VERSION 2.0
2018

ICCA REGULATORY TOOLBOX 2.0

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

ICCA REGULATORY TOOLBOX 2.0

INTRODUCTION

The safe management of chemicals is a key factor for economic and sustainable growth within a country. For this purpose, economies need to implement and enforce lifecycle-oriented and risk-based regulatory frameworks on chemicals management that are based on sound science. This document has been prepared to promote greater understanding regarding assessment and use of chemicals and to encourage sound regulations where needed. This document collects current information on the international regulatory environment for chemicals and may be useful to national and international regulators, managers and staff members of chemical companies, and others involved in the effort to ensure the sound management of chemicals around the globe.

SCOPE OF THE DOCUMENT

- Serving as a resource for national governments when developing and updating chemical management regulations
- Creating greater understanding regarding the assessment and use of chemicals
- Encouraging the establishment of sound regulations
- Collecting current information on the international regulatory environment for chemicals
- Providing support to national and international regulators, managers and staff members of chemical companies, and others involved in the effort to ensure the sound management of chemicals around the globe
- Identifying areas where improvement and/or greater coherence between current international regulations would significantly improve the ability of regulators and companies to meet health, safety, and environmental objectives while reducing obstacles to the manufacture and sale of chemicals in the global marketplace

As one of the most globalized industries in today's society, the chemical industry contributes significantly to the world economy. The U.N.'s Strategic Approach to International Chemicals Management (SAICM), adopted by 146 countries and approved by the UN Environment's Governing Council, aims to promote the sound management of chemicals around the world by the year 2020.[1] The development of high-quality regulatory environments around the world that incorporate transparency and stakeholder engagement will be essential to meet the 2020 goal. While it is widely accepted that the 2020 goal might not be reached, it is essential to continue developing high-quality regulatory environments around the world that incorporate transparency and stakeholder engagement beyond 2020. This document focuses on how industry and governments can continue to work together

[1] Strategic Approach to International Chemicals Management, http://www.saicm.org/index.php?option=com_content&view=article&id=72&Itemid=474

towards the 5 SAICM Objectives: Risk Reduction, Knowledge and Information Sharing, Governance, Capacity-building and technical cooperation, and reducing illegal international trafficking.[2]

This is not a static document; it is subject to continual review, update, and revision. This document represents the collective industry experience with various chemical management systems including the U.S. Toxic Substances Control Act (TSCA), European Union Registration, Evaluation, Authorization and Restrictions of Chemicals Regulation (EU REACH), Canada's Chemical Management Plan (CMP), and Japan's Chemical Substances Control Law (CSCL). This document is broken out into two phases:

- Phase I: Basic Elements for Chemicals Management
- Phase II: Advanced Elements of a Chemicals Management System

Within these Phases, there are multiple sections that can be implemented in a stepwise fashion to ensure any chemicals management system is comprehensive and effective. Depending on the needs of a country, resources (human and financial), and the level of knowledge, not all elements will be required in all cases. The various pieces will assist countries in developing and enforcing legislation to regulate the reporting, toxicological testing, and use of chemicals without interfering in any significant way with the growth and development of the country's economy. The goal of phases of implementation is to consider the varying degrees of resources and risks in order to regulate in the most effective way possible.

This document includes links and references to additional materials that may also provide more detail on each of the elements of a chemicals management system.

[2] SAICM, Overall Orientation Guidance, http://www.saicm.org/Portals/12/Documents/OOG%20document%20English.pdf

TABLE OF CONTENTS

CHAPTER 1: CHEMICAL REGULATORY APPROACHES

Science- and risk-based chemical regulations, paired with voluntary industry initiatives like Responsible Care® and the Global Product Strategy (GPS), are key to ensure that chemicals are handled safely across their lifecycle. However, when governments aim at establishing a new chemical regulation or updating an existing, resources can be saved if existing regulations from other countries are taken as the foundation and customized based on local needs and circumstances. Taking such a regulatory cooperation approach will benefit governments, industry and the public alike (see table 1.0).

1.0 BENEFITS OF REGULATORY COOPERATION

GOVERNMENT

- Resource efficiency and knowledge sharing leading to cost savings
- Strengthened transparency within and between regulatory systems
- Increased certainty for investors resulting in creation of new jobs, a decrease in unemployment and hence economic growth
- Increased economic growth directly leading to increased tax revenue
- Strengthened chemical management programs by leveraging information/assessments

INDUSTRY

- Easier access to other markets (especially for SMEs)
- Cost savings (therefore allowing resources to be re-directed to other areas, such as R&D)
- Increases in economic growth, resulting in higher net returns
- Faster innovation time to market
- More effective compliance
- Level playing field for foreign and domestic companies

SOCIETY

- Increased confidence in the regulatory system;
- Increased economic growth resulting from investments, job creation and higher standards of living
- Increased access to innovative products, greater consumer choice
- Increased competition and opportunities in domestic market

Over the years, governments and companies have addressed the likelihood of harm to humans or the environment posed by chemicals. The conduct of such hazard assessments and risk reviews has generated a substantial repository of chemical information as well as experience operating in different regulatory environments. A lot of this information on chemical safety is available on publicly accessible platforms, including the U.S. Environmental Protection Agency (EPA) website, European Chemicals Agency (ECHA) website, Health Canada and Environment & Climate Change Canada (ECCC) websites,

Japan Ministry of Environment website, and International Council of Chemical Associations Chemicals Portal, among many others. Stakeholders can utilize that information on a worldwide basis to develop programs for the sound management of chemicals in the most cost-effective way while providing relevant and responsible protection. The 2008 APEC Chemical Dialogue Principles for Best Practice Chemical Regulation provide guidance to governments on how to structure chemical regulations in order to increase the competitiveness and efficiency of chemicals in the marketplace while maintaining high standards of health and safety.[3] While this document focuses on a step-wise approach of implementing specific aspects of chemical regulation, the APEC Principles complement this guidance by highlighting the intersection of Good Regulatory Practices and chemical regulation to contribute to effective, safe and sound use of chemicals, a critical goal of any chemical management system.

A one-size-fits-all approach for chemical legislation does not exist, but country-specific needs and circumstances need to be acknowledged. Nevertheless, countries are encouraged not to reinvent the wheel, but take elements of systems from major trading partners into consideration when defining their own framework.

When contemplating chemical control regulations, governments should consider developing a National Plan or overarching strategy to outline their objectives through the regulation. Such a plan will help ensure governments deliver efficient and effective regulation without undue burden on those being regulated. Depending on the presence, or lack thereof, of the chemical industry in a country, the objectives of chemicals management may differ from country to country.

As one of the most regulated industries, it is essential for governments to have an overarching plan when imposing controls on the chemical industry to ensure policies do not result in duplication of regulatory efforts by governments and a burden on industry without adding a higher level of safety to humans and the environment. Any regulatory policies should be introduced on a step-by-step basis, increasing complexity over time, to build capacity and knowledge in both the industry and for regulators and to ensure regulations can be well managed by both authorities and industry. The development of a national plan will also ensure governments are doing a proper cost-benefit analysis for regulation and it will allow governments to explore opportunities to promote consistency and facilitate harmonized regulatory approaches.

[3] APEC Chemical Dialogue, Best Practices for Chemical Regulation, http://www.apec.org/Groups/Committee-on-Trade-and-Investment/~/media/B5821A4C2FCA4685A6192434457D6FF4.ashx

CHAPTER 2: PREREQUISITES FOR DEVELOPING A CHEMICAL MANAGEMENT POLICY

Implementing a chemicals management system is facilitated and managed through various tools, including:

- Regulations & Standards
- Voluntary actions taken by producers and users that demonstrate industry's own commitment to sound chemical management (including ICCA's Global Product Strategy and Responsible Care Program)
- Positive inducements, such as publicly-sponsored training and recognition programs.

An approach customized for each locality will derive the most effective utilization of public sector resources while having the largest environmental benefits.

The first step of developing a chemical control system is to establish an essential foundation that rests on the following four elements:

- Site and worker safety,
- Emergency response, and
- National objectives for regulatory action on chemicals management; and,
- Risk-Based Regulatory Systems versus Hazard-based Systems.

The elements identified in the first phase represent common fundamentals used to regulate chemicals across the world. These common fundamentals allow for customization, but also suggest opportunities for greater coherence within regions or with other existing systems. Implementation of basic elements utilized by other regulatory authorities may provide confidence that the element is effective and workable without draining resources, reduce unnecessary duplication, and minimize costs for governments and industry alike.

2.1 SITE & WORKER SAFETY

Site and Process Safety standards and systems are the first steps to help reduce risks and incidents at chemical manufacturing facilities for workers, the environment, and the public. While the chemical industry manufactures products that are critical to the everyday use, health and well-being of the public, the chemical sector can be a high hazard industry with the potential for catastrophic accidents. Yet, effective systems and regulations ensure site and worker safety by requiring facilities to identify and address any significant hazards and risks posed by the substances or processes present at the site and adhere to defined limit values. As demonstrated by the ICCA Responsible Care® Program, elements of site and worker safety practices encompass process safety, facility design, occupational safety and health, pollution prevention, waste management, and distribution safety.

It is essential such approaches are risk-based and flexible to still allow the industry to grow and deliver good performance in the long run. As stated in the *OECD Corporate Governance for Process Safety:*

Guidance for Senior Leaders in High Hazard Industries, there need to be high standards of corporate governance and a commitment from industry to implement such standards.[4]

2.2 EMERGENCY RESPONSE

Emergency response systems address chemical accidents, especially those occurring on plant sites and in transport situations. Effective Emergency Response systems require careful advanced planning and preparedness, rapid access to information, and cooperation between emergency responders and the private sector. One key document in this process is the Safety Data Sheet (SDS), in which all information on the chemical hazard are included. Countries can base emergency response plans on the information available on centrally stored SDSs in the country or region, and the compulsory provision of SDSs to occupational users of industrial chemicals. Promoting risk assessment implemented by industrial users and risk management based on SDS information can reduce the need for emergency response actions while also enhancing the efficiency of such actions. In the case of an emergency, it is crucial that all involved stakeholders including chemical factories, transporters, storage facilities, but also emergency responders have access to reliable and up-to-date information on the chemicals, thereby ensuring the implementation of adequate measures. As one element, the chemical industry's Responsible Care Initiative introduced a Code on this item that can be implemented by national associations.[5]

CONTRIBUTIONS TO SAICM OBJECTIVES

RISK REDUCTION

KNOWLEDGE & INFORMATION (FOR EMERGENCY RESPONDERS)

CAPACITY BUILDING & TECHNICAL COOPERATION

ADDITIONAL RESOURCES

ICCA Responsible Care® Program

OECD Process Safety Guidance

OECD Guiding Principles for Chemical Accident Prevention, Prepared and Response

UNE Awareness and Preparedness for Emergencies at Local Level (APELL)

Assistance in establishing an emergency response system can be obtained from the UN Program for Awareness and Preparedness for Emergencies at Local Level (APELL). This program was established with and continues to receive chemical industry support. Additionally, governments should reference the global website, initially created in the APEC Chemical Dialogue, (http://www.chemtrec.com) for information for first responders on hazardous materials response.

[4] OECD, http://www.oecd.org/chemicalsafety/chemical-accidents/corporate%20governance%20for%20process%20safety-colour%20cover.pdf

[5] Gulf Petrochemical and Chemical Association, http://www.gpca.org.ae/wp-content/uploads/2014/05/01-community_awareness-caer_code.pdf

2.3 NATIONAL OBJECTIVES FOR REGULATORY ACTION ON CHEMICALS MANAGEMENT

Developing national objectives and a timeline to achieve the objectives is essential to successfully implementing a chemical control law and regulation. First, governments should identify the problem they are trying to address through policy and regulation. A clear understanding of the problem can help focus regulatory priorities and determine the scope of regulatory activity. Based on this problem formulation, governments can draft step-wise objectives to reach the policy goal. These objectives should help ensure regulations - commensurate with the risk posed and the regulatory process remains transparent. This will also help identify opportunities for stakeholder dialogue and input, which is necessary to create high quality regulations.

CASE STUDY OF NATIONAL PLAN: MALAYSIA

As part of the Eleventh Malaysia Plan (2016-2020), Malaysia developed a National Action Plan to identify and address the gaps in chemicals management activities in Malaysia. The Action Plan consists of 6 strategies proposed to integrate and strengthen the chemical management framework system in Malaysia and incorporates priorities of all stakeholders.

2.4 RISK BASED SYSTEM VERSUS HAZARD BASED SYSTEM

A risk-based approach incorporates an understanding of both hazard and exposure. It considers both the degree of hazard (hazard identification and characterization) and the extent of exposure potential (exposure assessment). Identifying and prioritizing the risks to human health and the environment associated with the production, handling and use of chemicals can promote more effective decision making and understanding of what is required in a regulatory system. Unlike approaches based purely on hazard, risk assessment can help focus resources on the highest priority chemicals, promote greater transparency in decision making, and avoid unintended consequences from hazard-based restrictions. A risk-based approach can deliver a high quality, effective and cost-efficient instrument to mitigate risk.

Definitions:

- **Risk-based means** based on integration and assessment of data and information on hazards and exposures of one or more chemicals, chemical substances or mixtures, including the circumstances under which chemicals are used.
- **Hazard-based means** basing regulatory decisions simply on the potential hazards of a substance without consideration for exposure.
- **Risk Assessment means** the integration and assessment of data and available information on hazards and exposure for the conditions of use of a chemical substance.
- **Risk Management means** implementation of measures to mitigate risks based on risk evaluations that take a wide range of legal, economic, and social factors into account. Measures to reduce risk include a range of options from labeling to ban or phase-out as necessary.

CHAPTER 3: ESSENTIAL ELEMENTS OF CHEMICAL CONTROL LEGISLATION

The elements listed here are essential Good Regulatory Practice elements as defined by multiple international organizations, including the OECD and APEC, which should be implemented at any stage of a regulatory scheme. See explanations for each of these essential elements in more detail below:

1. Communication to all affected parties, foreign as well as domestic, of plans on implementing a chemicals legislation
2. Well-defined date when regulation becomes effective
3. Statement of what is covered and what is not covered
4. Definition of terms used in the regulation
5. Exemptions for low risk chemicals, including polymers, substances covered by existing policies
6. Timing requirements for various steps and/or requirements in the policy
7. Protection for trade secret or confidential business information (CBI)
8. Exclusion of non-tariff trade barriers
9. Acceptance of toxicological data developed in another country (mutual acceptance of data)
10. Acceptance of Alternative testing methods
11. Regulatory Cost/Benefit Analysis/Impact Assessment

3.1 COMMUNICATION

It is important to communicate the proposal to develop such a law on a worldwide basis with sufficient advance notice to allow companies to prepare accordingly. A minimum of 3 months should be provided to allow time for all affected parties to submit comments; as regulations might only be published in the local language, time should be sufficient to allow foreign stakeholders to translate and provide comments accordingly. Companies outside the country have a difficult time collecting information if the law proposal is published only locally. The chemical industry has a complex global supply chain. Information that is requested from regulators can reside with foreign suppliers, sometimes several steps up the supply chain, who will then have a strong interest to be part of the consultation process when a new regulation is being developed. Similarly, the final law should be communicated on a worldwide basis, such as through the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Notification system.

3.2 EFFECTIVE DATE

The law should have a specific date on which the law becomes effective. This date should allow for a sufficient transition time for the regulated community (see also 3.6).

3.3 INCLUDED & EXCLUDED SUBSTANCES

The law should clearly state which substances are included in the law and which are excluded. Recommendations for exclusions are those which are clearly covered by another law, for example:

a. Laws regulating the introduction and use of pharmaceutical products precursors and intermediates
b. Laws regulating the introduction and use of chemicals in food or intended to be in contact with food

c. Laws regulating the introduction and use of agricultural chemicals, pesticides, and biocides
d. Laws regulating the introduction and use of explosive materials
e. Radioactive and nuclear materials
f. Naturally occurring substances
g. Cosmetic products
h. Articles
i. Waste

3.4 DEFINITIONS

The law should give clear definitions or certain terms to avoid misunderstandings. Some recommendations are:

a. Substance-chemical elements in their natural or free state and chemical compounds formed by combinations of elements.
b. Preparations-mixtures or solutions of two or more substances
c. Polymer-substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecule must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number on monomer units.
d. Research-experimentation carried out under controlled conditions in a laboratory or pilot scale unit.
e. Development-work to find uses for a chemical or to solve a problem in the use of a chemical or to develop a process for the manufacture of a substance.
f. Inventory- a list of existing chemicals which are exempt from notification as new substances.
g. Hazardous (dangerous)-a property that is the cause of a health, safety or environmental concern, according to GHS criteria. The term 'dangerous' is usually used in the context of transportation (i.e. Dangerous Goods), whereas the term 'hazardous' is usually associated with chemicals in the workplace and facilities (e.g. hazardous chemicals).
h. Pre-market-before selling or in any way introducing into commerce. Import would constitute introduction into commerce.
i. Article-a material that is in a form peculiar to its final use including any ingredient needed to enhance the stability or processing of the material used.

3.5 EXEMPTIONS

Provisions should be made to exempt certain substances from notification, such as chemicals of low concern regarding health, safety, and environment. These might include:

a. Chemicals to be used for purposes of analysis, measurement of properties or toxicity testing.
b. Chemicals to be used exclusively for research and development purposes.

c. Polymers except those containing 2% or more of a new monomer or reactant; polymers pose little risk due to their limited solubility and reduced ability to pass through cell walls.
d. Chemicals which will be sold in quantities of less than 1000 kg/year which are nor classified as carcinogenic, mutagenic or reprotoxic (low volume).
e. Articles.
f. Mixtures of chemicals except that the chemical in the mixture should be on the inventory or should have been notified by the prescribed procedure.

3.6 TIMING REQUIREMENTS FOR NEW POLICIES

Recognizing that countries need time to review the information submitted, consideration should be given to the following:

a. Where a notification has been submitted and/or accepted in a jurisdiction, the designated authority should review the information and give approval or request additional information within a period of 30 days.
b. In all cases, the designated authority should decide within 30 days if the information submitted meets the requirements for assessment under the law.
c. The designated authority should in each case respond in writing to the submitter.
d. The designated authority may be able to extend the review period where the review of the information submitted presents some difficulty in making decisions. The submitter must be notified in writing and be given an option to discuss the need for the extension with the authorities.
e. If no response is received from the designated authority in the specified time period, the submitter should be free to manufacture or import the substance.
f. The manufacturer or importer should be responsible for the information submitted, however, due to concerns regarding proprietary information, a manufacturer located outside of the country may be able to submit the required information directly to the designated authority.

3.7 CONFIDENTIAL BUSINESS INFORMATION AND TRADE SECRET PROTECTION

Proprietary business and sensitive commercial and financial information, including trade secrets, qualify as confidential business information (CBI) and are entitled to strong protection from disclosure to domestic and foreign competitors. Some information is already covered by patent law and therefore does not need to be substantiated as qualifying as CBI (e.g., customer lists, sales information, etc.). Other information, such as confidential chemical identities qualify for CBI protection when substantiated by the owner. Substantiation is generally satisfied when the CBI owner establishes that:

a. the business has asserted a CBI claim that has not been waived or expired;
b. the business demonstrates it has taken reasonable steps to protect the confidentiality of the information and intends to continue to do so;
c. the information is not reasonably obtainable by other persons;
d. no statute or law requires the disclosure of the information; and
e. either the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business' competitive position or the information is voluntarily

submitted information and its disclosure would be likely to impair the government's ability to obtain the necessary information in the future.

Although not exhaustive, the following list identifies the types of information that should qualify for CBI protection where it can be substantiated by the submitter and agreed to by the designated authority:

a. The specific chemical name and associated identifying number of the chemical being notified.
b. Compositions and formula of chemical products
c. Link between a chemical to the trade names
d. The name of the submitter, both company name and the company personnel name(s).
e. Information about the manufacturing process.
f. Information about the specific use of the chemical.
g. The volume of the chemical expected to be sold, produced or imported.
h. The location of the manufacturer, importer or marketer.
i. Spectral data which can be used to deduce the specific chemical identity
j. Raw toxicity/ecotoxicity study data

In addition, it is recommended that the following guidelines be followed:

- The submitter should provide the designated authority with two documents: 1) a CONFIDENTIAL document containing all the information to be protected so the designated authority has access to the protected information and a duplicate; and 2) a PUBLIC, sanitized, version of document with the CBI information redacted from the document and marked by the submitter as CONFIDENTIAL to be shared with the public.
- The designated authority must have procedures in place, both in the physical and online space, for protecting information declared as confidential by submitters before the beginning of the notification process.
- Only select individuals should have access to the confidential information submitted in connection with any notification. These persons should be given special training in the handling and protection of such information.
- Health and safety effects information, exposure limits, protective equipment and storage recommendations should never be considered as confidential information.
- Companies that own health and safety studies that are proprietary and not in the public domain should be permitted to redact the key elements (not health and safety effects information) from the studies that confer commercial value to the owner.

The period for protection of confidential information should be unlimited unless the submitter withdraws the claim. If there are time limits imposed on CBI claims, they should be renewable as long as the submitter can substantiate its claim for CBI protection.

Significant penalties should be assessed for any person in the designated authority who discloses any confidential information. These should include monetary penalties and removal from the position having access to such information.

3.8 TRADE BARRIERS

The legislation should apply equally to domestic companies and importers to avoid the construction of non-tariff trade barriers.

3.9 MUTUAL ACCEPTANCE OF DATA

In accordance with the OECD Mutual Acceptance of Data Agreement, test data conducted in any country should be accepted providing that it was developed under the principles of good laboratory practice (GLP), OECD test guidelines and that the study and reports have been reviewed by qualified quality personnel. In alignment with the OECD MAD Agreement, there should be no requirement for the test laboratories to be certified by a government agency nor should it be required to perform the test in the country of registration. The mutual acceptance of data helps to significantly reduce the number of (unnecessary) duplicative animal tests and is therefore consistent with the Three-Rs approach (reduce, refine, replace).

3.10 ACCEPTANCE OF ALTERNATIVE TESTING METHODS

Determination of (eco)toxicological hazard requires substances to be tested for such properties. While animal tests have been the model of choice in the past, it is anticipated to reduce, refine and replace them by alternative methods without lowering the level of certainty obtained from test results. In the past, several OECD guidelines have been published to test various endpoints, including skin irritation, eye irritation, skin sensitization, dermal penetration and genotoxicity tests. Such results should be accepted by local authorities if performed according to OECD guideline. In addition, Quantitative Structure Relationship Analyses (QSAR) should be considered when analyzing the intrinsic properties of a chemical.

3.11 REGULATORY COST/BENEFIT ANALYSIS

A sound assessment of the benefits and costs of regulation must be a basic tenet of any effective regulatory process. Regulating authorities need institutional mechanisms to monitor and enforce the integrated policy and to oversee the cost benefit and regulatory impact assessment processes established to introduce transparency and accountability into the regulation making processes. The cost-benefit analysis and regulatory impact assessment should be aligned with the APEC Chemical Dialogue Principles for Best Practice Chemical Regulation.

CHAPTER 4: PHASES OF CHEMICALS MANAGEMENT SYSTEMS

4.1 PHASE I: BASIC ELEMENTS FOR CHEMICALS MANAGEMENT

4.1.1 Implementation of a Hazard Communication System

Classification and labeling systems provide essential product information, including safety precautions, to users. The Globally Harmonized System for Classification and Labeling (GHS) of industrial chemicals attempts to create a common set of building blocks for hazard classification and communications provisions. Clear criteria have been developed for the three classes of hazards (building blocks), i.e. physico-chemical characteristics of substances, human health hazard and environmental hazard. Specific OECD test guidelines are available for each hazard category[6]. Based on the respective results, GHS defines categories and criteria on how to classify and label chemicals.[7]

Governments should carefully consider how they implement this system through their domestic regulatory processes. The building block approach allows governments to customize the GHS regulation to best fit an individual country. Yet, this can lead to significant discrepancies in the regulations between countries and hence barriers to trade. Therefore, governments should consider adopting an existing scheme for classification and labeling or allow the use of schemes used by major trading partners to help establish consistent criteria and requirements for classification and labeling on a global level. Based on hazard categories/classes, substances will be labeled with a respective H-phrase and receive a certain pictogram.

Domestic manufacturers and other local parties should be encouraged to follow a preferred approach based on an existing scheme. This should include the ability for manufacturers and importers to self-classify a substance based on a weight-of-evidence approach when determining a hazard for any health effect. A system based on those used by the country's key trading partners and that takes a risk-based approach aimed at reducing risk in the most economically efficient way, would be the best approach. Such an approach would enhance the possibility of trade with other countries, while still protecting human health and the environment in the receiving country.

4.1.1.1 Safety Data Sheets

Regardless of the building blocks, the hazard communication regulations and standards require a product label and Safety Data Sheet (SDS) for all hazardous materials, which ensure that all environmental, health, and safety (EHS) information will be available to all stakeholders in the value chain. Dissemination of a high quality SDS is crucial to ensure all vital information on the hazards of the material are clearly communicated to all involved stakeholders along the product lifecycle (including transport workers, emergency response personnel, downstream customers and recipients of the

[6] OECD, http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm
[7] U.N. Sub Committee of Experts on GHS, https://www.unece.org/trans/danger/publi/ghs/ghs_rev06/06files_e.html

commodities) to allow them to safely handle the respective chemicals. The information communicated on the SDS can then be used in the regulatory process without duplicating the efforts of the regulators and industry. The benefits of an internationally harmonized system of transport regulations is that the regulated communities around the world have the same classification, packaging, documentation, and hazard communication requirements, which minimizes border delays. As international trade continues to increase, it becomes more essential to minimize such delays. Not only do harmonized regulations facilitate smooth border crossing of dangerous goods, but they also ensure that workers and a country's citizenry are protected and warned by regulations that have proven effective.

4.1.1.2 Hazardous Properties

A list of properties which are considered to be hazardous should be provided. Hazardous properties and class should align with the U.N. GHS Purple Book. For example, typical hazardous properties are:

a. Explosive
b. Oxidizing
c. Extremely flammable
d. Flammable
e. Very toxic
f. Toxic
g. Corrosive
h. Irritant
i. Carcinogenic
j. Mutagenic
k. Reproductive effects
l. Harmful to the environment

CONTRIBUTIONS TO SAICM OBJECTIVES

RISK REDUCTION

KNOWLEDGE & INFORMATION

GOVERNANCE

CAPACITY BUILDING & TECHNICAL COOPERATION

REDUCE ILLEGAL INTERNATIONAL TRAFFICKING

ADDITIONAL RESOURCES

UN Sub-Committee of Experts on GHS

The GHS allows individual countries or competent authorities to choose which GHS hazard classes to implement in national regulations. This is referred to as the Building Block approach. For each hazard class, there are designated categories of hazard. See below example of each of the GHS building blocks (health hazards, physical hazards, and environmental hazards) and the associated hazards:

HEALTH HAZARDS (GHS REVISION 7)

Hazard Class	Hazard Category				
Acute Toxicity	1	2	3	4	5
Skin corrosion/irritation	1	2	3		
Serious eye damage/eye irritation	1	2, 2A, 2B			
Respiratory sensitizer	1, 1A, 1B				
Skin sensitizer	1, 1A, 1B				
Germ cell mutagenicity	1A, 1B	2			
Carcinogenicity	1A, 1B	2			
Toxic to Reproduction	1A, 1B	2	Effects on or via lactation		
Specific target organ toxicity (single)	1	2	3		
Specific target organ toxicity (double)	1	2			
Aspiration hazard	1	2			

ENVIRONMENTAL HAZARDS (GHS REVISION 7)

Hazard Class	Hazard Category			
Hazardous to Aquatic Environment (acute)	1	2	3	
Hazardous to Aquatic Environment (chronic)	1	2	3	4
Hazardous to the Ozone Layer	1			

PHYSICAL HAZARDS (GHS REVISION 7)

Hazard Class	Hazard Category						
Explosives	Unstable	Div 1.1	Div 1.2	Div 1.3	Div 1.4	Div 1.5	Div 1.6
Flammable Gases	1	2					
Aerosols	1	2	3				
Oxidizing Gases	1						
Gas Under Pressure							
Compressed Gases	1						
Liquefied Gases	1						
Refrigerated Liquefied Gases	1						
Dissolved Gas	1						
Flammable Liquids	1	2	3	4			
Flammable Solids	1	2					
Self-Reactive Substances	Type A	Type B	Type C	Type D	Type E	Type F	Type G
Pyrophoric Liquids	1						
Pyrophoric Solids	1						
Self-Heating Substances	1	2					
Water reactive -> Flammable Gases	1	2	3				
Oxidizing Liquids	1	2	3				
Oxidizing Solids	1	2	3				
Organic Peroxides	Type A	Type B	Type C	Type D	Type E	Type F	Type G
Corrosive to Metals	1						
Desensitized explosives	1	2	3	4			

4.1.2 Identify Chemicals in Commerce (Periodic Reporting and Inventory)

To understand the chemicals in commerce at a given point in time, economies can ask manufacturers or importers to report information or high-level use information collected through the implementation of the GHS through hazardous substances listed on Safety Data Sheets. If any additional information is required, it should only be for high volumes (>1 metric T/yr) and should be related to the risk profile of the substance. If such information is necessary, economies can ask manufacturers and importers to directly report information, such as volume and general uses, on the high risk chemical substances they domestically manufacture or import into the country during the principal reporting year. A logical reporting period would be every three or four years (see examples below).

The information should all be collected in a centralized system for electronic data submissions for all types of reporting. Such a scheme should ensure all submissions are secure and protected, not just those containing sensitive information. This database of chemicals in commerce can later serve as the basis for further actions as described in Phase II.

4.1.2.1 Examples of Periodic Reporting Schemes:

A. **Canada Chemicals Management Plan (CMP) Overview --** The Canadian Environmental Protection Act (CEPA) established the Chemical Management Plan (CMP) to set priorities for assessing and managing chemical substances used in Canada. The regulatory agency, Environment Canada, established the Domestic Substances List (DSL) to compile the substances that were believed to be in use in Canada, so it is currently an "evergreen" list of such substances. The DSL is used to gather updated data on the substances in commerce. Canada requires cyclical reporting of key substance information. Quantity thresholds trigger reporting at levels relevant from an ecological or human health point of view. Data collection is a volume-triggered, tiered approach, where more information is sought based on substance categories, and efforts to assess the highest priority chemicals.

B. **U.S. --** One example of a periodic reporting scheme is the U.S. Environmental Protection Agency's Chemical Data Reporting (CDR) scheme. The purpose of CDR, formerly known as Inventory Update Reporting (IUR), is to collect quality screening-level, exposure-related information on chemical substances and to make that information available for use by EPA and, to the extent possible, the public. Manufacturers and importers are required to submit information every four years to EPA to ensure enough time for submission and review. The rule requires manufacturers and importers to provide the Agency with information on the production and use of chemicals in commerce in large quantities. The CDR data constitute the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA.

C. **Japan --** A third example of a periodic reporting system is the New Reporting Requirement in Japan. The primary chemical control law in Japan is the Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances (Law No. 117 of October 16, 1973). The law was most recently amended in 2009 to add, among other things, an annual reporting requirement. The new scheme imposes a reporting obligation on companies manufacturing or

importing more than one metric ton of a "general chemical substance" or a substance designated as a "priority assessment chemical substance" (PACS). METI has issued a list of chemical substances designated as PACSs as of April 1, 2011, available at http://www.meti.go.jp/policy/chemical_management/english/files/PACSs-list.pdf.

D. **EU --** In the EU all substances that were on the market before REACH entered into force could benefit from a registration, spread over three deadlines (2010, 2013 and 2018) if they have been pre-registered. So-called non-phase in substances have to be registered before they are brought on the European market. Registration is required for all substances on the European market in quantities above 1 ton per year. On top all substances on the European market below 1 ton per year had to be notified by end 2010, or when they are brought for the first time on the market, to the classification and labelling inventory if they are classified according to CLP.

CONTRIBUTIONS TO SAICM OBJECTIVES	ADDITIONAL RESOURCES
RISK REDUCTION **KNOWLEDGE & INFORMATION** **GOVERNANCE** **CAPACITY BUILDING & TECHNICAL COOPERATION** **ILLEGAL INTERNATIONAL TRAFFICKING**	ICCA Product Stewardship Guidelines

4.2 PHASE II: ADVANCED ELEMENTS OF A CHEMICALS MANAGEMENT SYSTEM

4.2.1 Prioritize List of Chemicals for High-Priority Risk Management

A list of chemicals for high-priority risk management (or prioritization list) should aim to identify and focus risk management activity on those chemicals that, in individual national circumstances, may pose an unreasonable risk to citizens and the environment. Prioritization, as such, will help focus scarce government and industry resources more efficiently on chemicals that are more likely to be of high risk. When prioritizing chemical substances, a country should consider the following:

- Chemical hazard
- Exposure and use scenarios
- Sensitive applications (e.g. in consumer products)
- Volume

In order to best address local circumstances, a country should employ criteria for selection of chemicals for priority risk management action at the national level, which are scientifically-based and flexibly applied. Priority setting based on risk and the opportunity to reduce risk to human health and the environment should be used, i.e. focusing on both the inherent substance properties and intended uses of that substance and associated exposures. Such prioritization will aim to identify and focus risk

management activity on those chemicals that, in individual national circumstances, may pose an unreasonable risk to citizens and the environment.

Substances can be separated into two categories: **low priority chemicals and high priority chemicals**. The low priority chemicals would not require any additional action or review due to their low risk. The high priority chemicals would be flagged for further review in the future.

4.2.1.1 Examples of Prioritization Schemes:

1. **U.S. Review –** Under TSCA, in 2012 EPA identified a Work Plan of priority chemicals for further assessment. The Work Plan was updated in November 2014 to reflect updated data submitted to EPA by chemical companies on chemical releases and potential exposures.[8] Under the recent amendments to TSCA, EPA will designate active chemicals in commerce as either high priority or low priority for EPA risk evaluations. EPA's prioritization process must include criteria on hazard and exposure potential and on conditions of use of chemicals. EPA's prioritization process rule can be accessed using this link.
2. **Canada Review –** In 2006, the Canadian government completed a prioritization process, reviewing approximately 23,000 chemicals on the Domestic Substances List (DSL) that had been in commercial use over the prior two decades. Environment and Health Canada used the Chemicals Management Plan (CMP) to identify 4,300 substances from the DSL for review. These 4,300 substances were then classified as of being low, medium, or high priority. The high priority substances (approximately 500 substances) are the main focus of the CMP.[9]
3. **ACC Prioritization Screening Approach[10] --** ACC developed this tool in 2011 to better explain its perspectives on ways to prioritize substances based on specific hazard, use and exposure criteria. This takes a more rigorous, risk-based approach to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures. US EPA's prioritization criteria are expected to be similar to this Screening Approach (expected June 2017).
4. **EU REACH Program --** EU REACH requires all chemicals >1 Ton/yr to be registered. In a three-tiered approach, the manufacturing/import volume (per registrant) defines the extent to which data need to be submitted within a certain timeframe. A single end-point classification under GHS is used as trigger for risk assessment. Prioritization in the evaluation of chemicals is mainly based on proposals put forward by EU Member States under the CoRAP (Community rolling action plan) program (120 substance evaluation for the year 2014-2016). For each substance on the list, the evaluating Member State, the (planned) year of evaluation and a short description

[8] U.S. Environmental Protection Agency, TSCA Work Plan for Chemical Assessments: 2014 Update, http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Work_Plan_Chemicals_2014_Update-final.pdf
[9] Government of Canada, Chemicals Management Plan, http://www.chemicalsubstanceschimiques.gc.ca/plan/plan-eng.php
[10] American Chemistry Council, ACC Prioritization Screen Approach, http://www.americanchemistry.com/Prioritization-Document

of the concern which led to it being placed on the list is noted.[11] However, listing is often been based on individual National lists/priorities. In addition to this, some substances are evaluated simultaneously via the CoRAP or other REACH-related processes, making the process rather complex and difficult to predict. The prioritisation of substances under EU – REACH is handled by the so-called Substances of Very High Concern (SVHC) roadmap. There a distinction is made whether the information that is already available is sufficient to do the risk evaluation or not. If it is considered that the information is not sufficient the substance is send into substance evaluation and it will come into the Community rolling action plan (CoRAP). The CoRAP 2017 – 2019 contains 115 substances, bringing the total number of substances in that process to 336 substances. After the evaluation, the substance will be picked up into the regulatory risk management discussions where different conclusions are possible: going from no action needed, to restriction, authorization or action under other EU legislation.

5. **Japan** – In 2009, the Japanese government made an amendment in order to introduce a comprehensive control system that covers the existing chemical substances. Companies that manufacture or import any chemical substance, including existing substances, in excess of the specified amounts are obliged to notify quantity and other information for every fiscal year. Chemical substances which the government identifies, based on the content of their notifications and available knowledge of their hazardous properties, as having higher priority in risk assessment shall be designated as "Priority Assessment Chemical Substances." Among the Priority Assessment Chemical Substances, substances which raise concerns about adverse effects on humans or the environment through the information gathering and the risk assessment shall be subject to regulations on manufacture and use as "Specified Chemical Substances," as in the existing Law.

Once the highest priority chemicals are identified, they should be subject to more detailed scientific evaluation and risk assessment. These scientific evaluations should identify potential health and environmental risks arising from the manufacture, processing, use, transportation and disposal of high priority chemicals. Assessments should be undertaken with validated data and information, with objective and accepted evaluation protocols, and in a transparent (peer reviewed) fashion. As noted above, there are opportunities for trading partners to collaborate on these risk assessments when substances have been identified as priorities in each country.

Substances found to present unacceptable risk to human health or the environment in certain uses and applications should be subject to risk management. The suite of measures to prevent or manage unacceptable risks can include restrictions on use, how a substance is made, or the amount released into the environment. Other risk management approaches including labeling requirements, codes of practice, or bans or phase-outs where there is unreasonable risk not otherwise manageable, may also be used. Regulatory cooperation may also promote alignment between trading partners on risk management measures, although final regulatory decisions should remain sovereign.

[11] ECHA, https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

CONTRIBUTIONS TO SAICM OBJECTIVES	ADDITIONAL RESOURCES
RISK REDUCTION **KNOWLEDGE & INFORMATION** **GOVERNANCE** **CAPACITY BUILDING & TECHNICAL COOPERATION**	ICCA GPS Risk Assessment Guidance

4.2.2 Refine National Chemical Inventories and New Substance Notification Requirements

National chemical inventories identify those chemicals in use in a country during a specific period of time. Generally, they are used as part of a new substance notification scheme, to identify those chemicals that are "new" as not included on the inventory and thus potentially subject to new chemical notification. Inventories alone do not provide a mechanism to identify those chemicals which may pose unreasonable risk to citizens and the environment. Countries should differentiate between chemicals that have been on the market prior to implementing a new legislation as compared to new ones. Accordingly, requirements for placing new substance on the market need to be installed.

Experiences of governments and industry from countries that have established inventories indicate that the process of establishing and maintaining the inventory is costly and time consuming. Other mechanisms (e.g. such as Safety Data Sheets, Classification and Labeling, and Emergency Response Systems) in a chemical management system are more cost-effective at protecting the citizens and the environment. Individual inventories may not always be appropriate, particularly if major trading partners have established inventories that contain a substantially similar list of substances.

Government and industry resources should be focused on chemicals of highest risk and therefore should allow for certain exclusions for chemicals of low risk. The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information. Such exclusions should include low volume chemicals, chemicals used for research and development (R&D), and polymers of low risk.

Periodic reporting as described in 4.1.2 can be considered as a better and more meaningful alternative to developing baseline data of chemicals in commerce since over time, inventories will eventually contain many obsolete chemicals.

4.2.2.1 Examples of Chemical Inventories

A country can establish an existing chemicals inventory by adopting the inventory of another country (such as that of a neighboring country or a major trading partner), or by establishing a "Mutual Acceptance" scheme[12], or by some combination of these options. As of October 2017, there were 8 such existing inventories:

- U.S. TSCA Chemical Substances Inventory
- Canada's Domestic Substances List
- Australian Inventory of Chemical Substances (AICS)
- EU REACH Registration and REACH registration number
- Korea Existing Chemicals Inventory (KECI)
- Taiwan – National Existing Chemical Inventory
- Japan – Existing and New Chemical Substances Inventory (ENCS)
- China – Inventory of Existing Chemical Substances.
- Philippines – Philippine Inventory of Chemicals and Chemical Substances (PICCS)

[12] See Australia-Canada Mutual Acceptance of New Chemical Notifications – ECCC, https://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=7BB979DD-1

CHAPTER 5: INDUSTRY'S ROLE IN PROMOTING SOUND CHEMICALS MANAGEMENT

Responsible Care® is an essential part of the global chemical industry's contribution to the SAICM and sound chemicals management. Through Responsible Care (and other similar voluntary programs), global chemical manufacturers commit to pursue an ethic of safe chemicals management and performance excellence worldwide. Our commitment helps to enhance public confidence and trust in the industry's dedication to safely manage chemicals throughout their lifecycle while ensuring that chemistry can continue to contribute to a healthier environment, improved living standards and a better quality of life for all.

As part of our commitment to implementing Responsible Care, industry is committed to assist in the implementation of the proposed chemical regulatory approach by working through the national industry associations. It is prepared to undertake the following actions, in accordance with nationally stated needs and objectives:

1. Participate in voluntary programs (e.g., ChemStewards, Responsible Care, Together for Sustainability, etc.) that demonstrate and ensure implementation of safety and continuous improvement in the safe use of chemical products throughout the entire product value chain.
2. Serve as a resource and subject matter experts for government officials and policy developers.
3. Constructively work with government and policy developers to develop and implement effective and efficient policies for chemicals management.
4. Participate in training sessions for regulatory authorities and local chemical industry, especially for small and medium-sized enterprises (SMEs).
5. Participate in activities of international organizations (e.g. UNITAR, OECD) and other opportunities for promoting ideas and building capacity/expertise in need-identified areas.
6. Make available expert advisors for visits to countries developing National Chemical Management Systems and assist visitors from such countries in obtaining information.
7. Support particularly SMEs in developing programs in line with ICCA Product Stewardship Guidelines in collaboration with national chemical associations and local authorities.
8. Coordinate involvement/partnership from other industry sectors.

APPENDIX A – ACRONYM DEFINITIONS LIST

ACC	American Chemistry Council
AICS	Australia Inventory of Chemical Substances
APEC	Asia Pacific Economic Cooperation Forum
APEC CD	APEC Chemical Dialogue
ASEAN	Association of Southeast Asia Nations
BIAC	Business Industry Advisory Committee to the OECD
CAER	Community Awareness and Emergency Response
CBI	Confidential Business Information
CCL	Chemical Control Laws
CD	Chemical Dialogue (APEC)
CDR	Chemical Data Reporting Rule (formerly IUR)
CEPA	Canadian Environmental Protection Act
CHEMTREC	ACC's 24-hour HazMat Communications Center
CHNC	Clearinghouse on New Chemicals (OECD)
CIAC	Chemistry Industry Association of Canada (formerly CCPA)
CLP	Classification, Labeling and Packaging Regulation (EU)
CMP	Chemicals Management Plan (Canada)
CMR	Carcinogen, Mutagen, Reproductive Toxin
CNCIC	China National Chemical Information Center
COC	Chemicals of Concern
CoCAM	Cooperative Chemicals Assessment Program (OECD)
CoRAP	Community Rolling Action Plan (REACH)
CSR	Chemical Safety Report (REACH)
CWC	Chemical Weapons Convention
DG	Director General
DOL	Department of Labor (US)
DSL	Domestic Substances List (Canada)
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EDC	Endocrine Disruptor Chemical
EHS	Environment, Health and Safety; Employee, Health and Safety;
EHS&S	Environment, Health and Safety & Security
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency (US)
EPCRA	Emergency Planning & Community Right-to-Know Act of 1986, also known as SARA Title III.
ePMN	Electronic Pre-Manufacture Notice (TSCA)
eSDS	Extended Safety Data Sheet (REACH)

EU	European Union
FTA	Free Trade Agreement
GHS	Globally Harmonized System for Classification and Labeling
GPS	Global Product Strategy
G.R.E.A.T.	GHS Reference Exchange and Tool Clearinghouse (APEC)
GRP	Good Regulatory Practices
HCS or HazCom	Hazard Communication Standard (OSHA)
HPV	High Production Volume Chemicals (> 1 million lbs/yr)
HSE	Health, Safety, and Environment
HTS	Harmonized Tariff Schedule; High Throughput Screening
IARC	International Agency for Research on Cancer
IATA	Integrated Approaches to Testing and Assessment
ICCA	International Council of Chemical Associations
ICCM	International Conference on Chemicals Management
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
ISHL	Industrial Safety & Health Law (Japan)
ISO	International Standards Organization
ITDS	International Trade Data System
IU	Inventory Update
IUCLID	International Uniform Chemical Information Database
IUR	Inventory Update Rule, now known as CDR (EPA)
JCIA	Japanese Chemical Industry Association
KPI	Key Performance Indicator
LCA	Life Cycle Assessment or Analysis
LCSA	Frank R. Lautenberg Chemical Safety for the 21st Century Act
LRI	ACC/ICCA Long-Range Research Initiative
LVE	Low Volume Exemption
MAD	Mutual Acceptance of Data
MoA	Mode of Action
MSDS	Material Safety Data Sheet
MT	Metric Ton
MW	Molecular Weight
NCN	New Chemical Notification (Taiwan) (China)
NGO	Non Governmental Organization
NICNAS	National Industrial Chemicals and Notification and Assessment (Australia)
NOAEL	No Observable Adverse Effect Level
NSN	New Substances Notification (Canada)
NTB	Non-Tariff Barrier to Trade
OECD	Organization for Economic Cooperation and Development

OEWG	Open-Ended Working Group (SAICM)
OIRA	Office of Information and Regulatory Affairs (OMB)
OMB	Office of Management and Budget
OPCW	Organisation for the Prohibition of Chemical Weapons
OR	Only Representative
OSHA	Occupational Safety and Health Administration (US)
p-phrases	precautionary phrases
PBT	Persistent, Bioaccumulative and Toxic
PCBs	Polychlorinated biphenyls
PMN	Pre-manufacture Notification (TSCA)
POPs	Persistent Organic Pollutants
PPE	Personal Protective Equipment
PPP	Plant Protection Products (EU)
QSAR	Quantitative Structure Activity Relationship
R&D	Research and Development
RC®	Responsible Care®
RCGC	Responsible Care Global Charter
REACH	Registration, Evaluation & Authorization of Chemicals, EU chemical regulation program
RFI	Request for Information
RFP	Request for Proposal
RIA	Regulatory Impact Analysis - analysis of the effects of a particular regulatory program on the regulated community and the economy.
RMP	Risk Management Plan
RoHS	Restriction of Hazardous Substances
SAICM	Strategic Approach to International Chemicals Management
SDG	Sustainable Development Goal
SDS	Safety Data Sheet
SEA	Southeast Asia
SIDS	Screening Information Data Sheets (OECD)
SIEF	Substance Information Exchange Forum (REACH)
SLRA	Screening Level Risk Assessment
SMEs	Small- and Medium-Sized Enterprises
SMOC	Sound Management of Chemicals
SNAc	Significant New Activity notice (Canada)
SNUN	Significant New Use Notice (TSCA)
SNUR	Significant New Use Regulation/Rule (TSCA)
SVHC	Substances of Very High Concern (REACH)
TBT	Technical Barrier to Trade (WTO)
TG	Test Guideline

TSCA	Toxic Substances Control Act (US)
UNCSD	United Nations Conference on Sustainable Development
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Program
UNITAR	United Nations Institute for Training and Research
UNSCEGHS	United Nations Subcommittee of Experts on GHS
USG	United State Government
UVCB	Substances of Unknown or Variable compositions, Complex reaction products and Biological materials
vPvB	Very Persistent, Very Bioaccumulative
WHO	World Health Organization
WoE	Weight of Evidence
WTO	World Trade Organization