow Chemical Company Product Risk Characterization and Management

2. **Industry Tools and Resources**
   - ACC Chemical Products & Technology Division panels
     ACC’s product-specific groups are comprised of large and small manufacturers, formulators, downstream users, distributors and other trade associations working together on chemical issues management based on shared risk information. Contact relevant groups at ACC or other trade associations for available risk information and/or consider joining them to leverage resources through Rob Simon at rob_simon@americanchemistry.com.

   - Cefic Guidance on Specific Environmental Release Categories (SPERCs)

3. **Life Cycle Analysis (LCA) Initiatives and Tools**
   There are numerous software packages and consultants for those wishing to do formal, quantitative life cycle assessments for risk characterization at each stage of the life cycle. There are also approaches for more qualitative “life cycle thinking” and life cycle management approaches that can focus on key areas of environmental, health, safety, economic and social issues. Some examples are as follows:

   - Eastman Chemical Company’s “From cradle-to-gate and beyond” Life Cycle Assessment approach
   - Avery Dennison™ Greenprint Product Life Cycle Assessment
   - European Commission lifecycle thinking and assessment
   - US EPA National Risk Management Research Laboratory’s Life Cycle Assessment (LCA)
• UNEP/SETAC’s Life Cycle Initiative (supported by ACC, USEPA, Plastics Europe, Recycle Quebec, etc.)

**MANAGEMENT PRACTICE 5: REFERENCE DOCUMENTS**

REFERENCE 1. Recommendation for Developing and Disseminating Hazard and Exposure Data: The Integrated Tiered Testing and Assessment Approach

REFERENCE 2. ICCA Guidance on Chemical Risk Assessment

REFERENCE 4. ACC Science Principles on Exposure Assessment

REFERENCE 5. ACC Statement on Weight of the Evidence

REFERENCE 6. ACC Statement of Principles on Children’s Health

REFERENCE 7. ACC PBT Policy

REFERENCE 14. Product Safety Integrated Assessment References
6. Product Safety Management

**Management Practice 6**

**Product Safety Management.** A process to identify, implement, document and communicate health, safety and environmental measures to manage risk so that products can be safely used for their intended purposes.

Companies implement a process to select, implement, document and communicate measures that appropriately manage health, safety and environmental risks of their products. A range of measures may be considered commensurate with the risk characterization, taking into account the feasibility of value chain implementation. Examples of such measures may include labeling, handling instructions, training, engineering and design controls, use restrictions and/or reformulations. Risk management actions may require modifications based on substantive new information on hazards, uses and exposures so that products can continue to be safely used for their intended purposes.

Based on the risk characterization results in Management Practice #3 (Prioritization) and Management Practice #5 (Risk Characterization), companies will make determinations about what measures/controls must be in place for their products to be safely managed and used. In some cases, a product may be completely benign and no specific management measures may be necessary. However, in some cases, the product’s risk profile will indicate the need to establish management measures/controls to safely manage and use the product in the value chain. These management measures/controls will be established consistent with the risk of the product and may include labeling, handling instructions, training, engineering and design controls, use restrictions and/or reformulations.

Management actions should be revisited when new information (hazard, use or exposure) in uncovered and processes will be in place to trigger the re-assessment of the management actions when substantive new information arises. The following are various strategies that companies can consider adopting to fulfill this management practice and manage the safety of their products.

**Sample Strategies**

- Have work processes and tools that identify, evaluate and manage EH&S risks.
- List event triggers that indicate when safety management re-evaluations are needed (i.e., new application, new area of sale, new product data, etc.)
- Document how the company has evaluated their products, applications and uses. Document any end use applications for which sales are not allowed or have restrictions that are important to maintain.
- Consider corporate policies that consider risk and end use of products, e.g., medical
applications policies, use of product in production of consumer products, etc.

- Consider downstream use and exposure based on the knowledge of the markets companies’ products serve, derived from typical business relationships and customer interactions. Companies are not expected to commission investigative exercises to gather specific exposure data from downstream users, but rather, should have a working knowledge of the ways their products are intended to be used.

- Manage risk so that the company’s products can be safely used for their intended purposes. Further, if a company learns of unintended uses for which it has not conducted risk characterization and management, it should evaluate the new use and related exposures and take appropriate risk management actions.

**MANAGEMENT PRACTICE 6: IMPLEMENTATION RESOURCES**

1. **Company Processes/Tools that Identify, Evaluate and Manage EH&S Risks**
   - **Air Products Product Risk Management**
     Air Products has a detailed process for characterizing, assessing and identifying management measures for the environmental, health and safety risks associated with the sale, marketing and use of company products. The process applies to new commercial products and existing products for which there are new applications and/or hazards data and products requiring REACH Chemical Safety Assessments. This risk management procedure is amenable to a step-wise evaluation within our new product development process (See Product Design section). Commercial products added to our product lines through acquisition also are evaluated using these risk management practices.

     Differing levels of review are conducted depending on the application of the product and its hazards characterization. Product Hazard Reviews are conducted for products having the lowest level of risk and include examination of hazards data and warnings to ensure the warnings are sufficient and consistent. Product Risk Reviews are conducted for products having a moderate level of risk and include review of hazards data, applicable regulations, customer use information, emergency response topics, customer considerations, and other issues specific to the product. Priority review is given to those end-uses intended for foods, in formulations for consumer/residential use and those with potential consumer exposure. The highest level review, a Product Risk Assessment, is conducted for products with intended direct consumer exposure. Product Risk Assessments build on the Product Risk Reviews and include in-depth review of issues and mitigation measures. Product Safety leads all of these reviews, engaging company businesses and other functional experts as required. Identified risk management measures are communicated and tracked for closure. In the rare case that risks or mitigation measures cannot be resolved by the review teams, risks are escalated to the Corporate Risk Council.
Simplified Product Hazard and Risk Assessment Process

New Commercial Product

Fit in Reviewed Product Family? No

Hazards Classification

Complete

Existing Product Requiring CSA

Yes

Product Risk Assessment

Direct Consumer Exposure?

No

Existing Product w/New Application/Data

Meet Toxicity Criteria?

No

Existing Product w/New Regulation

Product Hazard Review

Yes

Meets Escalation Criteria?

No

Meet Toxicity Criteria?

Yes

Product Risk Review

Air Products
Product Risk Management
Decision Tree
2. Selecting Risk Management Options
Once risk characterization has been done, the company needs to identify the types of risk management measures that should be taken throughout the value chain so that the product can be safely used for its intended purpose. It is also important to consider the feasibility of controls given the availability and costs of technology and the sophistication of potential value chain partners and users. Risk can be reduced by managing hazard and/or exposure. Risk management practices can cover a broad spectrum of activities over the life cycle of a product depending on the nature of hazards and exposures. Some examples are presented below and some others can be found in the CEFIC REACH guidance.

- **Labeling and other communication materials** are key requirements to maintain proper understanding of potential risks and the need for management by the value chain agent
  - MSDS (MSDS)
  - Technical Sheet, Product Information Sheet, Guidance addressing safety

- **Training in proper handling**
  - Some users may need more direct training by the manufacturer, commensurate with risk
  - Training videos
  - Onsite Training program

- **Product design** (packaging, composition and construction) risks can be minimized by reducing toxicity and/or exposure potential by the way a product and its delivery is designed
o Selling a solid particulate in liquid form or encapsulating or chemically binding hazardous components
o Automatic dispensing of metered amounts as needed
o Contained in internal, noncontact components of articles
o Changing the form, e.g., from a powder to pellets or wet product
o Reformulation - e.g., replacing hazardous mixture components or impurities with less hazardous materials.

• **Pollution control technologies**
  o Guidance on how to collect, recycle and reuse or treat hazardous wastes containing the chemical
  o Product recycling or reuse programs

• **Engineering controls** on process equipment that prevents loss to the environment or workplace
  o Closed systems design
  o Local exhaust

• **Personal protective equipment** to be relied upon only when engineering controls are not feasible and accompanied by instructions where necessary
  o Described in MSDS in sufficient detail
  o Provide guidance on detection in workplace

• **Transportation and safe handling measures**
  o Use dedicated storage and transportation equipment or provide special training for involved personnel
  o Qualify carriers in safe product handling practices and equipment
  o Test packaging under unique situations that may exist
  o [The CIAC TEAP III Transportation Risk Management Guide](#)

• **Use restrictions** when adequate exposure control technologies are not feasible or not reasonably expected to be practiced by downstream users
  o Requiring additional assessment and/or training prior to use
  o Distributor agreements to comply with market restrictions and to provide feedback on new uses and other product safety observations
  o Sales restrictions to countries with inadequate hazardous waste management infrastructure

3. **Risk Management Actions by Functional Corporate Area from ICCA Guidance on Risk Assessment**
Risk management can range from providing hazard and safe handling information via (Material) Safety Data Sheets and labels, to requiring customers to demonstrate the ability to safely receive, store and use the chemical prior to sale. If the customer fails to demonstrate the ability to safely handle the chemical, the supplier should take steps to help
the customer improve its practices. Below are some additional risk management options, though many other risk management actions are possible:

A. Chemicals
   1. Manufacturing specifications.
   2. Product hazard classification.
   3. (Material) Safety Data Sheets.
   4. Classification and packaging labels.

B. R&D
   1. Sourcing of alternative raw materials.
   2. Changes to product physical form to reduce exposure potential.

C. Purchasing
   1. Supplier materials contracts.
   2. Switching suppliers.

D. Manufacturing
   1. Engineering controls.
   2. Personal protective equipment.
   3. Maintenance schedules.

E. Contractors
   1. Toll-manufacturing contracts.
   2. Audits.

F. Marketing
   1. Voluntary restrictions on applications and uses.

G. Sales
   1. Customer assistance.
   2. Assessment of customer's safe handling of chemicals.
   3. Provision of advice, possibly equipment.
   4. Halt sales.

H. Distributors
   1. Product stewardship agreements.
   2. Distributor training.
   3. Audits.

I. Recycling and disposal
   1. Feasibility of recycling or reusing used and unused product or packaging.
   2. Labels, safety data sheets and other relevant guidance contain adequate disposal information.
3. Expertise available to advice on product and packaging disposal.

**MANAGEMENT PRACTICE 6: REFERENCE DOCUMENTS**

**REFERENCE 2.** ICCA Guidance on Chemical Risk Assessment

**REFERENCE 8.** Matrix comparing Product Safety Code and ACC RCMS/RC14001/GPS/Legacy Product Stewardship Code

**REFERENCE 9.** ICCA Product Safety Management Brochure – “Sound Chemicals Management as Global Responsibility”

**REFERENCE 12.** RC14001 Implementation Guidance

**REFERENCE 15.** RCMS Implementation Guidance (RC102)
7. Management of New Information

**Management Practice 7**

**Management of new information.** A process to identify and evaluate new information that may trigger changes to risk characterizations and product safety management actions. Such triggers include significant new product safety and stewardship information, including hazard, use and exposure information.

*Companies establish processes that enable new information to be brought to light and establish when and how to elevate product safety and stewardship issues within the company. New information could come from internal and external sources.*

New information about a company’s products can emerge from a variety of sources, including external scientific investigatory bodies, government agencies, downstream customers and internal employees involved in product safety and stewardship. Companies must have a process to bring new information to light and determine whether the new information affects prior prioritization, characterization and safety management decisions. The following are various strategies that companies can consider adopting to fulfill this management practice and manage new information about their products.

**Sample Strategies**

- Resources and processes are in place to actively screen literature, regulations and other information relevant to the company’s products.
  - set up search agents to monitor published literature
  - educate employees who are likely to receive pertinent product safety information (sales, technical service, EHS staff, attorneys, public relations, R&D, manufacturing, engineering, etc.) on the need to forward information quickly to product stewardship personnel for review and response
  - set up easy to use reporting mechanisms and data bases to track information
- Establish a “management of change” work process to identify new information affecting product safety information, so that product safety reviews are incorporated into your current Management of Change processes
- Set up review and approval systems for any changes that can affect product exposure throughout the life cycle whether it is caused by changes in the manufacturing process, packaging, distribution and especially new markets
- Triggers are in place to indicate when risk management re-evaluation should be initiated. Such triggers could include:
  - New markets where the nature of exposure changes such as moving from industrial use to professional or consumer uses, large increases in volumes, different geographic regions where infrastructures may be different than originally considered in new product development, new applications where the product is heated or sprayed or combined with other chemistry in unanticipated
ways, etc.
  o Incidents of misuse become known
  o New and novel applications become known
  o Injuries or allegations of injuries occur. Company TSCA 8(c) and (e) processes would be part of this management practice.
  o Business conduct helpline for use by employees or customers

**MANAGEMENT PRACTICE 7: IMPLEMENTATION RESOURCES**

**1. Company Processes For and Examples of Managing New Information**

- **Air Products Management of New Information**
  Air Products has an issue identification process within its EH&S organization. Through this process, Issue Identifiers are assigned by functional area (e.g., Product Safety) and/or geographic region. These Issue Identifiers screen information from various sources, such as ACC communications, regulatory updates, agency briefings, etc., to identify developments that may have an impact on the company. If an issue with impact is identified, it is communicated as appropriate within the function and may be assigned to an Issue Owner who will track the issues and take the appropriate steps to address the new or changed requirements, such as developing new standards, training, etc.

  For Product Safety, new issues typically include the promulgation or update of regulations and new toxicity data for chemical substances. These issues are often specific to a region, so Product Safety has established a global network of identifiers based on geography and focus area. These Issue Identifiers review developments and communicates them as appropriate to others in Product Safety and impacted businesses. Communications may be via meetings, presentations, email, or via the Product Safety website on the company’s Intranet. The new issues may trigger another work process within the department, such as the product risk assessment process. Likewise, the issues may be assigned to other members of the Product Safety team to track and manage.

- **Mitsui Chemicals Employee Hotline** for use in reporting environmental, safety and quality risks.
- **Praxair’s customer review process**

**MANAGEMENT PRACTICE 7: REFERENCE DOCUMENTS**

None
8. Product Design and Improvement

Management Practice 8

**Product design and improvement.** A process that considers health, safety and environmental impacts in the innovation, design, development, and improvement of products, their manufacture, and uses.

*Companies consider health, safety and environmental impacts when designing and improving their products, including factors such as intended use, expected product lifetime, durability, reuse, recyclability or beneficial disposition.*

As companies develop and improve their products, they take into account the health, safety and environmental impacts associated with the production of those products and their uses. Companies must have a process to consider these endpoints alongside the efficacy of the product for its intended use. Examples of the types of health, safety and environmental considerations that companies will make include energy impacts associated with the production of the product and its use; product durability; waste generation and other environmental impacts associated with the product manufacture and use; ability for the product to be reused/recycled. This management practice touches on health, safety and environmental attributes that are at the heart of many of today’s sustainability issues and corporate sustainability initiatives. The following are various strategies that companies can consider adopting to fulfill this management practice and design and improve their products while taking into account health, safety and environmental impacts.

**Sample Strategies**

- Establish and publish corporate sustainability policies that address product development and improvement
- Use your corporate websites to show the company’s commitment to minimize the health, safety and environmental effects of your products and their manufacture while maximizing the sustainability outcomes
- Include health, safety and environmental impact considerations in new product development programs
- Conduct training programs for various functions that explain green chemistry principles and other aspects of sustainability so that people responsible for product innovation are taking these things into consideration.
MANAGEMENT PRACTICE 8: IMPLEMENTATION RESOURCES

1. Company Product Development and Improvement Programs
   - Dow's Sustainable Chemistry initiative
   - BASF Eco-Efficiency Analysis and SEEBALANCE® Program
   - DuPont Product Stewardship Review Process
     From DuPont corporate website: “At DuPont there are internal Policies, Standards and Procedures specific to product stewardship and regulatory requirements that help product stewards manage the products or services that they are responsible for. For example, there is a DuPont standard that defines the requirement to complete a product stewardship review for all products before commercialization and a procedure that serves as a guide to doing the review.”
   - Bayer Commitment to Life-cycle Assessment

2. Examples of Company Product Development Programs Including EH&S Considerations
   - EPA Green Chemistry Award Recipients
   - ExxonMobil Chemical Products that Contribute to Sustainability
   - Dow Powerhouse™ Solar Shingles
   - American Chemistry Council Polyurethanes Lifecycle Database
   - Dow polymer example in ICCA GPS Sound Chemicals Management Brochure (p. 10)

MANAGEMENT PRACTICE 8: REFERENCE DOCUMENTS
None
9. Value Chain Communications, Cooperation and Outreach

Management Practice 9

Value chain communication, cooperation and outreach. Processes to work with suppliers, customers and other value chain participants to foster product safety management and information exchange along the value chain, commensurate with risk.

Commensurate with risk, companies work with and as appropriate, review customers, suppliers, contract manufacturers, carriers, distributors, contractors and third-party logistics providers based on Responsible Care or other health, safety, security and environmental performance criteria. Processes are in place to communicate, receive and evaluate product safety and stewardship information and requests from value chain participants. If improper practices involving a product are discovered, corrective measures are taken based upon a company’s independent judgment, ranging from resolving the improper practices to termination of business relationships, if necessary.

Working with the value chain to manage the safety of chemical products has long been part of Responsible Care. Participants along the chemicals value chain have unique responsibilities in the management of chemical products and the mutual sharing of information is part of this shared commitment to product safety. Companies will employ systems to share product safety and stewardship information along the value chain commensurate with the risks of the product which depend on its hazard, exposure and use. Companies will also actively work with their value chain to receive information about the use of their products and resolve improper practices, if uncovered. Processes to review value chain participants will be instituted commensurate with risk.

There is high variability in the degree of connection between participants in a chemical product’s value chain, requiring that each participant maintain its own product stewardship practices that include information sharing and risk management along the supply chain. Companies are expected to provide customers with appropriate hazard and risk information about their products to facilitate safe downstream use. Companies should rely on their knowledge of uses when providing this information, based on their typical business relationships and customer interactions.

It is important to facilitate the flow of information along the supply chain. This requires the company to develop dialogue and working relationships with suppliers, customers, and others in relevant value chains, including two-way communications between producers and downstream customers to ensure product stewardship information is shared among relevant parties. The organization will need to determine the extent of its interaction with commercial partners in the supply chain based on the product and risk involved in its handling and use. For some products, communication of basic safety and handling information in the form of a Material Safety Data Sheet may be sufficient. In other cases, a company may require its
customers to attend specialized briefings and training prior to receiving a product. The organization may also send its own personnel to a customer site to conduct on-site instruction and training. A consistent process based on risk is key to success.³

The following are various strategies that companies can consider adopting to fulfill this management practice and communicate, cooperate and reach out to their value chain.

**Sample Strategies**

- Develop standards and work processes to review ability of external manufacturers, distributors, and customers that receive hazardous products to safely manage them, as appropriate, based on risk.
- Develop a range of communication to your supply chain and customers, including training programs and agreements concerning appropriate product stewardship practices. Identify the processes used to share risk and safe handling information along the supply chain, establishing ownership and accountability for the processes.
- Review existing commercial partner communications regarding product hazards and risks, safe handling and other product stewardship information desired by your customers. Consider writing product safety provisions into contracts, commensurate with risk.
- Determine what information/guidance your organization would like to receive from a supplier and request the information.
- Conduct distributor assessments and/or have a process in place for distributors to report new product uses, product misuses and adverse effects.
- Work with other companies to share health, safety and environmental information on new applications.
- Information sharing may take place in both formal and informal settings such as:
  - online tutorials
  - at conferences, seminars and workshops
  - during the purchasing process and/or sales calls
  - during service provider selection processes
  - telephone contacts between company and service provider representatives
  - other social media contact
  - open houses and/or other outreach events
  - product associations that include multiple players throughout the value chain that share product safety information such as ACC Chemical Products & Technology Groups or panels are product-specific groups

**Definition**

Value Chain: The chemistry value chain includes the full range of activities that are required to bring a chemistry related output from its conception to its end use and beyond (e.g. design, procurement, production, distribution). Value chain activities can be contained within a single firm or divided among different firms, and can be contained within a single geographical

³ from RC102-02 Element 3.5.1 Guidance
location or spread over wider areas. (Includes products, processes, technology etc.)

**MANAGEMENT PRACTICE 9: IMPLEMENTATION RESOURCES**

1. **Company Value Chain Outreach Programs and Activities**
   - Bayer Product Safety First Program
   - Polyurethanes Walk the Talk Program
   - The Dow Chemical Company Code of Business Conduct for Suppliers
   - 3M Sourcing Sustainability Standard
   - Sika Sourcing Governance

2. **Sample Company Communications to Customers**

Mr. John Doe
Company Address
City, State ZIP
Email:

**Subject: {INSERT PRODUCT NAME}**

Dear Mr. Doe,

As part of [Company]'s Responsible Care® initiatives, before any quantity of {INSERT PRODUCT NAME} is sent to you, we want you to understand the hazards of this material and be able to handle it safely. We have enclosed a Material Safety Data Sheet for this product. In addition, we have enclosed a New Customer Questionnaire to be discussed by phone. Please read this information carefully, particularly the sections regarding the hazards, proper use, storage and safe handling. Within a few days, after you have had a chance to look over this package, a [Company] product safety representative will contact you to discuss the safe handling of {INSERT PRODUCT NAME} and any questions that you may have concerning their properties.

{INSERT PRODUCT NAME} is toxic by inhalation. This product is corrosive to the skin, eyes, and respiratory tract. {INSERT PRODUCT NAME} reacts violently with water and when released to air forms hydrogen chloride and phosphoric acid. This product is also highly toxic by ingestion. All personnel handling this product should carefully read the safety information and proper handling procedures. This material should only be used by those who understand and follow safe use and handling techniques. You are also responsible for the disposal of the containers and any unused portions according to the applicable safety and environmental regulations.

After you have received the attached literature and have been contacted by us, please sign below. This will indicate that you have read and understand the Material Safety Data Sheet and will instruct those handling this material regarding the associated health hazards and in the

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proper safety and handling procedure. This product will be shipped upon receipt of the signed letter and approval by our Product Safety Department.

Thank you for your cooperation. For further information, please feel free to contact the following personnel:

Company contact Product Safety
Company contact Product Safety

Sincerely,

Enclosure Cc:

3. Example New Customer Questionnaire

New Customer Questionnaire - {INSERT PRODUCT NAME}

As part of the [Company] Product Stewardship program, we are evaluating customers who will be handling {INSERT PRODUCT NAME}. We would like to be sure that you understand the hazards of this chemical and that you know how to handle it safely. After you have had a chance to look over the materials in this package, we will call you to discuss the questions listed below and also address any questions that you may have concerning {INSERT PRODUCT NAME}. Please also feel free to call us at any time. Thank you for your cooperation.

1. Have you read and understood the packet of information, including the Material Safety Data Sheet (MSDS) that we have provided to you?
2. Do you understand the hazards of this product?
3. Describe your experience (i.e., how long used, what used for, how processed) with other hazardous materials (which ones), including materials with similar hazards to these products.
4. Describe the process in which {INSERT PRODUCT NAME} is to be used, including materials of construction, ventilation, exhaust scrubbing and other safety devices or systems in the process. (i.e., how will you control the hazards of this product utilizing your equipment and facilities). How will material be transferred from the bulk container, describe this process. Will it be transferred from a bulk storage tank and then drawn directly into the process or will it be transferred to an intermediate vessel?
5. Who will be handling this product?
6. Specifically, what personal protective equipment will be used (will respirators be individually fitted) to control the hazards of this product?
7. Who is responsible for procuring safety equipment (e.g., protective clothing, respirators) and training employees in the proper use of such equipment?
8. Describe your worker training program. Also, who reviews safety and health information and assures employees are provided proper hazard communication training?
9. Do you have an industrial hygiene/occupational monitoring program in place to determine employee exposure(s) when handling and processing the product?
10. Describe your procedure for the admission of new chemicals into your facility.
11. Describe the first aid/medical capabilities at your facility, including location relative to where the workers are stationed (i.e., eye wash).
12. Describe how and where {INSERT PRODUCT NAME} will be stored at your facility.
13. Describe how you plan to decontaminate and/or dispose of empty drums. If you plan to have a 3rd party handle and decontaminate the empty drums, is there a procedure in place to notify the 3rd party as to the potential hazards of the product?
14. Describe your chemical emergency action plan and how you plan to deal with an emergency in the event one occurs (i.e., large spill, small spill).

4. Working with Distributors
The National Association of Chemical Distributors “Responsible Distribution” process provides third-party verification of distributors performance and systems.

MANAGEMENT PRACTICE 9: REFERENCE DOCUMENTS

REFERENCE 6. ACC Statement of Principles on Children’s Health

REFERENCE 15. RC102_02 RCMS GUIDANCE (Element 3.5.1)
10. Information Sharing

**Management Practice 10**

**Information sharing.** Public access to product safety and stewardship information.

Companies make product safety and stewardship information publicly available to enhance public knowledge of and confidence in the safe use of chemical products, while protecting confidential business information. Publicly available information includes relevant health and environmental effects and safety management measures to promote safe handling and use of products throughout their lifecycle.

Chemical products are building blocks for many other industries, sectors and consumer products. Responsible Care companies invest significant resources, through the implementation of this Code and otherwise, in managing the safety of their products along the supply chains. Providing publicly available information about the safety of chemical products can enhance the safe use of chemical products, while improving public knowledge and confidence in the safety and safe use of chemicals in general. This management practice requires companies to make safety and stewardship information about their products publicly available.

The following are various strategies that companies can consider adopting to fulfill this management practice and allow public access to product safety and stewardship information.

**Sample Strategies**

- ACC and the ICCA have developed templates for companies to use to provide the public with product safety and stewardship information through summary documents.
- Work with trade associations and other existing dialogue mechanisms to disseminate safety information.
- Use your corporate website to publish safety information.
MANAGEMENT PRACTICE 10: IMPLEMENTATION RESOURCES

Industry-wide Product Safety Information
  o The ICCA IT Portal provides searchable product safety information in the form of summaries as well as available chemical studies

Company websites that allow access to Product Safety Summaries include:
  o Bayer Material Science;
  o ExxonMobil Chemical;
  o Eastman Chemical Company; and
  o Dow Product Safety Assessment Finder

Company websites that contain a variety of product safety information, including product stewardship contact lists
  o Bayer MaterialScience
  o Dow Microbial Control - Oil and Gas Applications
  o ACI Ingredient Inventory

MANAGEMENT PRACTICE 10: REFERENCE DOCUMENTS

REFERENCE 13. ACC Proposed Elements to Include in Publicly Available Product Stewardship Summaries/Product Profiles

REFERENCE 6. ACC Statement on Principles on Children’s Health

REFERENCE 15. RC102_02 RCMS GUIDANCE (Element 3.5.2)
11. Performance Assessment and Continuous Improvement

Management Practice 11

Performance assessment and continuous improvement. Routine monitoring and assessment of product safety and stewardship, with processes in place to drive continuous performance improvement and implement corrective actions when needed.

Companies implement an internal process to monitor and assess product safety and stewardship performance, utilizing appropriate indicators. Companies report their activities associated with implementation of this Code to ACC to facilitate public understanding of the industry’s overall product safety commitment and performance.

Monitoring and assessing performance is a fundamental part of the management system “Plan-Do-Check-Act” approach. It allows companies to track their performance against objectives and make any necessary adjustments to their processes and system. Each company will report “macro-level” performance information to ACC in terms of their progress on implementation of the Code through annual attestation statements in years 2014 - 2016. Additionally, companies are required to identify “micro-level” product safety and stewardship performance indicators that it will use internally to track and drive performance improvements.

The following are various strategies that companies can consider adopting to fulfill this management practice and monitor, assess and continuously improve their performance.

Sample Strategies
- Set and evaluate progress toward goals for implementation of each of the Product Safety Code management practices on a regular basis with management.
- Track product safety indicators at both the corporate and facility level.
- Incorporate Product Stewardship Code elements into your RCMS evaluation/audit program.
- Use the Responsible Care Management System review process to set product safety goals following the same processes used in the RCMS of setting goals and reviewing progress to monitor performance and drive improvements over time.
MANAGEMENT PRACTICE 11: IMPLEMENTATION RESOURCES

1. Corporate Product Safety Performance and Tracking Programs
   - Dow Chemical quarterly public Sustainability Reporting, tracking the goal “increase the percentage of sales to 10% for products that are highly advantaged by sustainable chemistry” and “publish product safety assessments for all products”
   - Akzo Nobel Supplier Management Program, Measurement and Tracking
   - Bayer MaterialScience Sustainable Development Reports
   - LANXESS Performance Assessment and Continuous Improvement
   - ExxonMobil Chemical Corporate Citizenship Report

2. ACC Reporting of Product Safety Performance
   ACC will collect an annual attestation from each member company on its progress in implementing the Code and its individual elements, as was the case with the Responsible Care Security Code. The staged implementation deadlines for Code elements, to be reported on annually by companies through ACC Executive Contact attestations, are as follows:

<table>
<thead>
<tr>
<th>Management Practice</th>
<th>Implementation Deadline</th>
<th>Verification Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>12/31/14</td>
<td>ACC Executive Contact attestation</td>
</tr>
<tr>
<td>4-7</td>
<td>12/31/15</td>
<td>ACC Executive Contact attestation</td>
</tr>
<tr>
<td>8-11</td>
<td>12/31/16</td>
<td>ACC Executive Contact attestation/RCMS certification</td>
</tr>
<tr>
<td>All (1-11)</td>
<td>Beyond 2016</td>
<td>RCMS/RC14001 certification</td>
</tr>
</tbody>
</table>

The Implementation Affirmation Statement will be an attestation that the relevant management practices have been implemented. If companies are moving ahead of the ACC schedule, their attestations could include management practices beyond the minimum requirements.

MANAGEMENT PRACTICE 11: REFERENCE DOCUMENTS

REFERENCE 15 - RCMS Implementation Guidance (RC102)
V. Reference Documents

1. Recommendation for Developing and Disseminating Hazard and Exposure Data: The Integrated Tiered Testing and Assessment Approach

2. International Council of Chemical Associations (ICCA) Guidance on Chemical Risk Assessment

3. ACC Science Principles on Animal Testing and Alternative Methods

4. ACC Science Principles on Exposure Assessment

5. ACC Statement on Weight of the Evidence

6. ACC Statement of Principles on Children’s Health

7. ACC PBT Policy


10. ACC Prioritization Tool

11. ICCA Product Stewardship Guidelines

12. RC14001 Implementation Guidance

13. ACC Proposed Elements to Include in Publicly Available Product Stewardship Summaries/Product Profiles

14. Product Safety Integrated Assessment References

15. RCMS Implementation Guidance (RC102)
REFERENCE 3.

ACC Science Principles on Animal Testing and Alternative Methods

Recognizing that responsible use of animals in research and testing will continue to be required to protect human and animal health and to safeguard the environment, when animal testing is necessary, the Council is firmly committed to minimizing the use of laboratory animals. The Council is equally committed to conducting animal research in the most humane ways possible.

At this time, science depends on the use of animals (primarily rodents) to predict the effect a chemical may have on humans and other species. Animal testing is a way to collect scientifically valid information that domestic and international policy-makers, the public and manufacturers need to help ensure public health and safety. In the absence of human data, chemical research and testing with laboratory animals is the most reliable means of detecting toxic properties and for estimating risks to human health and the environment. In addition to large-scale research programs, chemical manufacturers are required by state and federal laws to test individual products. These investigations rely on validated, predictable, reliable test methods that are accepted by regulatory bodies, not experimental methodologies.

Given the above, the American Chemistry Council:

I. Encourages the use of alternatives to animal testing when these alternatives are scientifically valid and predictive and acceptable to regulatory bodies.

   A. Reliable alternatives to animal testing are not presently available for every type of toxicity testing now required. Research to reduce, refine or replace the need for laboratory animals should continue. Alternative methods need to be proven as suitable replacements for currently accepted methods. They need to provide an appropriate level of understanding to address concerns for human health and the environment with an adequate degree of scientific certainty.

   B. Some of the alternative methods provide limited information that is relevant to a very specific test condition and may not adequately predict results in a complicated organism such as humans.

   C. As new methods and techniques are developed and applied the Council will work collaboratively to reduce the use of animals.

II. Works to implement tiered (phased) testing approaches that use results-based prioritization to focus testing on chemicals of greatest concern to public health,
thus reducing the total amount of testing and animal research necessary to protect public health.

III. Supports using hazard and exposure data to prioritize substances for further evaluation, which provides more efficient use of resources, including laboratory animals.

IV. Supports integrating various government and industry chemical evaluation initiatives and, when conducting initial hazard assessments, grouping chemicals with similar characteristics, reducing duplication of testing and, therefore, the total number of laboratory animals required. Supports coordinated testing programs that help avoid the need for individual countries or industries to duplicate testing on the same chemicals.

V. Encourages agencies to work proactively with the Society of Toxicology, the American Association for Laboratory Animal Care (AALAC), and other similar professional organizations and stakeholder groups to address laboratory animal welfare concerns related to regulatory testing policies and procedures.

VI. Encourages agencies to work within the framework of the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), and internationally within OECD, to ensure the scientific acceptability of alternative test methods.
REFERENCE 4.

ACC Science Principles on Exposure Assessment

The American Chemistry Council believes that exposure assessments should meet recognized standards of good practice for completeness, communication, and documentation. They should be conducted using a "tiered" approach whereby exposure assessment procedures are selected based on the current need for, and availability of, exposure information.

I. Exposure assessments should strive for verified adequacy and transparency at all “tiers” and assure that the process is structured and documented so that others may understand the assumptions made and the approach used and can thereby reproduce the results.

II. Tiered exposure assessments should be guided by risk management needs and available information. Because exposure assessment methods of differing complexity are espoused in various initiatives, a tiered exposure assessment framework meets the diverse needs of these initiatives. By following a tiered approach, exposure assessors can efficiently find the level of complexity that is appropriate given the available exposure assessment data and other aspects of a chemical product’s development stage, its sources, its intended uses, or its known hazards.

III. Exposure estimates should reflect the understanding of the chemical’s distribution and fate in the environment and its intended uses and reasonably foreseeable misuses. Further, the exposure assessment’s objectives (assessing the potential exposure of people, ecological receptors or both), as well as the state of the available data, should guide the assessment’s design. Given the tier and the exposure assessment assumptions, the results should be physically, chemically, biologically, and logically plausible.

IV. A complete, transparent and well-documented exposure assessment will do the following:

A. Identify all significant assumptions and areas of uncertainty;

B. Provide a quality assurance review of the data and calculations used in the exposure assessment;

C. Verify that models are appropriate for the use, with their strengths and limitations clearly described and include documentation of models used and other inputs so modeling can be replicated and verified;
D. Include sensitivity and uncertainty analyses as appropriate given the assessment methods used;

E. Clearly identify emission sources, intended uses, reasonably foreseeable misuses, and scenarios with the most potential for significant exposure;

F. Discuss the exposure assessment limitations, its range of validity, and appropriate interpretation of the results;

G. Consider the potential need for and form of peer review and the potential for public access to the assessment, as well as the documentation, transparency and communication aspects of the exposure assessment; and

H. Evaluate the reasonable maximum exposure to define the upper bounds of potential risk.

I. Employ probabilistic approaches where the importance of the assessment and resources warrant.
REFERENCE 5.

ACC Statement on Weight of the Evidence

The American Chemistry Council supports a “weight of the evidence” approach for evaluating the toxicity of chemical substances and other scientific questions pertaining to human health and the environment. This includes a data collection step during which available credible data are sought and a data evaluation step during which the relevance, quality, and significance of the data are weighted.

Chemical regulation must be based in science. Since studies vary in quality and results, the full range of scientific data, including toxicological studies, epidemiological studies, clinical studies when available, and other pertinent data must be evaluated and considered.

Studies can have positive or non-positive outcomes – that is, they support or do not support findings of an adverse effect for a particular substance. They can be of different quality – that is, they can be conducted under standard Good Laboratory Practices or peer-reviewed, or they can lack these quality assurances. When the information on results and quality are all taken together, an understanding of what is known or unknown and with what level of confidence should result. This weight of evidence evaluation is the most reasonable approach to informed evaluation and decision-making.

Although there is no universally accepted framework, the Council supports a weight of evidence approach that, at a minimum, contains the following:

I. A critical examination and “weighing” of results from available credible studies to determine the extent to which a consistent and biologically plausible scientific understanding of adverse effects emerges.

II. At least two basic components:

   A. A data collection step during which available studies are searched for in the published literature and other sources, with the goal of ensuring that the breadth of reasonably available information is gathered for a particular decision.

   B. A data evaluation step that considers the following issues: 1) The data relevance, 2) The data quality (including the extent of peer review), and 3) The data significance (the “weight” it deserves).

III. In an objective manner, a weight of evidence evaluation considers the adequacy, strength, and consistency of the each study, and in turn, the overall data set. The following factors add to the weight of the evidence that a substance has the potential
to pose a risk to humans (or other species). Concomitantly, absence should subtract from the overall weight of evidence:

- Similar results in independent studies by different investigators;
- Similar effects across species, strains and routes of exposures;
- Clear evidence of a dose-response relationship;
- A scientifically plausible relationship between mode or mechanism of action, the effect of concern and data on absorption, distribution, metabolism and excretion;
- Similar toxicity exhibited by structurally related compounds;
- Scientifically supported link between the chemical and clinical evidence of the effect of concern in humans, or evidence at the population level in other species.
- Where there is a lack of concordance in the overall data set, decisions should be based on the preponderance of available data; in certain cases, development of additional new data may be beneficial to resolve conflicting information.

IV. Positive studies do not inherently deserve greater weight; higher quality studies, positive or negative, do.
REFERENCE 6.

ACC Statement of Principles on Children's Health

Protecting the health and well-being of children is a fundamental value the chemical industry shares with society. Children live safer, more healthful lives thanks to the development of chemical products and technologies that improve public health and safety.

Children also benefit by the chemical industry's enduring commitment to health and environmental research. This research is the cornerstone of the American Chemistry Council’s commitment to the protection of public health, and the health and well-being of children.

ACC’s Responsible Care® initiative, a condition of association membership, represents a commitment by our members and partners to make continuous progress toward a shared vision of no accidents, injuries or harm to the environment. Through Responsible Care, the Council’s members and partners pledge to operate in ethical ways that benefit society, the economy and the environment. American Chemistry Council believes that health, safety and environmental protection policies are most effective when they incorporate risk-based priorities and cost effective decision-making. The Responsible Care initiative embodies these values and has led to continuous health, safety and environmental performance improvement.

While great progress in protecting children has been made, real risks remain. These risks include accidents, violence, alcohol and drug abuse, tobacco use, poverty, nutrition, infectious diseases, child abuse, and potential environmental hazards, to name only a few.

The chemical industry will continue to work with domestic and international governments and other stakeholders to help ensure that children’s health initiatives:

1) Protect children.
2) Rely upon a scientific foundation for risk-based decision making by government, industry and other stakeholders.
3) Focus resources on those issues of greatest concern to children.
4) Provide relevant information in a context that policy makers, parents and concerned citizens can understand.
5) Build on existing government and industry research and testing programs to ensure global harmonization and mutual acceptance of data to improve corporate and regulatory decision making.

1) Protect children.
   - Research and testing should address any unique susceptibilities and disproportionate exposures of children to natural substances and synthetic chemicals.
• Data generated from research and testing initiatives should be relevant to the protection of children and incorporate previously developed exposure and hazard information from peer reviewed scientific literature and other sources.

2) **Rely upon a scientific foundation for risk-based decision making by government, industry and other stakeholders.**
   • Risk considerations should guide priority setting for all public and private health and environmental initiatives. Comparative risk is a tool for better, more cost-effective decision making. Risks to children’s health should include consideration of all risk factors, not just chemicals.
   • With respect to potential chemical hazards, priority should be given to research initiatives that will improve government and industry’s ability to better understand the role and magnitude of children’s exposure to and risks from chemicals.

3) **Focus resources on those issues of greatest concern to children.**
   • Proper prioritization of risks and allocation of resources requires an informed, fully engaged public. Policy makers, industry, children’s advocates, the medical and scientific communities, and the public need to work in partnership to ensure that the greatest threats to children’s health and safety are identified and addressed in a timely fashion.
   • In addressing exposures to chemicals as part of the broad range of issues affecting children’s health a tiered evaluation approach is the most effective method to ensure proper prioritization of concerns and allocation of resources. Tiered evaluation can provide greater protection of children because it focuses testing on chemicals of greatest concern to children and on chemicals that reflect actual exposures encountered by children.

4) **Provide relevant information in a context that policy makers, parents and concerned citizens can understand.**
   • Information on relative risks to children from chemicals and all other risk factors should be communicated to improve the public’s understanding of the issues.
   • Data generated from governmental and industry initiatives should include hazard, exposure and risk information in a simple, easy-to-understand format for policy makers and the public to make informed, educated decisions.
   • When chemicals are selected for more extensive scientific evaluation, existing hazard information should be accompanied by information on exposure and likely risk so that risks can be clearly understood and interpreted.

5) **Build on existing government and industry research and testing programs to ensure global harmonization and mutual acceptance of data to improve corporate and regulatory decision making.**
   • The chemical industry continues to participate actively in many important research and testing initiatives throughout the world that will assist scientists, policy makers, and the public better understand how chemicals interact with human health. The
following programs are examples of the chemical industry’s commitment to research and testing that should serve as building blocks for future initiatives:

a. ACC’s multi-year Health and Environmental Effects Research Initiative (approximately $25 million per year).
b. The Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) program.
c. High Production Volume Chemical (HPV) Challenge.
d. EPA’s Endocrine Disruptor Screening Program (EDSP).
e. New testing initiatives should build upon data from existing testing programs.
f. New testing initiatives should rely upon existing statutory authorities whenever feasible, (e.g., Toxic Substance Control Act – TSCA) and build on statutory goals and requirements, including risk based objectives and due process protections.
The chemical industry is committed to reducing the risk from PTB materials (chemical products, by-products, and wastes) as identified and managed by the following process of:

1. Committing to engage in the development and implementation of a process for identifying materials for risk management, based on sound science and professional judgment, and considering persistence, toxicity and tendency to bioaccumulate. Whether applied voluntarily by individual companies or codified through public policy mechanisms, the process should include:

   - Evaluating persistence and bioaccumulation with guiding criteria;
   - Evaluating toxicity;
   - Evaluating likely exposures; and,
   - Conducting a risk characterization.

The process of evaluating and identifying these materials should be evergreen, reflect new scientific data, and provide a mechanism for re-evaluating materials as new information becomes available or scientific understanding evolves.

2. Applying prompt, appropriate risk management action to materials identified through this process. Whether applied voluntarily by individual companies, or by public policy mechanisms, selection of the appropriate risk management action should:

   - Consider the full range of risk management options;
   - Consider the associated costs and benefits of the risk management options;
   - Consider current risk management activity;
   - Consider current and future product benefits; and,
   - Reflect sound science.

Voluntary industry risk management is the preferred approach in order to encourage rapid, efficient and innovative actions;

3. Committing to place a high priority on voluntary risk characterization and management of PTB materials, through Product Stewardship and Pollution Prevention;

4. Participating in the public policy debate around the PTB issue with all stakeholders in appropriate forums; and,

5. Partnering and cooperating with government to engage discussions and policy decisions that address PTB materials.
IDENTIFICATION OF PTB MATERIALS VIA SCREENING AND RISK CHARACTERIZATION

One of the most critical elements of the PTB debate is the definition and identification of specific chemicals. Most stakeholders enter the public policy debate wielding a "short list" of PTB materials for immediate action (often bans or phase-outs; in the case of Canada, “virtual elimination”).

This policy does not propose a specific U.S. industry list. Instead, consistent with CMA policies promoting use of sound science and risk, this policy proposes a stepwise process to identify PTBs that begins with screening criteria for persistence and bioaccumulation, followed by an evaluation of toxicity, consideration of likely exposures, and culminates in a risk assessment.

Working drafts of criteria for persistence and bioaccumulation and guidance on evaluating toxicity have been developed [see Attachment El by an ad hoc group of technical specialists from various companies and CMA and CCC committees. Because the criteria are intended to be used as an implementing tool to support this policy, a specific approval of these definitions is not being requested. It should also be noted that the draft criteria are likely to be modified somewhat with further technical review, scientific debate and discussion at the international meetings.

The criteria and guidance will serve a dual function. They will help member companies internally identify materials that are PTBs for risk management through existing Responsible Care® programs. The criteria and guidance will also support advocacy efforts in international arenas where global definitions for PTB criteria will be negotiated and established. The criteria can be employed as useful screening tools to narrow the universe of substances that require an evaluation. However, even then, a significant degree of professional judgment is required to properly apply the criteria for persistence and bioaccumulation. This is even more true of toxicity, where the complexities of multiple endpoints, use of structural activity relationships, differences in the effects on receptor sites, and accounting for data gaps renders the setting of numeric ranges impracticable.

However, it should be noted that evaluating materials against the persistence and bioaccumulation criteria, and toxicity guidance, are only an initial step in a more comprehensive process of risk assessment needed to identify PTBs. Finally, as with any evaluation of risk, evaluation of likely exposures is also required. As noted earlier, this is especially challenging to assess for PTBs, which can be dispersed globally through a variety of media.
RISK MANAGEMENT OF PTB MATERIALS

The risk management of PTB materials is especially challenging, both with respect to Responsible Care® implementation and development of appropriate public policy. The policy establishes that the industry considers proper risk management of PTBs to be a high priority. (It does not, however, declare PTBs to be the highest priority of any company—its relative ranking internally will be determined individually by each company). Consistent with existing CMA policies addressing toxics use reduction, TSCA, the Risk Principles and Product Stewardship Code, this policy advocates consideration of the full hierarchy of risk management options when determining the appropriate course of action.

These options may include, but are not limited to:

- providing additional information and training to users of PTB materials
- instituting special packaging and transportation
- requiring use of special equipment and procedures in the manufacture and use of PTBs
- promoting the use of reasonable substitutes for specific applications
- restricting or withdrawing specific uses
- ceasing manufacture of the material
- reducing releases of by-products and wastes to air, land and water through Pollution Prevention

Selection of the appropriate risk management action must consider costs and benefits of various options and evaluate which options are most cost-effective at reducing risk. In addition, when the material under review is a product, the current and future benefits of that product should be considered, as well as the risks posed by any substitutes or by withdrawing the product from the market.
REFERENCE 8.


PSC Matrix Guide
12-1-12.xlsx
This document identifies elements that companies should consider as they develop their publicly available product stewardship summaries referenced in the ACC Responsible Care performance metrics and in the ICCA Global Product Strategy.

**GENERAL:**
The publicly available summaries should be written in layman’s terms. The document should not include specific details on testing protocols, scientific jargon and technical descriptions. It would likely be more prudent to provide very general overview of the information elements, with a caveat that more details could be available upon request.

**INFORMATION ELEMENTS**

1. **Chemical identity:** Identify the chemical or category of chemicals being addressed in the summary
   a. If using a category approach, provide justification as to why the chemicals belong in one category
   
   *Information could be derived from: MSDS, OECD SIAR, work completed for HPV, REACH and/or GHS*

2. **Uses**
   a. APPLICATIONS: Provide a brief description of the type of products that the chemical is used in (e.g., soaps, plastics, adhesive, synthetic rubber, other chemical manufacturing). Include multiple applications as appropriate.
   b. FUNCTIONS: Provide a brief description of how the chemical is used in products (e.g., solvent, function fluid, intermediate, fixing agent, reducing agent) Include multiple functions as appropriate.
   c. BENEFITS: Include a discussion of the associated benefits of chemical in the particular function(s)
   
   *Information could be derived from: OECD SIAR, work completed for IUR, E-HPV, and/or REACH*

3. **Physical/chemical properties:** Provide a brief description of available information on physical or chemical hazards related to the chemical.
   
   *Information could be derived from: MSDS, OECD SIAR, work completed for HPV, REACH and/or GHS*

4. **Health effects:** Provide a brief description on available information for human health effects (mammalian toxicity). Read across or family approach for hazard determinations could be appropriately used to describe human health effects.
Information could be derived from: MSDS, OECD SIAR, work completed for HPV, REACH and/or GHS

5. Environmental effects
   a. Environmental Fate Information: Provide a brief overview of available information related to the environmental fate for the chemical. Description can be general or by environmental compartment (e.g., soil, water, air). Indicate whether the data is derived from study test or from modeling programs.
   b. Aquatic and/or Terrestrial Toxicity: Provide a brief description of available aquatic and/or terrestrial toxicity information. Information could be derived from: OECD SIAR, work completed for HPV, REACH and/or GHS

6. Information on Additional Hazards (optional): Highlight additional hazards that may be expected when the chemical is handled, stored, used or misused. This information may include hazardous reaction products and decomposition products that may form when the product is handled/ stored/used, or misused. Information could be derived from: MSDS, work completed for GHS

7. Exposure
   a. Exposure Potential: Explain the circumstances in which exposure to the chemical might occur. Description could be in general terms, or could be broken out into exposure per sectors (e.g., worker exposure; general information on environmental releases; and/or anticipated consumer exposures) Information could be derived from: OECD SIAR, work completed for IUR, EHPV, and/or REACH
   b. Production (optional): Provide information to indicate the level of production or production capability. Information could be provided on company, regional or global level. Consider types of information already publicly available.
      i. Provide information on production volumes (manufactured and imported)
         1. Report aggregate production volumes for US from most recent EPA Inventory Update Rule database
         2. Report production volume in ranges as listed in EPA Inventory Update Rule
      ii. Provide information on nameplate capacity
         1. Report on published data on nameplate capacity
      iii. Provide information on global demand
         1. Report on published data on global demand
            Information could be derived from: OECD SIAR, work completed for IUR, EHPV, and/or REACH
8. **Risk Management**
   a. **RECOMMENDED RISK MANAGEMENT**: Provide information on recommended risk management approaches to reduce exposure potential.  
   *Information could be derived from: MSDS, work completed for GHS*
   
   b. **PRODUCT STEWARDSHIP PROGRAMS** (optional): Describe applicable product stewardship programs (e.g., restricted sales to those companies with demonstrated safety programs; specific training programs provided to downstream users, etc.)

9. **Federal/Science Agency Findings** *(optional)*: Provide information on available government and/or science agency assessments.

10. **Regulatory Compliance** *(optional)*: Identify regulations that the product must comply with.  
    *Information could be derived from: MSDS, work completed for GHS*

11. **Conclusion statement** *(optional)*: Provide a concluding statement from company or consortia on the safety or risk of the product related to the intended uses.

12. **Contact Information**: Provide contact information for persons looking for additional information
   a. Consider generic e-mail or phone number versus individual listed by name.

13. **Date**: Providing a date will allow the company and the reader to assess how current the summary is.
### Recommended elements in product stewardship summary

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<th>REACH Chemical Safety Report</th>
<th>Work in reviewing for GHS compliance</th>
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### Optional elements for product stewardship summary

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**Product Stewardship Summary Elements: Sources of Information from other Programs**

See “Elements to Include in Publicly Available Product Stewardship Summaries” above for more details on each of these information elements. This document, as well as other resources and guidance for ACC member companies are available on MemberExchange (under **Health, Product Stewardship and Chemical Regulation**).
REFERENCE 14.

Product Safety Integrated Assessment References

[Excel sheet reference from R. Becker]