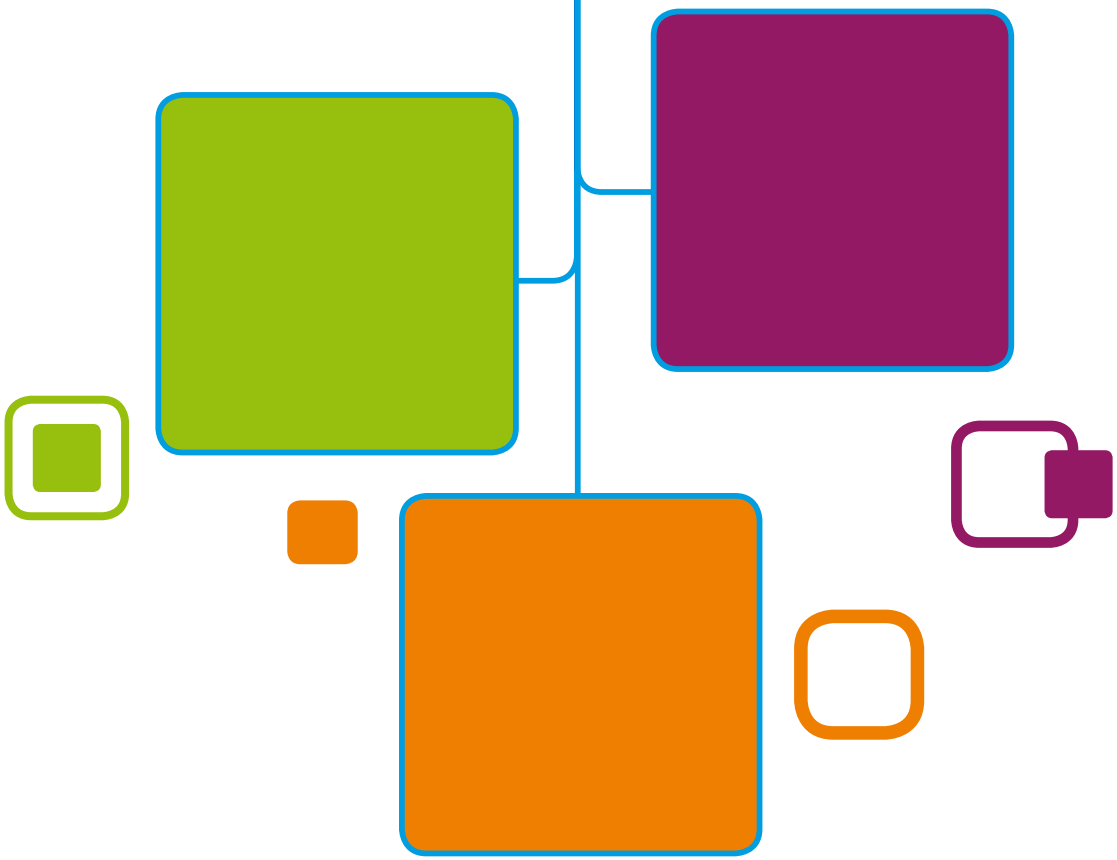
INTERNATIONAL COUNCIL OF CHEMICAL ASSOCIATIONS

ICCA Regulatory Toolbox

Guidance on the Introduction or Revision of Legislation on Chemicals Management for Developing Countries



1st Edition - 2013

BACKGROUND

ICCA believes the most effective and efficient chemicals management is achieved through a combination of science and risk-based regulation and voluntary industry initiatives such as Responsible Care and the Global Product Strategy (GPS). Responsible Care and GPS are the chemicals industry's key voluntary contributions to UN's Strategic Approach to Chemicals Management (SAICM). Many developing countries currently lack adequate regulatory frameworks for managing chemicals. ICCA is collaborating with the United Nations Environmental Programme (UNEP) under a joint Memorandum of Understanding to, among other things, develop guidance for governments for improving their chemical management systems with a goal of having them science and risk-based and more globally harmonized.

GPS fulfils the requirements of a modern chemical management system. ICCA views GPS as an example of a best practice and believes it could serve as a basis for new or improved regulation in developing countries.

To support local governments we are developing this toolbox to provide guidance on how to integrate GPS elements into national legislation concerning chemical management.

Our aim is to contribute to coherent chemicals management globally based on common principles, which will:

- Reduce the differences in the safe handling of chemical substances between developing, emerging and industrialized countries;
- Minimize costs and complexity for the local industry to comply with regulation;
- Eliminate or reduce non-tariff barriers to trade.

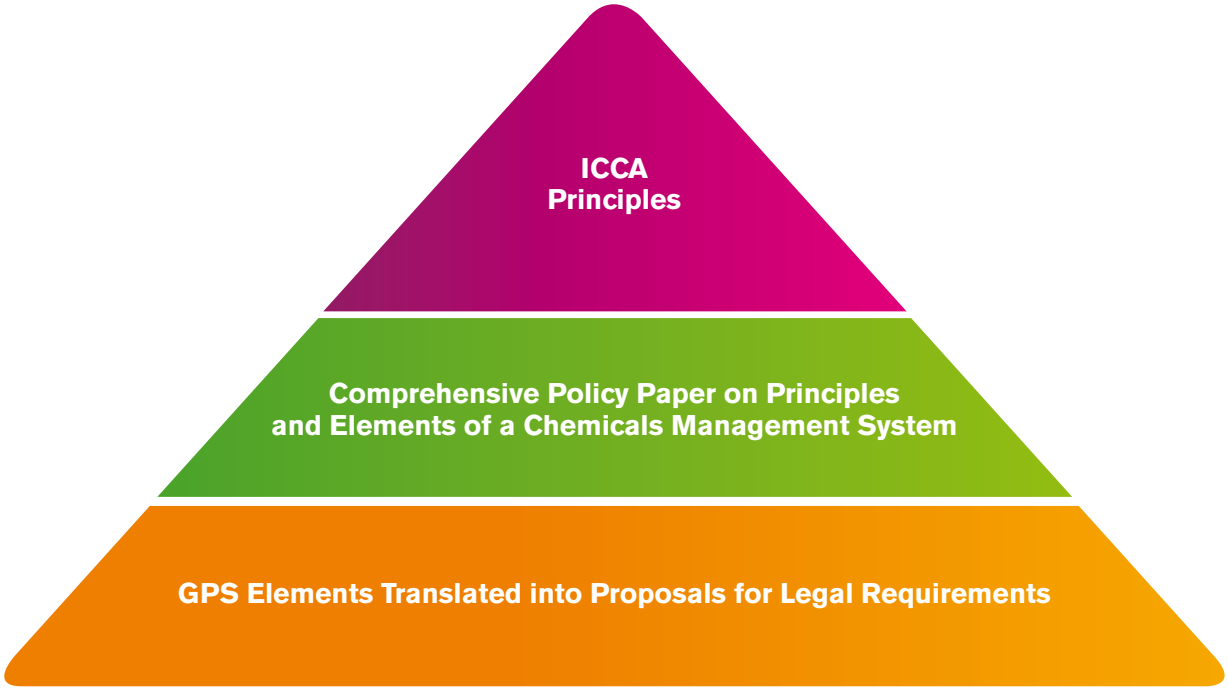
Guidance
All references to the "GPS Guidance on Chemical Risk Assessment" can be accessed on **www.icca-chem.org** (Home > Publications > Brochures)

INTRODUCTION TO THE TOOLBOX

This toolbox primarily gives guidance to governments in developing countries considering introducing or revising their legislation/regulation on chemicals management.

It covers principles as well as a more detailed description of the GPS elements and how they can be introduced into national legislation. The toolbox consists of modules in order to take the different situations of countries into account.

The Regulatory Toolbox consists of three parts with increasing level of details:



- Guidance on Principles that should underpin chemicals management;
- Guidance on the different elements of a framework for chemicals management and their order of importance based on industry's experience of regulation implementation;
- Practical examples of how GPS principles and elements fit into a national regulatory system.

ICCA Principles

The "Principles" are based on ICCA chemicals management principles first promulgated in 2001 and updated in 2006. They are divided into: general principles which reflect fundamental aspects of a regulatory system for chemicals, and principles related to *risk assessment* of chemicals in a regulatory framework.

The principles provide the framework for the GPS regulatory toolbox and are then developed into more detailed guidance in the remainder of the toolbox.

General Principles

- Definition of respective responsibilities of industry and competent authorities;
- Transparency and consumer confidence;
- Explicit and transparent risk management framework;
- Conformity with international trade rules;
- Reward sustainable innovation.

Principles Related to Risk Assessment and Communication

- Scope;
- Science based risk-assessment;
- Prioritization for assessment of chemicals of highest concern;
- Quality and extent of data;
- Shared responsibility between suppliers and downstream users and communication of information through the supply chain;
- Facilitate and take advantage of mutual acceptance and exchange of data and assessments;
- Utilise alternative approaches to minimise animal testing.

Comprehensive Policy Paper on Principles and Elements of a Chemicals Management System

This part of the toolbox illustrates industry's experience in implementing regulatory frameworks, which should be considered in the development of a national chemical management system. It explains some of the principles in light of companies' experiences and addresses the key elements of a chemicals management system. Furthermore it identifies how ICCA GPS can reinforce parts of a national regulatory framework.

This part must be viewed in the context of UNEP's LIRA Guidance[1]. It complements the work of UNEP. Industry supports the objectives of the LIRA Guidance to provide practical, step-by-step support to policymakers to strengthen the sound management of chemicals.

The Guidance includes General Considerations on Accountabilities, Information Sharing, Transparency, CBI and Funding, and identifies how GPS can contribute i.e. through Development of Inventories, Classification and Labelling, Prioritization, Safety Determination, and Risk Management.

GPS Elements Translated into Proposals for Legal Requirements

The last and most detailed part of the toolbox consists of a set of examples (modules) showing how GPS elements could be introduced into national legislation. It focuses on introducing risk assessments into the regulatory framework. The GPS methodology has been developed in particular for developing countries and small and medium sized companies and references are made to the GPS Guidance. The following modules will be available: Scope, Prioritization, Data requirements, Tiered risk assessments and Risk Management (safe use).

[1] Guidance on the Development of Legal and Institutional Infrastructures for Sound Management of Chemicals and Measures for Recovering Costs of National Administration.

PRINCIPLES FOR CHEMICALS MANAGEMENT

The global management policy elements described below are based on ICCA principles first promulgated in 2001 and updated in 2006. They are divided into two sets of "principles", general principles which reflect fundamental aspects of a regulatory system for chemicals and principles related to risk assessment of chemicals in a regulatory framework.

The principles provide a framework for the GPS regulatory toolbox. In the different modules of the toolbox the principles are translated into more detailed guidance.

General Principles

Definition of Respective Responsibilities of Industry and Competent Authorities

- Industry is responsible for undertaking safety assessments (including exposure and hazard information) and implementing risk management measures to ensure that chemicals can be managed safely through the value chain and are safe for their intended uses;
- Competent authorities are responsible for the oversight or evaluation of industry sponsored safety assessments within a defined framework. Evaluation will normally take place according to a defined system of prioritization based on a combination of hazard and likelihood of exposure;
- Safety assessments may be submitted on request of competent authorities or based on some other mechanism dependent upon the form of individual legislations;
- Enforcement authorities shall provide for a level playing field.

Transparency and Consumer Confidence

- There is a need for an instrument or mechanism to maintain a record of chemicals in commerce within a given jurisdiction;
- There is a need for a system to provide the appropriate notification to competent authorities and review as new chemicals enter commerce;
- There should be systems that facilitate the use of available information about exposure, use, hazard and risk assessments generated under programmes in other countries and regions;
- There should be a framework to ensure fair compensation to companies for the costs of generating the information and conduct safety assessments;
- Provide access to meaningful and relevant information regarding hazards, exposures and risk management of chemicals in commerce based on safety data sheets and GPS safety summaries;
- Advance and promote cooperation between industry (throughout the supply chain) and other stakeholders to educate and inform consumers on chemical risks and safe handling practices;
- Advance classification and labelling requirements so that information is understood and relevant for targeted end user on the basis of UN GHS.

Explicit and Transparent Risk Management Framework

- Employ an explicit and transparent framework for science-based and proportional risk management measures;
- Ensure that science- and risk-based assessment is the foundation of any regulatory mandated risk management measures. The risk assessment should be a separate process from risk management;
- Define when/how other considerations (e.g., socio-economic) will be incorporated and establish a transparent process in risk management decisions;
- Promote international harmonisation of risk management practices.

Conformity with International Trade Rules

- Ensure conformity with international rules, and in particular the WTO Technical Barriers to Trade Agreement.

Reward Sustainable Innovation

- Address regulatory barriers to innovation;
- Recognise innovation as central to the development of sustainable solutions for products, processes and services.

Principles Related to Risk Assessment

Scope

- Chemicals in commerce excluding those chemicals and/or uses covered by other laws (e.g., drugs, pesticides etc.), as well as appropriate exemptions for certain low risk/exposure substances. New and existing chemicals to be evaluated using common criteria to a consistent standard of risk assessment and standardized approach to risk management (not necessarily but preferable via a common regulatory pathway);
- Appropriate exemptions for R&D and testing to encourage rather than inhibit development of new chemicals;
- Clarity on scope vis-à-vis chemical substances incorporated within mixtures and articles note: if the provisions cover chemicals in imported articles or not and vis-à-vis chemical intermediates (that are consumed in chemical reactions) and polymer variants.

Science-based Risk Assessment

- Employ scientific risk-based assessments that incorporate internationally recognised principles and practices to protect and ensure human and environmental safety;
- Risk assessment for evaluating and managing ingredient and product safety requires information on use, exposure and hazard;
- Promote science and risk based approaches to emerging issues.

Prioritization for Assessment of Chemicals of Highest Concern

- Prioritization of chemicals based on combination of hazards and probable exposures;
- Efficient prioritization which allows a focus on substances of highest concern first, and then defines which substances may be of "medium/low/no concern" and may thus be subject to lighter/no assessment.

Quality and Extent of Data

- Identify and employ an appropriate information set on identity, uses, exposures and properties (including hazard);
- Maximize use of existing data and information;
- Evaluate data for safety assessment purposes based on explicit quality and weighting criteria (without prejudice to source, age, etc.).

Shared Responsibility between Suppliers and Downstream Users and Communication of Information through the Supply Chain

- Share/divide responsibility for safety of chemicals along the supply chain and for compliance (including information collection and data generation) between the chemical manufacturers and the downstream industries depending on who has control of the chemical at a particular stage of the life-cycle;
- Facilitate bidirectional flow of information along the supply chain between the suppliers and downstream users.

Facilitate and Leverage Mutual Acceptance and Exchange of Data and Assessments

- Leverage exposure, use, hazard information and risk assessments employed in regulatory or voluntary chemical management programmes in other countries and regions;
- In particular, mutual acceptance of notifications/registrations from other countries should be established. Alternatively, the requirements should be based on complete compatibility with already existing programmes.

Utilise Alternative Approaches to Minimise Animal Testing

- Incorporate validated and accepted alternatives on methods and approaches to chemical risk assessment, including those that do not involve animal testing;
- Promote the development, validation and acceptance of methods that do not involve animal testing.

CHEMICALS MANAGEMENT ASPECTS AND ISSUES

The chemical industry globally, organized under the umbrella of the International Council of Chemical Associations (ICCA), and UNEP share the objective to provide practical, step-by-step support to policymakers to strengthen processes to achieve the sound management of chemicals. Whereas ICCA has developed and is committed to implement the Global Product Strategy (GPS)[2] to achieve this objective, UNEP has recently developed the so-called Guidance on the Development of Legal and Institutional Infrastructures for Sound Management of Chemicals and Measures for Recovering Costs of National Administration (LIRA-Guidance).

[2] Global Product Strategy, International Council of Chemical Associations Guidance on Risk Assessment, 2nd edition 2011.

The purpose of this paper is to offer comments that may be taken into consideration, specifically when chemical management requirements are introduced for the first time for instance in developing countries and economies.

Specifically, approaches are offered that:

1. Identify how the ICCA Global Product Strategy (GPS) can support parts of a national regulatory framework;
2. Identify and share industry learning regarding the implementation of regulatory frameworks that should be taken into consideration in the development of a national chemical control process.

The focus is on the aspects and issues that are of key importance to any chemicals management system:

- Accountability of public and private sector, including funding and capacity building;
- Risk Based Prioritization;
- Chemical Inventories;
- Classification and Labeling;
- Risk Assessment;
- Risk Management;
- Information Sharing, Transparency and Confidential Business Information;
- Funding of Chemicals Management systems.

Accountability of Public and Private Sector

The following are key elements of any voluntary or regulatory chemicals management system:

1. Identification and assessment of chemicals' hazardous properties and risks (including pre-marketing/manufacturing testing and classification), labeling and development of safety data sheets, updating of the information base when required;
2. Dissemination of hazard, risk and safety information to customers and encourage others to forward relevant information (to others further down the value-chain);
3. Making informed choices of chemicals to be placed on the market considering the hazards, risks and safe-handling conditions;
4. Organization of safe use;
5. Compliance monitoring.

Industry supports the position that the safety of chemicals placed on the market is a *shared responsibility* between the public and private sector, (including between chemical manufacturers and users). Both sectors have to provide expertise and capacity to execute their duties. Whereas governments of individual jurisdictions have the right to allocate tasks between parties of the public and private sector, it is the view of industry that a global consistent approach provides the highest efficiency with respect to the achievement of safe use of chemicals globally. Therefore through a global approach will the highest level of confidence in the safety of chemicals be achieved.

Responsibilities of the Industry

Industry believes that it owns the responsibility for making informed choice of chemicals to be placed on the market. In that process the industry has to make technical and economic trade-offs to provide products that provide a level of performance, but also are safe for intended use. Many companies in the industry have embedded pre-marketing/manufacturing reviews under a Sustainable Development framework and have aligned it where applicable, with their Responsible Care commitments.

Chemicals placed on the market have been reviewed and selected to provide the most viable solution. The key is the Risk Assessment conducted by industry – to ensure that the chemical can be used safely. In order to conduct a high quality risk assessment the industry has also the task to collect information on hazard properties as well as use related exposure information. Gathering knowledge about the uses and conditions of use of chemicals placed on the market should be part of the Product Stewardship program (i.e., GPS implementation) implemented by each supplier of chemicals.

Chemical producers should also be responsible for the integrated analysis of the appropriate Risk Management measures that should be applied based on hazard and foreseeable use. They should further work with the supply chain to the extent practical to ensure those conditions are met. Risk Management measures may include safe handling guidelines, use of specific procedures and precautions and use of engineering controls, in order to ensure safety of humans and the environment. Risk management measures should represent a minimum standard of care and should be applicable to identical exposure scenarios regardless of the country where the product is produced and marketed. By applying adequate risk management measures chemicals can be used safely and control measures like bans and restrictions will only be necessary in exceptional cases.

Industry has the responsibility to disseminate the outcome of risk assessments and guidelines for safe use into the supply chain, usually in the form of safety data sheets.

Global Product Safety Summaries[3] produced under the auspices of the Global Responsible Care initiative are offered as a complementary instrument to assist others to have access to understandable information sufficient to help responsibly manage chemicals. They are also available to the public, an important stakeholder of both industry and the regulating body. These Global Product Safety Summaries can be supported by safety data sheets or other relevant information.

The Role of Authorities in Chemicals Management

The primary role of authorities is to ensure that that all actors along the supply chain are executing their duties to support the safe management of chemicals. Authorities therefore have an important oversight and enforcement role.

Secondly regulatory authorities should make an informed decision regarding priorities and pace of implementation of a new regulatory framework.

When incidents do occur in the handling of chemicals, the public sector should lead the process to identify causes and ways to avoid re-occurrence. Industry should readily cooperate in the process to lend knowledge and expertise and implement agreed upon remedial activities. Responsibility for incidents (immediate response or remediation, investigation, learning and corrective action) needs to closely align with the local legal framework.

[3] Global Product Strategy (GPS) was developed by the International Council of Chemical Associations (ICCA) as part of its commitment to the United Nations Strategic Approach to International Chemicals Management Program. GPS provides for the preparation of GPS summaries on chemicals placed on the market.

Shared Responsibility for Funding and Capacity Building
A goal is to have comparable performance globally. However, the mode of implementation needs to be adapted to local conditions as to the maturity of both industry and authorities.

Authorities have a responsibility to ensure that both the public and private sector are well prepared and trained and that capacity, expertise and funding mechanisms are in place prior to introducing more sophisticated regulatory schemes. Industry has role to support the authorities, particularly with respect to sharing product risk information and building capacity within the industry. More highly resourced and globally active companies should play a role in building capacity both within the industry as well as on the side of the authorities.

Finally the authorities have to ensure a funding mechanism for the implementation of a chemicals management system in their country. Only through sustainable funding are the continuity of implementation and ultimate achievement of the objectives of chemicals management guaranteed. Industry should expect to play its part in funding, e.g. through the payment of fees to reimburse authorities on a proportionate basis for legitimate costs incurred in administering chemicals management systems.

Prioritization

Each country should determine the priority and pace for implementation including deciding whether sufficient awareness of basic chemical safety is in place prior to taking the next steps in regulatory control.

Chemical control frameworks should be science- and risk-based to ensure appropriate allocation of resources and to achieve effective risk reduction to society.

Priority setting based on risk and the opportunity to reduce risk to human health and environment should be used, i.e. focusing on both the inherent substance properties and intended uses of that substance and concomitant exposures. Country specific concerns, specifically related to local conditions of use or disposal related exposure, may be key factors to take into consideration.

Industry believes based on prior experience, that quantity or volume manufactured or imported alone are not appropriates factors for prioritization. Also, the use of reference ‘lists’ may represent one source of information to aid in prioritization. However it is believed that the framework identified in the GPS offers a consistent approach using available data.

GPS provides for a Risk Assessment System that incorporates a prioritization scheme based on the likelihood of risk to the public. This risk assessment system is viable for use by small and medium sized companies and it provides a tested solution for authorities that are planning to implement new chemical control plans.

The GPS Risk Assessment is complementary to the development of an inventory of chemicals at the national level and is an effective tool for further governmental review and regulatory judgments.

It is recognized that a number of challenging concerns have emerged in recent years such as the risk of exposure where more than one chemical is involved such as with a mixture or preparation. GPS provides guidance for such scenarios. In the absence of data on the mixture itself, often the most hazardous constituent will dictate the overall risk assessment.

Development of Chemical Inventories

Industry recognizes the need for inventory creation as part of the regulatory process so that authorities know which chemicals are being manufactured or brought into the country. It is also important to consider the scope of the inventory, i.e. which substances should be included and how to create it.

The inventory required by a country may range in complexity from the simple to providing for a complex range of data elements regarding chemical identity, classification, intended use, importer name, etc.

Scope of Chemical Inventories
Industry recommends that all chemicals in commerce be included unless otherwise excluded. Many countries have successfully used 1mt/a quantity of the substance (placing on the market) threshold as a pragmatic cut off, although other appropriate thresholds have been applied. Under the GPS, industry would also include any chemical having a highly toxic/eco-toxic profile and that could represent potential harm even in very small quantities.

New inventory reporting requirements should be phased in, perhaps starting with a higher quantity threshold. This would permit both industry and the regulatory authorities to develop supporting procedures.

Exemptions should include chemicals in the early stages of research and development (may offer time limited exemptions, typically not handled above 1mt/a) and articles unless the intended use of the article would purposely release a substance for exposure.
Listed naturally occurring substances such as crude oil and natural gas, pharmaceuticals, cosmetics, should be exempt and regulated separately from the mainstream chemical control framework.

Information Requirements and Submission of Information
GPS provides for a minimum information set as part of a basic inventory based on risk potential. The risk potential of a substance is determined by considering available information on intrinsic hazard properties and information relating potential exposure associated with the intended uses of the substance. More information is required as the perceived risk of the chemical and its uses increases.

Industry recommends the use of a harmonized set of procedures for testing based on the work of OECD.

If a country has other regulations requiring the submission of chemical safety information then the industry advocates for a single submission of information in order to avoid multiple submissions in different formats or with different information requirements. Industry would also prefer the use of electronic submission devices.

Phasing-in Substances Already on the Market
The reporting of chemicals imported or manufactured in the current year and within the last 3 years is a reasonable compromise to having to report for the last decade to avoid missing chemicals that may still be in storage. It is believed that the reporting of substances in mixtures and preparations imported more than 3 years in the past would not yield a dependable data set.

Classification and Labeling

Authorities should provide for sufficient oversight and control to ensure differences in classification, particularly for the most hazardous chemicals, are resolved. Industry strongly supports adoption of the full Globally Harmonized System for Classification and Labeling (GHS) framework and a harmonized, science based classification. While GHS provides a 'flexible' menu of options, deviations from the use of the full classification scheme represents additional complexity for industry considering the global nature of the market for chemicals.

Industry supports the position that it should have the lead role in determining the hazard classification of its products.

Classifications provided by individual companies should be presumed to be correct unless demonstrated otherwise and there should be an obligation to take reasonable steps to provide correct classification. Industry should also take reasonable steps to resolve differences in classification for the same substance.

GHS classification should be the sole approach for preparation of safety data sheets. Use of parallel or overlapping requirements represents a significant burden to industry. The best approach is to have an appropriate transition period during which GHS would be implemented. We support an approach to GHS that leverages work done in other regions or countries. Industry does not favor an 'imposed' GHS classification but seeks to use established classifications where agreement has already been achieved.

Risk Assessment

Hazard and exposure information only become meaningful if they are used to assess human and environmental risk associated with the intended uses of chemicals. Risk assessments should cover the entire life cycle of a chemical substance. The purpose of a risk assessment and of the definition and implementation of risk management measures is to ensure that the exposure of humans or the environment to a chemical is always below levels that may cause harmful effects. Therefore Risk Assessment and Risk Management are the core elements of any voluntary or regulatory chemicals management system.

Industry believes it has the responsibility to perform and deliver a risk assessment regardless of the particular design and allocation of other chemicals management responsibilities between the private and public sector. Manufacturers should provide the basis for their determination and recommendations for safe handling for particular uses.

The role of the public sector in the risk assessment process is to provide oversight that the risk assessment requirements are being met by the industry. The public sector has the responsibility to review chemicals that are perceived as having high risk. A risk assessment requires an adequate review of hazard and exposure information and should support a conclusion that the chemical can be safely handled or used under the use conditions that have been reviewed. This should take into account the uses that might be relevant to vulnerable or sensitive populations.

The risk assessment is the foundation upon which both industry and the public sector should build confidence that a chemical is or can be responsibly managed.

A detailed process for conducting a risk assessment has been described by ICCA in the GPS Guidance on Chemical Risk Assessment. This includes the identification of an appropriate set of human health and environmental information needed to conduct a robust risk assessment and risk management. An outcome of the risk assessment process is the identification of the types of measures needed to safely manage the substance or product. Generally, a "sentinel exposure" is considered, i.e. the risk assessment step should take into consideration the most 'risky' exposure scenario to simplify the analysis.

The ICCA process provides for the creation of a "GPS safety summary". The safety summary is intended to be used as the communication tool by which the outcome of the risk assessment and product safety information are communicated to the general public. Safety summaries are published on individual company websites and are then accessible via a common portal on the ICCA website. National chemical management systems should promote the development and sharing of GPS safety summaries in order to further build public confidence that chemicals are assessed and managed safely.

National chemical management rules should promote innovation with regard to the development of new chemicals by acknowledging the limited exposure to humans and the public at this stage in the commercial development of a substance. Thus, requiring only a limited amount of testing prior to commercialization may be appropriate. GPS incorporates this approach by acknowledging that less information may be available during the research stage of product development when exposures to humans and the environment are limited.

Risk Management

It is important to make the distinction between Risk Assessment and Risk Management, the latter representing a range of possible options available to reduce risk during any stage of the life cycle of a chemical substance, from R&D through to disposal/recycle.

The Purpose of Risk Management

The Risk Assessment described above may involve the identification of risk management measures in order to control exposures below levels that may cause harmful effects, including exposures to sensitive subpopulations. Risk Assessments may have to be re-iterated taking into account increasingly strict Risk Management measures to ensure that the risk is adequately managed. In principle, scientifically proven cause – effect relationships should drive the identification of a need for risk management measures and the selection of specific risk reduction options.

Identification, Selection, Communication and Implementation of Risk Management Measures – Roles of Industry, Authorities and Public

Identification of risk management measures is an integral part of the risk assessment process. Therefore industry, typically the manufacturer or importer of a substance, should be responsible for identifying and selecting risk management options. The importer or manufacturer is also accountable for providing adequate information to the supply chain, including hazard and risk management information, so that users can safely handle and use the chemical. Providing safety data sheets to downstream users is one method of communication, but does not preclude the use of other communication and dialog approaches. For instance, for the most hazardous chemicals, many manufacturers provide their customers with on-site training and other services to help them manage the chemicals safely. Each actor in the supply chain is responsible for the successful implementation of appropriate risk management measures that apply to his activities.

The regulatory authorities play an important role in increasing confidence of the public relating to the safety of chemicals by providing oversight of the risk assessment process and the effectiveness by which industry is managing chemicals across the supply chain. Oversight includes ensuring all actors in the supply chain responsibly manage chemicals given the information that has been provided to them. Oversight also includes a requirement that industry periodically review the need for updating the information that is provided to their customers and distributors. Updating is needed if new risk management measures are defined, e.g. on the basis of new hazard or exposure information.

There should be a dialog with the regulatory authorities where concerns regarding risk management decisions are anticipated. Evaluation and decision processes should be transparent and invite public comment. Industry experience highlights the importance of having a systematic risk-ranking process or criteria that provide insight into the specific uses of chemicals that are of concern.

Various approaches to dealing with uncertainty should be considered such as requiring a more rigorous demonstration of safety, use of a license where a substance is needed for a particular use or application – providing the additional level of control desired proportionate with the risk.

Restrictions and Substitution

Restrictions and substitution represent extreme risk management options and are justified when other risk management activities are deemed insufficient or impractical to achieve safe use conditions. Where companies have adopted *restrictions* on a chemical's use in one part of the world, they have the responsibility to review why such restrictions should not also be adopted elsewhere in the world. Geographic differences in use conditions or in the implementation of risk management measures may justify differences in the adoption of restrictions. If uses and applications are not proven safe by a risk assessment then that should be clearly communicated through the information provided by industry to their customers and distributors.

Mandatory *substitution* of a substance should not be required in situations where risk management measures can be demonstrated to be effective and feasible for the protection of human health and the environment. Any proposed 'substitution" should be based on peer reviewed science and risk assessment results of both the substance and potential alternatives, rather than solely based on the intrinsic hazard properties of a chemical substance. Mandatory substitution or bans of certain uses of chemicals should only be considered if unacceptable and otherwise unmanageable risk has been identified. Alternative or substitute chemicals need to be shown to provide improved safety as well as technical and overall economic feasibility.

Geographic Differences in Risk Management

Care should be taken when extrapolating risk assessment results and risk management measures from one country to another, taking in consideration factors that may influence specific local conditions, priorities and risk tolerance. Any socio-economic analysis is an assessment building on national and/or regional data and therefore has to be performed locally.

Information Sharing, Transparency and Confidential Business Information

Industry believes that hazard and safe use information on chemicals that is necessary to protect human health and the environment should always be made available to the value chain and downstream users and should never be claimed as Confidential Business Information (CBI). However, some stakeholders are demanding even greater transparency and want industry to divulge product ingredients and health studies which are not necessary to protect health and the environment and are sometimes legitimate CBI. Industry supports the principle that there should be a balance between the public right to know and the right of industry to protect CBI, particularly through an up-front justification of the CBI claim. Areas of concern include the scope and breadth of the information submitted by industry to the regulatory authorities and the safeguards provided by government to protect CBI. This includes processes for protection where there is needed exchange of information between governments of different jurisdictions.

On the basis of experience in a range of jurisdictions, industry advocates that the following issues relating to the protection of CBI are adequately addressed in any chemicals management regulation:

- Types of information should be defined that would always be considered as business confidential;
- Provisions should be made to protect information, other than health and safety studies and technical Health Safety or Environmental information, deemed confidential by the manufacturer;
- Provisions should be made that the owner of information has the right to review and comment on the possible release of CBI prior to any transfer of information to other government agencies or foreign governments;
- Provisions should be made to enable limited release of appropriate information in emergency situations where harm to public health or the environment is imminent, and where adequate emergency response requires a release of confidential business information;
- Reporting requirements must protect CBI. This would include engineering process information (e.g. process design) on the part of manufacturers and potentially content of impurities and composition of preparations where the importer does not know the composition or even the actual out of country manufacturer. Arranging for the reporting of confidential composition information by the Manufacturer not importer should be provided for where the importer does not have access to such information.

PRACTICAL EXAMPLES

Scope

Rationale

An efficient chemicals management system should focus on those chemical substances and/or uses where a better understanding of the risks provides increased protection to workers, consumers and the environment. Therefore the scope of any voluntary or regulatory chemicals management system should be well defined to ensure a focus on those chemical products and/or uses where further assessment results in clear benefits. Efficient use of government and industry resources is a collateral benefit of a well-defined scope. The scope of a chemicals management regulation not only defines the substances to which the regulation applies but also the life cycle steps covered as well as the actors along the supply chain who each have active roles to play to ensure the success of the chemicals management system.

Key Issues

Chemical Substances and Mixtures.

The scope of a chemicals management system is, to a certain extent, the first level of prioritization. By defining the scope, substances and/or uses are identified that will be subject to the requirements of the system. For those substances and/or uses a better understanding of their risks, the identification of appropriate risk management measures as well as hazard and risk communication needs is required in order to enhance the protection of workers, consumers and the environment. Therefore the scope focusses both government and industry resources on those substances and uses requiring chemicals management attention. Typically chemical management systems do not distinguish between different substances in their application unless, for specific reasons, they are excluded from the scope.

Substances are typically excluded from the scope for the following two reasons:

1. Certain substances may be subject to other chemicals management requirements, particularly specific use requirements.
   Examples of specific use legislation:
   - Chemicals used as active pharmaceutical ingredients, agricultural active ingredients (pesticides, insecticides, herbicides, fungicides), biocides, cosmetic ingredients, food and feed ingredients;

- Chemicals used for military applications (e.g. explosives);
- Waste and or recycling products that may be covered by waste specific requirements.

2. Substances that are used under controlled conditions which pose a very low exposure potential.
   Examples of substances used under controlled conditions are:
   - R&D chemicals;
   - Non-isolated, non-transported intermediates;
   - Isolated intermediates that are used on-site under strictly controlled conditions.

Some chemicals substances may have multiple uses where the individual applications are exempted as use legislation prevails however the manufacturing or import of the substance will still be governed under a general chemical management system. Substances may be used for multiple applications. Some applications may be excluded from the scope of a regulation. For all other applications the requirements of the regulation may be applicable to the substance.

For workability reasons the risk assessment of chemicals should primarily be based on substances and address the risks associated with the use of those substances in their various applications. A risk assessment should cover the entire life cycle of a substance and the uses supported by the manufacturer/importer, including uses in mixtures and articles.

Life Cycle Steps and Responsible Actors

The scope of a chemicals management system can also define the steps of the life cycle that are covered under the chemicals management system. Immediately connected to that is the definition of the actors in the supply chain that will have responsibilities under the system. Typically actors that bring chemicals into commerce should have responsibility for assessing and managing risk and ensuring product safety. Often the original manufacturer of a chemical substance is given the primary responsibility for characterizing risks for the uses for which it markets and sells its products, for defining risk management measures and for communicating the results of risk assessment. If a product is manufactured outside a specific jurisdiction then the importer has to assume such responsibilities. Downstream users may also have to assume responsibilities, e.g. for informing the manufacturer or importer about the conditions under which chemical products are used, for implementing the risk management measures (i.e., complying with the safe use conditions) recommended by the original manufacturer and for passing on relevant hazard and risk information in the supply chain.

Example of Possible Legal Provisions*

- Subject to this regulation are chemical substances. The provisions of this regulation shall apply to the manufacture, placing on the market and/or use of such substances on their own or in mixtures;
- Under this regulation manufacturers and importers of chemical substances or mixtures are responsible for ensuring that substances or preparations that they manufacture, place on the market or use do not adversely impact human health or the environment. They have responsibilities for gathering hazard and exposure information associated with the use of the substances, as such, in the form of mixtures or in articles, for assessing risks and for communicating information to ensure safe use of the substances;
- This regulation shall not apply to substances or mixtures that are regulated under the following use specific regulations: active pharmaceutical ingredients, agricultural active ingredients (pesticides, insecticides, herbicides, fungicides), biocides, cosmetic ingredients, food and feed ingredients;**
- This regulation shall not be applied to: **
  - R&D chemicals;
  - Non-isolated, non-transported intermediates;
  - Isolated intermediates that are used on-site under strictly controlled conditions;
  - Polymers where there are no reactive moieties present.

Guidance

* **Many terms in this section will need to be precisely defined in a Definitions section of the regulation**

** **GPS guidance section 1, page 12**

Hazard and Exposure Information Requirements

Rationale
A good understanding of the intrinsic hazard properties and the exposure potential during all stages of the life cycle of a chemical substance or product is the foundation of any voluntary or regulatory chemicals management scheme. Hazard and exposure information are the basis for performing risk assessments where the results allow for conclusions concerning the safety of the intended conditions for use of products.

Key Issues
Science and technology provide various methodologies to collect information on the intrinsic properties of chemicals and on environmental or human exposure to chemical products. Methods range from modelling studies for intrinsic properties and exposure to in vitro studies and whole animal tests to predict human toxicology and ecotoxicity. In addition, numerous monitoring techniques exist to quantify environmental and human exposure. The question is what level of detail, quantity and quality of the information is actually required to assess and ensure the safe use of a chemical product. Another question is whether the same kind of information is required to ensure the safe use of every single chemical product and for every condition of use. In order to decide what constitutes sufficient or adequate information as input for risk assessment several considerations must be taken into account.

Substances or products and uses which on the basis of available information are known to have a low hazard or exposure potential may not require an extensive additional data set. Alternatively chemical products or uses which are known to have a high hazard or risk profile typically require a more extensive data set in order to assess and ensure safe use of such products. I.e. information requirements should be proportional to available knowledge about intrinsic hazard and exposure potential. Animal welfare considerations and the right timing (in the product's development cycle) are factors that also need to be considered.

Therefore hazard and exposure information requirements should be based on the following principles:

Gather Information on a set of Standard Hazard and Exposure Parameters for any Substance*

In order to make an initial assessment of the hazard potential of a chemical product or substance at least one set of standard parameters (Annex I to this document) must be available for any chemical substance.

Standard parameters include information relating chemical identity and use, classification and labelling information, physical/chemical properties, environmental fate as well as environmental and mammalian toxicology.

With respect to exposure information should be collected related to the type of uses and associated volumes, to the use conditions by workers and consumers, to the risk management measures and to the environmental characteristics and environmental exposure.

Assess the Need for Additional Information based on Hazard and Exposure Potential**

With the standard set of hazard and exposure information chemical products and substances can be prioritized from high to medium, to low and finally to very low hazard or exposure potential (Annex III).

Define and Gather a Base Set of Information According to Hazard and Exposure Potential***

Dependent on the prioritized hazard and exposure potential, priority specific hazard and exposure information should be gathered or generated to form a base set of information together with the set of information on standard priorities gathered earlier in the process (Annex II). This base set now forms the input information for a risk assessment.

Use Available Information****

For the vast majority of chemical substances and products intrinsic hazard property information and exposure information is available. Often relevant information is available from public sources or can be derived from analogous products or applications. In order to speed up the risk assessment and risk management process and to reduce animal testing, available information should be used as much as possible.

Information requirements based on these principles render them proportionate to the risk to be expected and strongly consider animal welfare interests. There is always the option to extend the hazard and exposure information should circumstances warrant.

Example of Possible Legal Provisions

- Manufacturers and importers of substances shall as a minimum collect a base set of information. The base set shall consist of information on a set of standard parameters as specified in Annex I and of priority specific information as specified in Annex II. The priority specific information shall be collected or generated in accordance with the prioritization criteria as specified in Annex III;
- Manufacturers and importers may provide information on intrinsic properties generated by means other than tests. Any information must be scientifically sound and adequate for the purpose of performing a risk assessment. The manufacturer or importer has the responsibility to ensure that the information is relevant, reliable and fit for the purpose of a risk assessment of the substance and its uses. The manufacturer or importer has the responsibility to ensure that he has the right to use any information that he has not generated himself;

- Authorities may examine the results of a risk assessment conducted by a manufacturer or importer and the quality of the base set of hazard and exposure information, used by the manufacturer or importer, for the purpose of drawing unambiguous conclusions about the safe use of the substance. If any of the information used by the manufacturer or importer is deemed not adequate for the intended purpose than the Authority may decide to request additional information.

Institutional Requirements and Competencies

The manufacturer or importer has the responsibility to collect or generate hazard and exposure information and ensure that the information is adequate for the purpose of conducting a risk assessment which will allow scientifically sound decisions concerning the safe of the product.

The authorities have the responsibility to evaluate the quality of the risk assessment, and its conclusions (including risk management measures). In doing so the authorities may also assess the fitness of the hazard and exposure information, provided by the manufacturer and importer, for the purpose of sound risk assessment. The authorities may conclude that additional information is required, in which case the authorities shall draft and communicate such a decision to the manufacturer or importer.

The manufacturer or importer shall have the right to be heard and to appeal against decisions of the authority, if e.g. authority and manufacture or importer can't agree on the required hazard or exposure information.

Guidance

* GPS guidance section 1, pages 14-16
** GPS guidance section 1, pages 28-43
*** GPS guidance section 1, pages 44-52
**** GPS guidance section 1, pages 15, 18-21, 49

ANNEX I **INFORMATION ON STANDARD PARAMETERS**

Standard Parameter	Description
Chemical Identity and Use	• CAS number(s) • Name • Structural formula • Composition of the chemicals (s) being assessed. In cases where confidentiality issues are involved, the values can be reported in ranges): For a single chemical: degree of purity, known impurities or additives, details of stereo-isomers if relevant. • Use pattern (categories and types of use) • Sources of exposure: Is there potential for human exposure to the chemical for example via occupational exposure, consumer exposure and indirect exposure of man via the environment (companies are not requested to provide proprietary information). • Route of exposure (route of expected human intake): inhalation, dermal, oral for human exposure. • Molecular weight
Classification and Labeling Information	• Physical hazard; Health hazard; Environmental hazard
Physical-Chemical Properties	• Physical state • Melting point • Boiling point • Relative density (required for inorganic chemicals, and should be provided if readily available for organic chemicals) • Vapour pressure • Partition co-efficient: n-Octanol/Water • Water solubility • Ignition temperature (flammability)
Environmental Fate	Aerobic biodegradability
Environmental Toxicology	Acute Toxicity (algea or fish or daphnia)
Mammalian Toxicology	Acute Toxicity required only on the most relevant route of exposure (route of exposure that most resembles the route of expected human intake) either by oral route, dermal route or inhalation). In most cases the ambient physical state of the chemical will determine the relevant exposure.

- Product characteristics (e.g. volume used in different sectors, packaging);
- Product uses (e.g. transported isolated intermediate used/stored off site; chemical included into or onto a matrix, non-dispersive use, professional industry point sources, wide dispersive use);
- Operational conditions and risk management measures (e.g. process conditions protective equipment, ventilation, typical handling);
- Environmental characteristics (e.g. surrounding environment, waste water treatment, typical sector info from ERC or SPERCs.

ANNEX II **PRIORITY SPECIFIC INFORMATION**

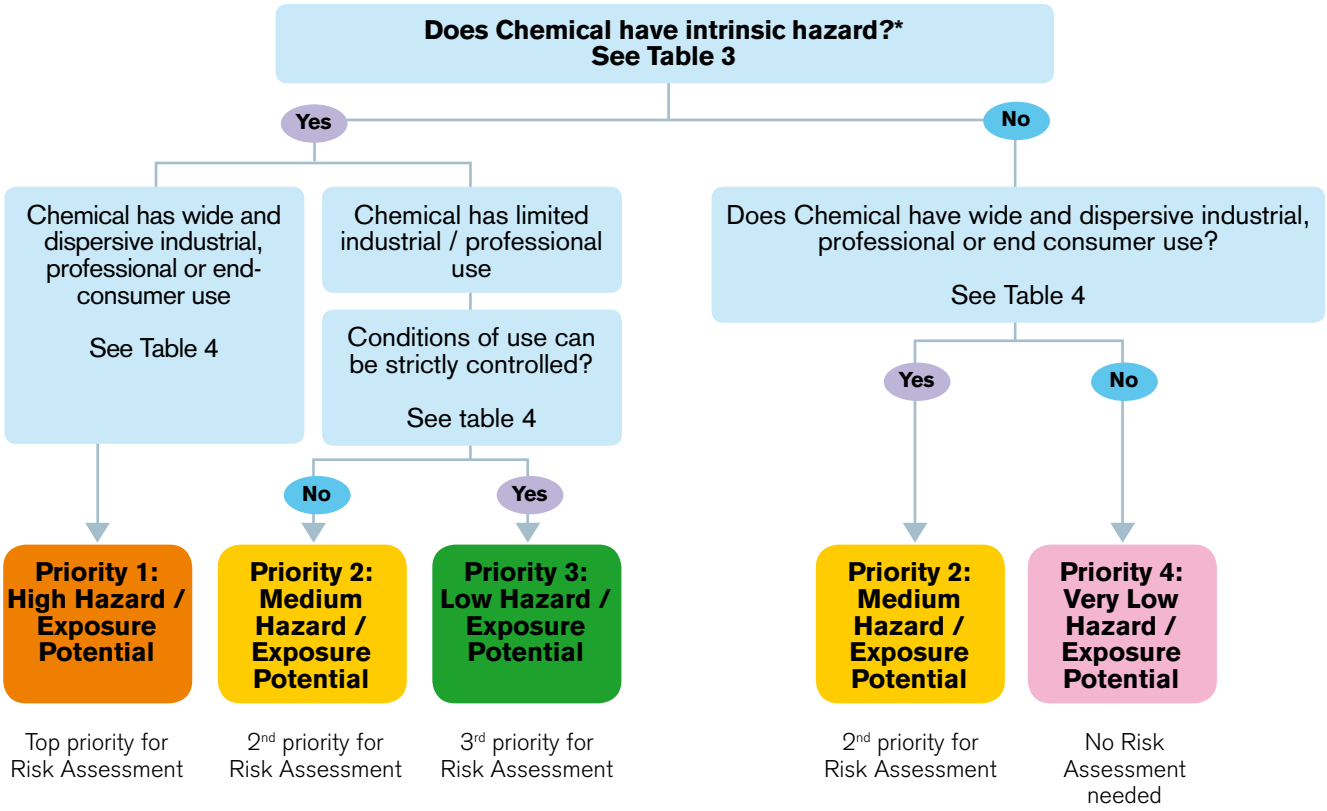
a) Human Health

Priority 1 (High hazard and/or high exposure potential)	**Priority 2** (Medium hazard and/or medium exposure potential)	**Priority 3** (Low hazard and/or low exposure potential)	**Priority 4** (Very low hazard and/or very low exposure potential)
Irritation (Eye / Skin) (e.g. in vitro test)	Irritation (Eye / Skin) (e.g. in vitro test)	Irritation (Eye / Skin) (e.g. in vitro test)	Irritation (Eye / Skin) in case of accidental exposure (e.g. in vitro test)
Mutagenicity (e.g. Ames, mammalian cell in vitro, in vivo micronucleus - only if positive in both in vitro tests)	Mutagenicity (e.g. Ames, mammalian cell in vitro, in vivo micronucleus - only if positive in both in vitro tests)	Mutagenicity (e.g. Ames test)	
Sensitization	Sensitization	Sensitization (required if triggered by structural alert)	
Repeated dose toxicity	Repeated dose toxicity		
Reproduction / developmental toxicity test			

b) Environment

Priority 1 (High hazard and/or high exposure potential)	**Priority 2** (Medium hazard and/or medium exposure potential)	**Priority 3** (Low hazard and/or low exposure potential)	**Priority 4** (Very low hazard and/or very low exposure potential)
Acute toxicity to fish (e.g. short-term fish embryo test)	Acute toxicity to fish (e.g. short-term fish embryo test)	Acute toxicity to fish (e.g. short-term fish embryo test)	Acute toxicity to fish (e.g. short-term fish embryo test)
Acute Toxicity to Daphnia	Acute Toxicity to Daphnia	In case of accidental exposure relevant ecotoxicological data is needed	
Acute Toxicity to Algae	Acute Toxicity to Algae		
Chronic Toxicity (fish or daphnia) within limitations of the chemical properties			

ANNEX III **PRIORITIZATION BASED ON STANDARD PARAMETER INFORMATION**



Guidance
Table 3: GPS guidance section 1, page 30.
Table 4: GPS guidance section 1, page 42.

Prioritization of Substances for Assessment

Rationale
A balanced and justified approach on how to prioritize substances is necessary and will allow a focus on substances and uses of highest concern to the environment and human health. Consequently, this will also facilitate an efficient use of resources by addressing those chemicals in further provision in the context of risk management.

Key Issues
Requirements of a legal framework for chemical management should be driven by available intrinsic hazard properties of a chemical in conjunction with exposure potential related to its uses. Substances with low to very low hazard and/or exposure potential should have a lower priority for further assessment and less extensive information sets should be required. However if a priority screening based on hazard and exposure potential results is a higher priority outcome then that does not imply that the current production, handling and use of the chemical is not safe through the risk management measure in place. A higher priority outcome suggests that more extensive information will be required to further assess the risks and that a risk assessment should be completed faster than for a low priority chemical substance.

Hazard should be identified in accordance with UN GHS and the prioritization for a legal framework governing chemical management should refer to existing hazard classes in UN GHS.

Priority 1: These substances are High Priority for risk assessment (high hazard and/or exposure potential). In certain cases, more information needs to be gathered to complete a risk assessment and/or to ensure that adequate risk management measures are employed.

Priority 2: These substances are Medium Priority for risk assessment (medium hazard and/or exposure potential). In certain cases, more information needs to be gathered to complete a risk assessment and/or to ensure that adequate risk management measures are employed.

Priority 3: These substances are of Low Priority and required only limited risk assessment due to their low combined hazard and exposure potential, where likely exposure would result in low level impact. Furthermore, substances in this category also need less data to complete the assessment.

Priority 4: These substances are of minimum priority as they have minimum potential to cause harmful effect to human health and/or the environment. Examples include those chemical where no exposure can occur to consumer, workers or the environment and non-isolated intermediates. In the majority of cases, only the “standard parameters” are needed to complete the assessment together with information on hazard potential for skin and eye irritation in case of accidental exposure.

Example of Possible Legal Provisions

- Manufacturers and importers of substances shall maintain a company inventory of substances they place on the market;
  1. Upon request, manufacturers and/or importers shall make their inventory available to the authorities for those substances falling within the scope of the regulation.

- Manufacturers and importers shall, based on combination of hazards and probable exposures, prioritize chemicals for assessment.
  1. Upon request from the authorities, manufactures and/or importers shall make their prioritization and justification known to the authorities.

Or

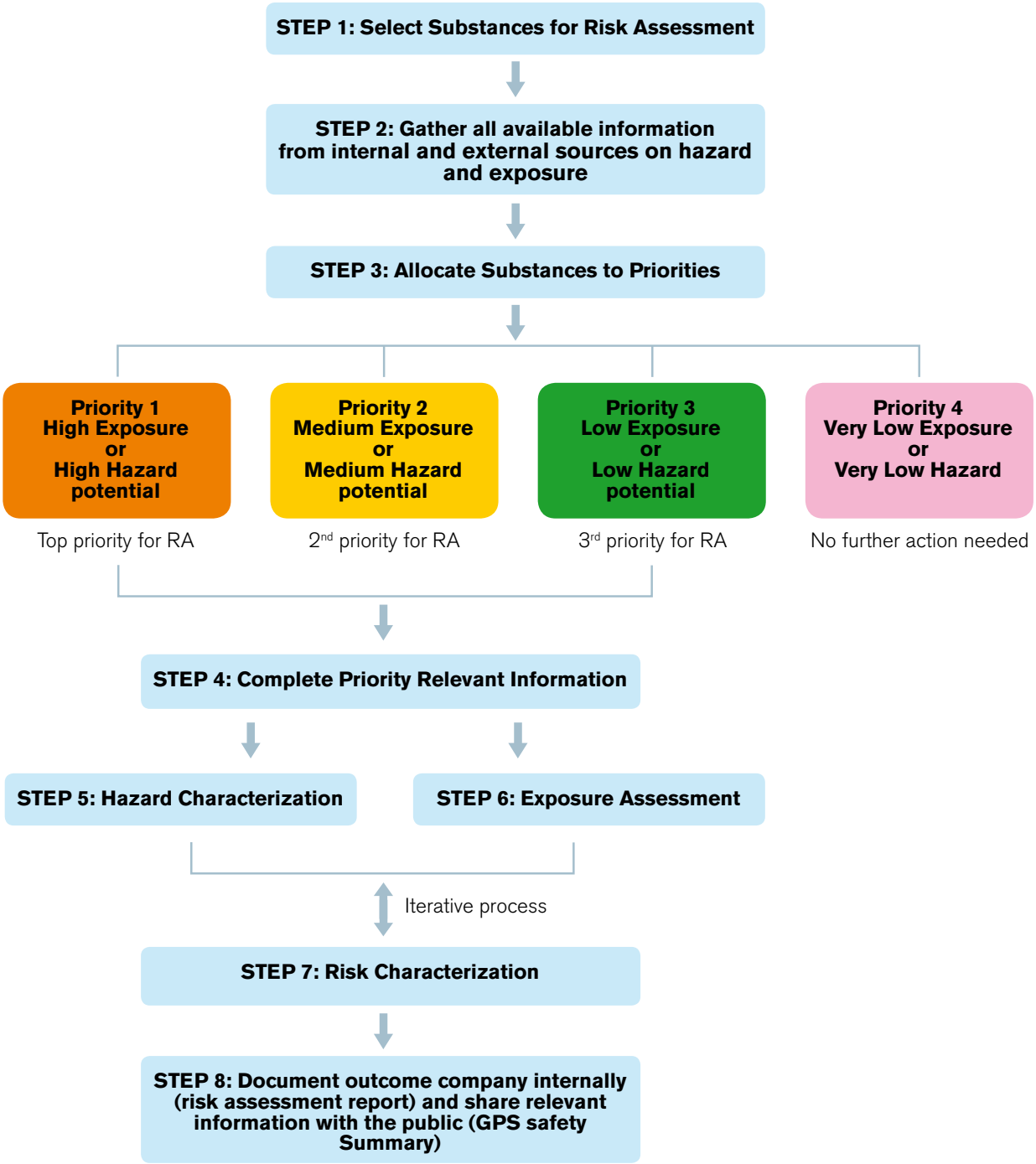
- Authorities shall, based on a combination of hazards and probable exposure, prioritize chemicals for assessment.
  1. Prioritization and its justification shall be subject to public consultation with set deadlines to allow for industry to submit additional information.

  2. Any stakeholder who disagrees with a decision for prioritization shall have right to appeal in accordance with a defined process.

  3. Information requested from industry to make decision on prioritization of chemicals for assessment shall take confidential business information into account and have a process in place to ensure non-disclosure of such information.

     a) Clear criteria for and further guidance on how to claim CBI.

Guidance
GPS guidance section 1, page 27.


STEP 1: Select Substances for Risk Assessment
STEP 2: Gather all available information from internal and external sources on hazard and exposure
STEP 3: Allocate Substances to Priorities
Priority 1 High Exposure or High Hazard potential
Priority 2 Medium Exposure or Medium Hazard potential
Priority 3 Low Exposure or Low Hazard potential
Priority 4 Very Low Exposure or Very Low Hazard
Top priority for RA
2nd priority for RA
3rd priority for RA
No further action needed
STEP 4: Complete Priority Relevant Information
STEP 5: Hazard Characterization
STEP 6: Exposure Assessment
Iterative process
STEP 7: Risk Characterization
STEP 8: Document outcome company internally (risk assessment report) and share relevant information with the public (GPS safety Summary)

Risk Assessment

Rationale

Hazard information alone increases the knowledge about the inherent potential of chemical products to cause harmful effects. But without exposure information little can be said about the probability of harmful effects actually occurring. In a risk assessment the intrinsic hazard properties and the exposure potential under use conditions are jointly evaluated. The objective of a risk assessment is to identify the conditions under which human and environmental exposure to chemical products can be controlled below levels that may cause harmful adverse effects.

Key Issues

The Tiered Risk Assessment Approach

Prior to the actual risk assessment step substances should prioritized (see Prioritization module). Substances with a high hazard or high exposure profile should be assessed early in the process.

The objective of risk assessment is to establish how exposure under normal expected conditions of use relates to the exposure level at which adverse health or environmental effects are expected to actually occur. If the outcome of a first risk assessment suggests that a chemical substance cannot be safely used under the assumed use conditions then reiteration of the risk assessment is required. For instance additional risk management measures may be defined in order to reduce the exposure. It could also be the case that the hazard or exposure information used for the risk assessment is further refined or complemented by additional information to reduce the degree of uncertainty that might be associated with the information used for the first assessment.

The risk assessment can then confirm whether the exposure based on the new information and in the specific use conditions can be considered acceptable. It may be necessary to consider additional risk management measures and risk assessment may be repeated until a set of satisfying conditions to ensure safe use of a chemical substance is found.

Hazard Characterization

For each health or environmental hazard endpoint, dose-response descriptors are taken as a starting point. These descriptors provide information about the exposure level at which a certain adverse effect or no effects have been observed (e.g. acute toxicity, mutagenicity, fish toxicity). Hazard information may be generated in laboratory animal or non-animal in vitro studies. Alternatively hazard information may be predicted by using models such as Quantitative Structure Activity Relationship (QSAR). Examples of dose-response descriptors are e.g. LD50, LC50, NOEL or LOEL.

There are essentially 2 options to conduct a hazard characterization (Annex 1)*

Option 1 – DNEL/DMEL Approach
The available dose-response descriptor information (typically based on animal data) may be modified with Assessment Factors (AF) to bridge any uncertainty over the extrapolation and applicability of animal data to humans, to estimate for each endpoint the highest acceptable exposure level to which humans can be exposed to a chemical without any adverse effects occurring. This is called the DNEL (Derived No Effect Level), if the mode of action for the endpoint is such that a no-effect threshold can be established. For other effects, like certain carcinogenic or mutagenic effects a no/effect threshold cannot be defined. In that case a probabilistic approach should be considered and a so-called DMEL (Derived Minimal Effect Level) can be established. For environmental exposure the PNEC (Predicted No Effect Concentration) is established. The DNEL, DMEL and PNEC can later be directly compared with the actual use related exposure levels to assess the risks.

Option 2 – The MOS or MOE Approach
The available dose-response descriptor data is expressed in terms of No Observed Adverse Effect Level (NOAEL) or Concentration (NOAEC) for each endpoint. These are later in the risk assessment step used to calculate MOS (Margin of Safety) or MOE (Margin of Exposure) levels.

Exposure Assessment

Exposure assessment** is very complex. First of all the entire life cycle of a substance, from manufacturing to waste disposal has to be considered. For each of the steps there may be different ways of processing or using the substance, each with a unique human or environmental exposure profile.

Particularly for the phase in the life cycle during which the product is actually used the human and environmental exposure may vary significantly depending on the actual application. There may be industrial uses in closed systems with practically no exposure to the industrial worker or the environment. There may be industrial uses with point emissions to the environment and exposure to industrial workers, who however may be well protected by e.g. personal protective equipment. On the other end of the scale there may be wide dispersive use by consumers and exposure to the environment. For each of these scenarios it has to be established whether the exposure is well below the levels that might cause adverse health or environmental impact or not.

In the vast majority of cases actually measured exposure information is not available and therefore must be estimated on the basis of models or computational tools. For many typical uses of substances information relating to exposure route and level is available.

A pragmatic approach is thus needed in order to make exposure assessment a manageable task. Several standardized categorization systems based on use descriptors and use categories*** are available to facilitate human exposure, including workplace and consumer as well as environmental exposure. Based on these categorization systems the exposure Scenarios can be defined and route specific exposure levels for each Exposure Scenario can be calculated.

Risk Assessment

Now the results of the hazard characterization and exposure assessment are combined**** in order to quantify the probability of harmful adverse effects from the identified hazard properties under the intended conditions of use of a substance (Annex II).
Similar to Hazard Characterization there are 2 options to characterize risk.

Option 1 – the Risk Characterization Ratio (RCR) Approach

Risk Characterization Ratios (RCRs) are calculated by dividing the relevant exposure level for each Exposure Scenario by the maximum allowable exposure level for the health effect of most concern (the DNEL or DMEL established in the Hazard Characterization).
A similar RCR is calculated for environmental risks by dividing the Predicted Environmental Concentrations (PEC) by the PNEC value.

If the RCR for a certain Exposure Scenario is below 1, then the actual exposure is below the level that causes harmful effects. The risk is controlled and no further action is required. If the RCR is larger or equal to 1 then additional risk management measures may be needed and a re-iteration of the risk assessment process may be required.

Option 2 – the MOS / MOE Approach

Here the NOAEL and NOAEC values, established under option 2 of the Hazard Characterization, are used to characterize the risks for each Exposure Scenario.

The MOS or MOE is calculated by dividing the NOAEL or NOAEC by the human resp. the environmental exposure. This ratio is just a first indication of risk, because it the following factors have not yet been taken into account:

- The uncertainty arising, among other factors, from the variability in the experimental data;
- Intra- and interspecies variation;
- The nature and severity of the effect;
- The human population to which the quantitative and/or qualitative information on exposure applies;
- The differences in exposure (route, duration, frequency and pattern);
- The dose-response relationship observed;
- The overall confidence in the quality of the data.

Therefore expert judgment is required to establish an Overall Assessment Factor for each Exposure Scenario. If the MOS or MOE is larger than the Overall Assessment Factor then there is no concern. If the MOS or MOE is smaller than the Overall Assessment Factor then additional risk management may be needed and a re-iteration of the risk assessment process may be required.

Documentation

In order to provide evidence that all relevant risks have been taken into account and that the risk management measures are effective the risk assessment process followed needs to be well documented*****. The documentation should cover the following information:

- Criteria used for prioritization of the chemical;
- Hazard information collected;
- Outcome of the hazard characterization;
- Exposure information collected;
- Outcome of the exposure assessment;
- Outcome of the final risk assessment (e.g. safe, not safe, further steps required, etc.);
- Risk management measures implemented or to be implemented down the supply chain.

Example of Possible Legal Provisions

- The manufacturer or importer of a substance shall perform a risk assessment for any substance, on its own, in a preparation or in an article, that:
  a) is manufactured or placed on the market in quantities of more than 1 metric ton per year per manufacturer or importer and;
  b) is manufactured or placed on the market in quantities below 1 metric ton per year per manufacturer or importer and that is classified as a PBT or a CMR cat. I or 2a.

- A risk assessment does not need to be performed for substances present in mixtures or in an article in concentrations below 0.10 % by weight;

- A risk assessment shall include the following steps:
  a) a hazard characterization;
  b) an exposure assessment;
  c) a risk assessment.

- The manufacturer or importer shall for each risk assessment create a report covering:
  a) Criteria used for prioritization of the chemical;
  b) Hazard information collected;
  c) Outcome of the hazard characterization;
  d) Exposure information collected;
  e) Outcome of the exposure assessment;
  f) Outcome of the final risk assessment (e.g. safe, not safe, further steps required, etc.);
  g) Risk management measures implemented or to be implemented down the supply chain.

- The manufacturer or importer shall update the risk assessment when new information about the hazards or use and exposure come available;
- The manufacturer or importer shall make the report on the risk assessment of a substance available on request to the competent authority;
- The manufacturer or importer shall make a summary of the report on the risk assessment of a substance publicly available.

Guidance

* GPS guidance section 2, pages 58 - 69
** GPS guidance section 2, pages 106 - 120
*** GPS guidance section 2, pages 122 - 131
**** GPS guidance section 2, pages 132 - 138
***** GPS guidance section 2, page 146

ANNEX I **HAZARD ASSESSMENT – DNEL/DMEL VS. MOS/MOE APPROACH**

Option 1
According to REACH
(Threshold / non threshold)

Option 2
Margin of Safety / Margin of Exposure
(Threshold / non threshold)

1. Identify dose descriptors for each endpoint based on available information and toxicological studies

2. If necessary, modify the dose descriptor to the correct point of departure (POD)

3. Decide on Mode of Action (threshold / non-threshold)

4. Apply overall assessment factor (AF) to the corrected point of departure

5. Derive endpoint-specific DNEL or DMEL by dividing the dose descriptor with the overall AF

6. Select leading health / environmental effects and corresponding DNEL/DMEL

Proceed to Step 7
Calculate Risk Characterization Ratio (RCR)

Proceed to Step 7
Calculate Margin of Safety / Margin of Exposure

NOTE: The DNEL / DMEL derivation takes into account the relevant assessment factors. They are already accounted for in the result. In case of a MOE / MOS calculation the appropriate assessment factors are not already accounted for in the result and need to be considered before coming to a conclusion on risk.

DNEL versus Margin of Safety (MOS)

MOS = $\frac{\text{NOAEL OR NOAEC}}{\text{Exposure}}$

If MOS > Overall Assessment Factor → No concern
If MOS < Overall Assessment Factor → Concern

DNEL = $\frac{\text{NOAEL or NOAEC}}{\text{Overall Assessment Factor}}$

If Exposure < DNEL → Risk is adequately controlled
If Exposure > DNEL → Risk is NOT adequately controlled

Risk Management Measures

Rationale

The outcome of a risk characterization may indicate that the exposure level to a chemical substance is below the level that may cause harmful effects to the environment or the health of humans. In that case no additional risk management measures are required. If however the results of the risk assessment indicate that the exposure levels under the intended conditions of use are such that harmful effects have the potential to occur, then additional risk management measures must be defined. The purpose of risk management is to reduce the exposure to ensure that a chemical substance can be used safely. A re-iteration of the risk assessment may be necessary to verify the effectiveness of the selected risk management measures.

Key Issues

Risk management measures* can have different forms ranging from measures that reduce chemical hazard, to measures to check or monitor exposures to ensure exposure does not exceed certain levels and finally to measures that raise the awareness about the need to control exposure.

Exposure Reduction

The routes of exposure for humans are ingestion, inhalation and skin or eye contact. Environmental exposure is via emissions to air, water or soil.

To reduce human exposure in industrial settings, measures may be taken to reduce or eliminate the probability of contact with a chemical substance (e.g. closed systems, local air extraction). If exposure in industrial or professional use settings cannot be sufficiently eliminated than additional protective measures may have to be taken like e.g. the use of chemical suits, respiratory protection devices.

The impact of exposure for consumers may be mitigated by measures such as labelling, application restrictions, reducing the concentration of a harmful substance in a mixture or an article, or if necessary by substituting it by a less harmful alternative.

To reduce environmental exposure reductions may be achieved by changing such elements as process or storage conditions, by eliminating substances from emission streams (e.g. by filtering or incineration) or by reducing amounts used or stored.

Checking, Monitoring and Auditing

Whereas exposure reduction measures are the core of risk management, other measures may need to be taken in addition to ensure the effectiveness of exposure control measures. Depending on the risks, continuous monitoring of human or environmental exposure levels or periodic worker health checks may be necessary. Auditing of compliance with internal environmental, health and safety management systems can effectively support the implementation of risk management measures.

Risk Communication and Raising Awareness

Risk communication and increasing awareness are important elements of risk management. Various tools are available to inform users of chemical substances and other stakeholder about use related risks and risk management measures that should be taken to ensure safe use of a chemical product.

Safety data sheets convey detailed hazard and risk as well as risk management and emergency response information, primarily to industrial and professional users. Labels cover mainly hazard information and address industrial and professional users as well as consumers.

Training helps specifically industrial and professional users to better understand risk, the need for risk management measures to protect their own health and safety and how to correctly apply risk management measures like e.g. personal protection equipment.

The publication of risk assessment summaries helps consumers and other stakeholders to understand risks and risk management measures.

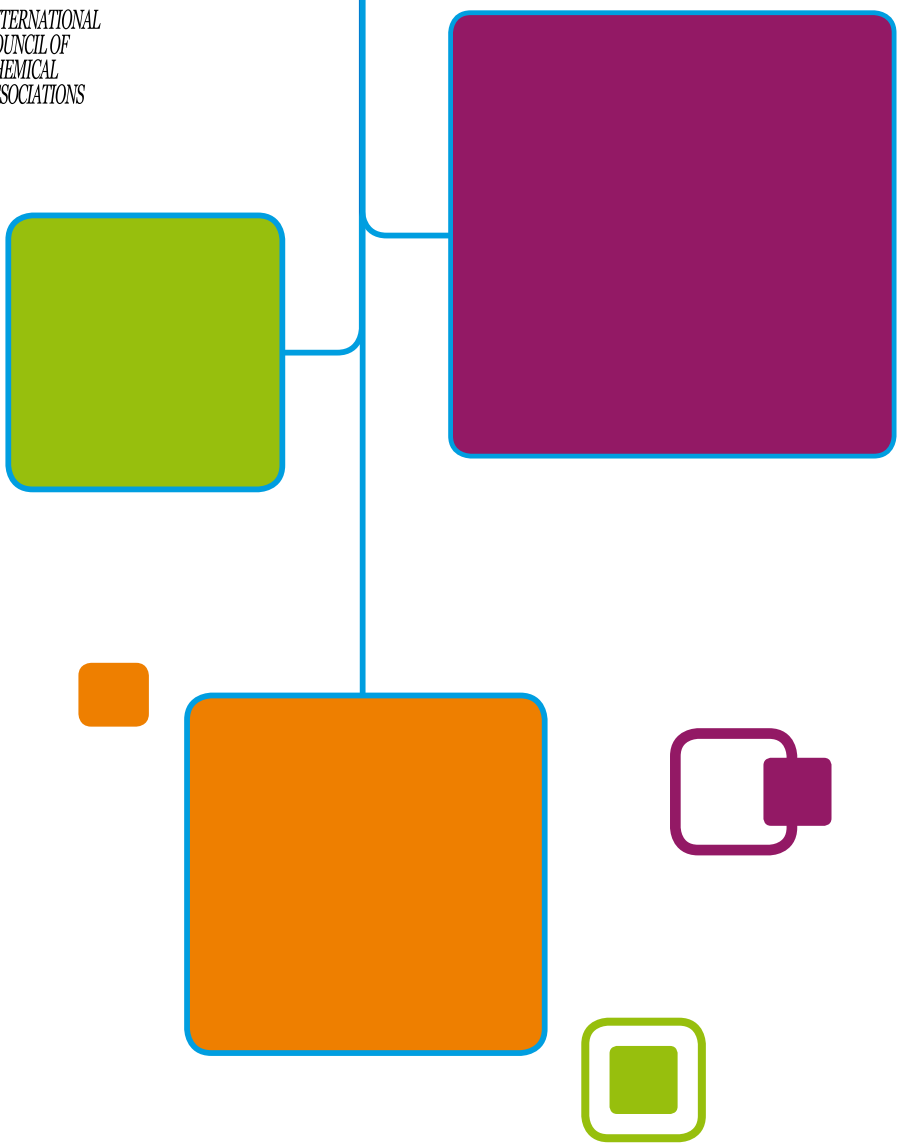
Example of Possible Legal Provisions

- The supplier of a substance or a preparation shall provide to the recipient of a substance or a mixture a safety data sheet, if the substance or the mixture is classified as harmful in accordance with the locally applied classification and labelling criteria.;
- The safety data sheets shall contain the following information:
  1. Identification of the substance;
  2. Hazards identification;
  3. Composition/information on ingredients;
  4. First-aid measures;
  5. Fire-fighting measures;
  6. Accidental release measures;
  7. Handling and storage;
  8. Exposure controls/personal protection;
  9. Physical and chemical properties;
  10. Stability and reactivity;
  11. Toxicological information;
  12. Ecological information;
  13. Disposal considerations;
  14. Transport information;
  15. Regulatory information;
  16. Other information.
- The manufacturer or importer of a substance shall make a summary of the report on the risk assessment of a substance publicly available, such as the product safety summary that is the output of the GPS.

Guidance

* GPS guidance section 2, pages 139 - 141

INTERNATIONAL COUNCIL OF CHEMICAL ASSOCIATIONS



Design: www.landmarks.be - May 2013

ICCA aisbl
Avenue E Van Nieuwenhuyse 4, box 1
B-1160 Brussels, Belgium
www.icca-chem.org

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY