ASEAN Guidance Document on Developing a Chemical Inventory

An Initiative of the ASEAN Regulatory Co-operation Project

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Contents

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Version History

March 2019: First version published.

March 2024: Revised Section 8 on Polymers to be consistent with the ASEAN Guidance on New Substance Notification. In particular, the statement, “In the initial phase, it would be sufficient to have its monomers listed on the inventory”, has been deleted. The revised statement reads as, “Once chemicals with a higher risk profile have been addressed, polymers can be considered to be included in the inventory in a second phase, and when it has been decided it is relevant to do so.“ This is based on the feedback gathered from the November 2023 ARCP workshop, where both industry and government representatives agree to focus their scarce resources in reviewing higher risk non-polymeric substances during the initial phase of chemical inventory and new substance notification.

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Acknowledgement

The development of this ASEAN Guidance Document on Developing a Chemical Inventory has been the product of partnership between the ASEAN government agencies and chemical industry associations through virtual meetings and face-to-face discussions over 2 years from 2017 – 2019

Brunei – *Ministry of Energy and Industry*

Cambodia – *Ministry of Industry and Handicraft*

Indonesia – *Ministry of Industry* and *Responsible Care Indonesia*

Lao PDR – *Ministry of Industry and Commerce*

Malaysia – *Department of Environment* and *Chemical Industry Council of Malaysia*

Myanmar – *Ministry of Industry*, and *Myanmar Chemical Industry Association*

Philippines – *Environmental Management Bureau* and *Chemical Industry Association of Philippines* (SPIK)

Singapore – *National Environment Agency* and *Singapore Chemical Industry Council*

Thailand – *Department of Industrial Works* and *Federation of Thai Industry-Chemical Industry Club*

Vietnam – *Vietnam Chemicals Agency* and *Chemical Society of Vietnam*

The team also acknowledges the continuous support of the International Council of Chemical Associations (ICCA) in enabling the ASEAN Regulatory Cooperation Project.

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Introductions

The Virtual Working Group on Chemical Inventory (VWG-CI) has discussed and developed this document to capture the key elements of a chemical inventory. The output of this document are not mandatory regulatory requirements. Instead, the intention of this document is to provide a set of principles and technical guidance for ASEAN member states who are developing a chemical inventory, or in the event that a regional chemical inventory becomes appropriate, would provide the technical basis for it. A chemical inventory should only be developed after sufficient considerations of the overall objectives, resource availability, and sufficient consultation with the impacted stakeholders.

Both industry and government representatives have collectively developed this document, which records the technical considerations and by best practices for ASEAN member states to develop a chemical inventory. Sections and parts of this document can be utilized as appropriate to the local regulatory environment. However, we encourage full alignment to the document as far as possible, because a consistent approach will reduce technical barriers to trade and facilitate trade.

1. Purpose of a Chemical Inventory

It is generally agreed that a chemical inventory provides the baseline data of chemicals used in commerce in a particular country or region, specifically by identifying the chemical substance and its annual usage volume within the boundary. A chemical inventory does not stand on its own, for it will be meaningless if used in isolation. Instead, it provides the baseline data for which management policies are formed and further regulatory decisions can be made. Examples can include providing insights to authorities where to focus attention on, or differentiating 'new' chemicals versus existing chemicals, so that importers and/or manufacturers of 'new' chemicals can provide information to regulators for evaluation.

Although it can appear like a simple exercise, in reality, developing and maintaining a chemical inventory is challenging, and there will be many complex details that would need to be worked through. It is not a one-time exercise, but it requires a long-term commitment to maintain it. This will require professional resourcing with competent personnel. It will have impact on international trade; therefore, proper cost benefit analyses and impact assessment should be part of such decision.

Chemical Inventory
A chemical inventory should be developed only when clear objectives and purpose have been established, as its purpose is to provide baseline data for management policies and regulatory decisions.

2. Difference between a Chemical Inventory and a Chemical Database

There are various regulatory jurisdictions that have established chemical inventories. Most of them contain basic baseline data of chemicals manufactured, imported and used in the country/region. This can include chemical substance identity, volumes associated with the chemical, information on the chemical manufacturer, importer, and/or notifier, among others. The level of details varies, but information that is made publicly available are restricted to:

- Substance identity, which can include CAS numbers, CAS names, or IUPAC names, which can be confidential, and there are a few ways to protect this.
- Quantity of the chemical substance, which is available in a few jurisdictions. Where quantity is included in the inventory, it is usually expressed as a range or quantum and not as a precise number

Other information can be collected, but different jurisdictions have different practices. However, such information reside within the authority's database and are not published publicly. Such data can include:

- Uses
- Properties – physical/chemical, toxicological or ecotoxicological

The above two sets of information could be considered to be part of a 'database' in some jurisdictions. What remains clear is that there are differences in practices among regulatory jurisdictions, and the line between an inventory and a database is not clearly defined. However, what is common in all jurisdictions is the set of data that is publicly known and the set of data that is not publicly known.

In totality, the baseline data informs the specific regulatory evaluation and decisions/actions. For example, the collected information is the basis for a regulator to prioritize chemicals in their jurisdiction for risk assessment. Those identified for further evaluation will then go through a more rigorous risk assessment, and subsequent risk management actions.

3. Alternatives to a Chemical Inventory

3.1. Post-Market Reporting to Build a Chemical Inventory

An underlying common high-level objective for the ASEAN regulators, who are establishing chemical inventories, is to better manage chemicals to protect people and the environment. The inventory is the first step to understand what chemicals are active in commerce in the country, and the quantity of those chemicals.

Bearing in mind this objective, one alternate method for developing and maintaining a chemical inventory is to implement a post-market annual or periodic reporting of all chemicals locally manufactured or imported. Taking a step-wise approach, the reporting can be required only if a chemical is imported or manufactured above a certain threshold (e.g. > 1ton/yr). The benefits of taking this approach include:

- Baseline data developed from annual reporting ensures that the data are always current, thus, more accurate. In contrast, the typical pre-market chemical inventory captures data at the start of the inventory or when the chemical is about to be introduced. Since the chemical industry is very dynamic, it is possible that after several years, the inventory may contain chemicals that are no longer active in commerce or have never been actually introduced. Accurate baseline data can then be used for further actions such as prioritization of chemicals for risk assessment and risk management measures. This leads to regulatory considerations and actions that are meaningful, reduces redundant efforts of evaluating decommercialized chemicals, and focuses resources on current issues.
- It is less resource intensive for regulators, and a reasonable step-wise approach for managing chemicals. The traditional approach where industry nominates chemicals into the inventory is very resource intensive and takes significant amount of time. The latest inventory to be developed is from Taiwan, and this exercise took more than 5 years to complete.
- It is less resource intensive and less disruptive to the chemical industry because the traditional approach requires a nomination process, and subsequently pre-market notifications for 'new' chemicals.

For the above reasons, this alternative can be considered a good step-wise approach for ASEAN regulators, and as a first step towards strengthening chemical management in the country/region. A more complex approach can be considered later on when regulators, industry and all other stakeholders have gained more experience in this area.

3.2. Import and Manufacturing Controls

Another alternative to building a traditional chemical inventory is to establish import and manufacturing controls. Prior to importing or manufacturing, data on the chemicals should be submitted to the authorities for their approval.

Benefits of such an approach would be that it allows control prior to a chemical entering the country through import or manufacture, and this would be based on real time data. However, disadvantages include the need for additional inter-agency coordination to ensure timely approvals, as well as CBI concerns when the importing legal entity is not the manufacturer.

3.3. Sector Prioritization

This approach means that regulators would prioritize specific market sectors based on safety, health, environmental and security concerns for controls. This allows a highly focused assessment on areas of concern. However, it may be difficult to get buy-in from stakeholders when addressing the issue of which sectors to prioritize first.

3.4. Chemicals new-to-the-world vs. Chemicals new to ASEAN

It should be noted that most chemicals that are 'new' to ASEAN countries are not necessarily new-to-the-world. They are usually developed in other regions/countries, and they would have gone through a robust evaluation process which should not be duplicated, so that both regulators and industry focus its often limited resources on higher priority chemicals. A recognition scheme can be considered for chemicals evaluated by other jurisdictions, if a 'new substance notification' scheme is considered.

Several alternative chemical control approaches exist

1. Post-market reporting is an alternative method to build a chemical inventory
2. Chemicals can be controlled at the point of import or manufacture by a pre-import/pre-manufacture approval system
3. Chemicals can be controlled sector by sector, and with prioritization of the sectors

The controls scheme should consider that chemicals new to ASEAN may not be new to the world and may have been evaluated elsewhere

4. What is in and what is out of scope of a Chemical Inventory?

The scope of a chemical inventory should clearly define what is included and what is not. Often other existing regulatory frameworks cover specific sections of chemistry (e.g., food additives, pharmaceuticals, agrochemicals) and duplication of efforts or potential conflicts with existing regulations should be avoided.

In general, "articles" where its form is intended to serve a specific function is more important than its chemical composition, are excluded from chemical inventories.

4.1. Exclusions

Considerations for exclusions are those which are explicitly covered by other National legislations. Below are examples that can be considered:

a) Medicines, including human and veterinary drugs
b) Medical device
c) Food and food additives – food additive Regulations and or Food Chemical Codex
d) Animal feed additives
e) Pesticides – including inert/inactive ingredients
f) Radioactive and nuclear materials
g) Munitions
h) Cosmetic products
i) Gun powder and pyrotechnics

j) Tobacco, tobacco products
k) High pressure gas already regulated by high pressure gas safety law
l) Micro-organisms
m) Mixtures of which the components have already been controlled by chemical inventory legislation
n) Waste
o) Chemical substances, which on their own or present in a mixture that are subject to customs supervision and which are in temporary storage, a Free Trade Zone (FTZ), or Customs bonded warehouse, with an intention to be re-exported or in-transit
p) Non-isolated intermediates
q) The carriage of dangerous substances and dangerous mixture by rail, road, in land, waterway and sea or air

4.2. Exemptions

Provision should be made for exempting some categories of chemicals from notification to the inventory, but still make it possible for appropriate risk management measures. Examples 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) Impurities in chemicals, as most chemicals are not 100% pure in nature, chemical by-products, and incidental reaction products
d) Articles, except intentionally released chemicals from Article
e) Polymers, provided that the monomers and reactants included in the polymer above 2% are listed on the inventory
f) Chemicals which will be sold in quantities of less than, for example, 1000 kg/year
g) Naturally occurring substances
h) Site limited intermediates
i) Chemicals produced for the export only
j) Hydrates of existing chemicals
k) Glass, frit, pottery, ceramic raw material, steel, cement, metal alloy
l) List of substances or categories of substances considered to be safe as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties (see Appendix A) like biocides, if there's existing regulation and the chemical is not used for other purpose

NOTE: Most chemical inventories do include polymers, however due to its generally low hazard nature, and high number of variation of polymers, it should be considered for exemption from the scope of notification like in EU REACH.

5. Definitions and References

The use of proper definitions is essential for every type of regulation to avoid misunderstanding. Similarly, for a chemical inventory, definitions and references are an essential part and should be aligned with international terms and definitions as far as possible.

The following definitions are recommended:

ASEAN Guidance Document on Developing a Chemical Inventory

Phrase(s)	Definition
Additive	A substance that has been intentionally added to stabilise the substance. Contributes to the substance composition (but not to the naming). *Source: ECHA*
Alloy	A metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. *Source: ECHA*
Article	A manufactured object formed to a specific shape or design relevant to its function. An article undergoes no change of chemical composition or form during its use, other than that which is incidental to its use, that which is an intrinsic part of its use, or that which has no commercial purpose separate from that of the article. *Source: OECD: ENV/JM/MONO(2007)13*
Baseline data	This is basic information about chemicals within a defined geography and can include chemical substance identity, volumes, uses, and other information that forms the basis of regulatory actions.
By-Product	A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s). *Source: TSCA*
CAS Number	Chemical Abstracts Service (CAS) is a division of the American Chemical Society, and produces Chemical Abstracts, and related products. The CAS Number or more exactly the CAS Registry Number (CAS Reg. No.) is the registry number of the Chemical Abstracts Service. *Source: American Chemical Society*
Chemical Inventory	This is the baseline data of chemicals manufactured, imported, used in a country (i.e. all chemicals in commerce) and may form the basis for further regulatory evaluations. In order to function properly, there needs to be processes in place for the continuous addition of new substances to the inventory. This means there needs to be personnel in regulatory agencies continuously looking at new submissions.
Composition	A (chemical) composition means typical concentration and concentration ranges (minimum and maximum values) for all known constituents for a given substance. Consideration should be given to ensure the concentration ranges are reasonable, i.e. not overly broad, and reflect the reality. *Source: OECD*
Confidential Business Information (CBI)	This refers to information which concerns or relates to trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the [authority's] ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the [authority's] is required by law to disclose such information. The term "confidential business information" includes "proprietary information". *Source: US: 19 CFR 201.6 - Confidential business information*
Constituent	It is any single species present in a substance that can be characterised by its unique chemical identity. *Source: ECHA*
Consumed	This refers to the substance that has chemically reacted to form a different chemical substance, although some of the substance may remain as an impurity in the final product. *Source: OECD*

Phrase(s)	Definition

Database	A database is a collection of structured data of a specific subject area (e.g. substance data) which are stored in a system and can be queried and/or modified (i.e. created and/or edited) by one or more appropriately authorized users or applications.
GHS (Globally Harmonized System)	GHS stands for the Globally Harmonized System of Classification and Labelling of Chemicals. GHS defines and classifies the hazards of chemical products and communicates health and safety information on labels and safety data sheets). The goal is that the same set of rules for classifying hazards, and the same format and content for labels and safety data sheets (SDS) will be adopted and used around the world. An international team of hazard communication experts developed GHS.
HS Code	The Harmonized Commodity Description and Coding System, generally referred to as “Harmonized System” or simply “HS” is a multipurpose international product nomenclature developed by the World Customs Organization. It comprises about 5000 commodity groups; each identified by a six-digit code, arranged in a legal and logical structure and is supported by well-defined rules to achieve uniform classification *Source: WCO*
Hydrates	Hydrates of a substance or hydrated ions formed by association of a substance with water are considered to be a mixture of that substance and water”. *Source: OECD: ENV/JM/MONO(2007)13*
Importer	This refers to any natural or legal person established within the ASEAN member state who is responsible for import. *Source: ECHA*
Impurity	It is an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present along with the final substance it is not intentionally added, nor does it enhance the commercial value of that substance. *Source: OECD: ENV/JM/MONO(2007)13*
Incidental reaction products	These are substances produced when a substance undergoes a chemical reaction that is consequent to the use to which the substance is put or that results from storage or from environmental factors.
Intermediate	It is a substance produced and consumed in the course of the manufacture of another substance. *Source: OECD: ENV/JM/MONO(2007)13*
Manufacturer	This refers to any natural or legal person established within the ASEAN member state who is responsible for manufacturing of the chemical; substance. *Source: ECHA*
Mixtures	This is a mixture or a solution composed of two or more substances in which they do not react. *Source: OECD: ENV/JM/MONO(2007)13*
Monomer	It is a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. *Source: ECHA*
Mono-constituent substance	A substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w). *Source: OECD, ECHA*
Multi-constituent substance	A substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w). A multi-constituent substance is the result of a manufacturing process. The difference between mixture and multi-constituent substance is that a mixture is obtained by blending of two or more substances without chemical reaction. A multi-constituent substance is the result of a chemical reaction. *Source: OECD, ECHA*

Phrase(s)	**Definition**

Naturally occurring substances	These are substances occurring in nature that are unprocessed; processed only by manual, gravitational, or mechanical means; processed by dissolution in water, by flotation, or by heating solely to remove water; or extracted from air by any means, without chemical change in the substance. *Source: OECD: ENV/JM/MONO(2007)13*
Polymer	This is a 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 the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein the differences in the molecular weight are primarily attributable to differences in the number of monomer units. *Source: OECD: ENV/JM/MONO(2007)13*
Research and Development substance	This refers to a substance that is undergoing systematic investigation or research, by means of experimentation or analysis, other than test marketing, the primary objectives of which are: 1) to create or improve a product or process; 2) to determine the technical viability or performance characteristics of a product or process; and/or 3) to evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials other than marketing, in order to modify the technical specifications in response to the performance requirements of potential customers. *Source: OECD: ENV/JM/MONO(2007)13*
Site	It is defined as an individual location, which includes one or more different legal entities, to which there is controlled access.
Site-limited Intermediate	It is an intermediate that is manufactured and consumed at the site of manufacture. *Source: OECD*
Substance	This refers to a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. *Source: ECHA*
UVCB (Unknown or Variable composition, Complex reaction products or Biological materials)	There are substances for which the number of constituents is high, or the composition is to a significant extent unknown, or the variability of composition is large or unpredictable. In these cases a straightforward identification is not possible because the substance cannot be sufficiently identified by the chemical composition and it will be considered as a substance of Unknown or Variable composition, Complex reaction products or Biological materials. Various types of substances can be grouped under the UVCB umbrella. They must be identified by considering the origin material of the substance and the most relevant steps during the manufacturing process. *Source: ECHA (https://echa.europa.eu/documents/10162/13643/nutshell_guidance_substance_en.pdf)* *See also Section 6*
Waste	These are substances or objects which are disposed of, are intended to be disposed of, or are required to be disposed of by the provisions of national law.
Non-isolated intermediate	It is an intermediate that is not intentionally removed (other than sampling or disposal), from the equipment in which it is produced. The equipment includes the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, any equipment through which the chemical substance passes during a continuous flow or batch process, and vessels in which the substance is transiently held.

6. Substance Identity

Industrial chemicals are often used because of the specific function or purpose they serve. They may come in the form of well-defined substances (mono-constituents or multi-constituents), or UVCB's (Unknown or Variable Composition, Complex Reaction Products and Biological Materials).

Not all industrial chemicals have well-defined constituents. In fact, industrial chemicals may have many different constituents that may be unknown. Their composition can be variable or difficult to predict. As a result, chemical compositions of industrial chemicals may have complex composition and descriptions. Chemical substances derived from petrochemical streams or from natural resources are examples of these complex substances and often referred to as UVCB's. These type of chemicals (also substances by definition) require a description of the manufacturing process and other types of information, such as the starting materials and process. Therefore, they bring additional complexity when setting up a chemical inventory. This complexity will become apparent if those chemical substances are being evaluated in a later phase.

What is common for all substances is that the term "substance" refers to a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

In summary there are 3 categories of chemical substances

- Mono-constituent substances
- Multi-constituent substances
- UVCBs

Mono-constituent substance:
A substance is a mono-constituent substance when one main constituent makes up at least 80% of the substance. A mono-constituent substance is named after the main constituent. Its impurities do not need to be mentioned in the name

Multi-constituent substance:
A substance is a multi-constituent substance if the substance consists of several main constituents. Each of these main constituents will be present at a concentration of between 10% and 80% in the substance. The chemical identity of each main constituent is identified. Concentrations can be provided in ranges. A multi constituent substance can have impurities. A multi-constituent substance is the result of a chemical reaction.

UVCB:
UVCB stands for unknown or variable composition, complex reaction products or of biological materials. For a UVCB substance, the substance has many different constituents, some of which may be unknown. The composition can be variable or difficult to predict. UVCB substances are often not fully identifiable and therefore require a description of the manufacturing process and other types of information, such as a boiling range. In general, the name of a UVCB substance is usually a combination of the starting materials and process. By definition, a UVCB has no impurities.

Following are examples to illustrate each of the three (3) types of chemical substances.

Type	Chemical Substance Name	CAS #	Description
Mono-constituent	Sodium Chloride	7440-23-5	98% Pure Sodium Chloride 2% Impurity/ies*
Multi-constituent	Reaction mass of isomers: (2S,3R)-2,3-dihydroxybutanoic acid and (2S,3S)-2,3-dihydroxybutanoic acid	5057-93-2 759-06-8	25% (2S,3R)-2,3-dihydroxybutanoic acid 74% (2S,3S)-2,3-dihydroxybutanoic acid 1% Impurity/ies*
UVCB	Distillates (petroleum), heavy catalytic cracked	64741-61-3	A complex combination of hydrocarbons produced by the distillation of products from a catalytic cracking process. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C35 and boiling in the range of approximately 260 °C to 500°C (500°F to 932°F). This stream is likely to contain 5 wt. % or more of 4- to 6- membered condensed ring aromatic hydrocarbons.

** Impurity: Refer to Definitions*

Due to the complexity of chemical substances, there is a need to have a clear methodology of identifying chemical substances for the following reasons:

- To avoid ambiguity in identifying a chemical substance
- To check whether it is in scope of the chemical inventory
- To facilitate further actions necessary (e.g. chemical prioritization, risk management measures)

The most appropriate reference to identify a chemical substance is the Chemical Abstract Service identification number or "CAS number" and chemical name (e.g. CAS name[1] and/or IUPAC[2] name). The use of the trade and tariff related HS codes, are NOT appropriate for this purpose as they originate from a different focus (trade tariffs) and lack precise identity description.

For example, Fragrance Oils are assigned an HS Code of 3301.29.90. However, there are many types of fragrance oils that are assigned with their respective unique CAS Registry Numbers. They are, to mention a few: Agarwood Oil (CAS# 94350-09-1); Basil Flower Oil (CAS# 8015-73-4); Cedarwood Oil (CAS#8023-85-6); Dill Seed Oil (CAS# 8006-75-5); and Eucalyptus Citriodora Oil (CAS# 129828-24-6).

UVCB's, due to their complex nature, may often have different CAS number assignments, although they may, from a hazard - risk management point of view be captured under a group or a single definition. When justified and documented, this may result in a single or group inclusion in the chemical inventory.

Examples of those groupings can be found for petroleum streams, oleochemicals, rosin resins and its derivatives.

7. Protection of Confidential Business Information

[1] It should be noted that chemicals may have a CAS *name* but not CAS *number*.
Not all substances will have a CAS number assigned. This may be applicable for substances in a research and development stage or those which are subject to a Trade Secret.

[2] IUPAC applies for pure chemicals only.

The protection of confidential business information is often an area overlooked, but it is extremely important for industry where a lot of knowledge and competitive advantage have been developed over the years.

Confidential Business Information (CBI) broadly encompasses proprietary information, considered confidential to the submitter, and for which the release would cause substantial business injury to the owner. In general, disclosure of confidential business information may be harmful to business while a competitor or the public can obtain an economic advantage.

CBI is entitled to strong protection from disclosure to domestic and foreign competitors. However, transparency of information may be viewed positively by downstream users and the public. There must be a balance between transparency and protection of information.

Information transparency

- Without sufficient transparency and engagement, the public may not properly interpret scientific data, potentially leading to alarm and mistrust, as well as potential misuse or misrepresentation of data;
- Perceived lack of transparency may lead the public to exert pressure on government bodies for regulations or legislations that could result in lost CBI;
- Indiscriminate and inconsistent claims of CBI may lead to loss of credibility; and
- With greater transparency, a company may be seen as responsible and open to communicate about its products.

Information protection

- Loss of CBI jeopardizes business sustainability and/or growth and threatens jobs;
- Protection of CBI allows recovery of investment in innovation, which leads to accelerated technical advances and improved quality of life;
- Without assurance of CBI protection by governments, companies may decide not to participate in certain markets; and
- Potential long-term negative impact on society because of reluctance to investing in “greener alternatives” if trade secrets generated by the investment cannot be protected.

With balance, sufficient information is disclosed for protection of human safety, health and the environment while CBI is protected;

A deeper discussion on CBI protection and management of CBI is included in Appendix B.

Data that should be allowed CBI protection
For the purpose of the inventory (based on recommendations of data in Section 9), the following data should be allowed for CBI protection • CAS number/CAS name • Unique chemical name or identifier • Detailed use information • Manufacture or import quantities • Full toxicology/ecotoxicology study reports

8. Polymers

Polymers form an important and large group of chemicals. From a hazard point of view, polymers in general fall in a much lower hazard category of special substances. There are many variations of polymers, making it highly complex to assess all polymer species. In addition, specific polymer knowledge and expertise is required to assess polymers. Because of this, it is recommended that polymers are exempted from an initial chemical inventory. Once chemicals with a higher risk profile have been addressed, polymers can be considered to be included in the inventory in a second phase, and when it has been decided it is relevant to do so.

It is important to make a distinction between what is technically defined as a polymer and what is not a polymer (i.e. just a substance which requires listing on an inventory).

Polymer definition (OECD):

Polymers are substances 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 molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

The above means that polymer molecules must be distributed over a range of molecular weights. More than 50% of molecules must contain at least three monomer units covalently bound to at least one other monomer unit or another reactant. No single molecular weight can be more than 50% of the total distribution. A polymer may include small amounts of monomers and reactants that are not included in the polymer name. It is recommended to use the 2% rule in this respect, which is used in virtually all countries that have a polymer ruling.

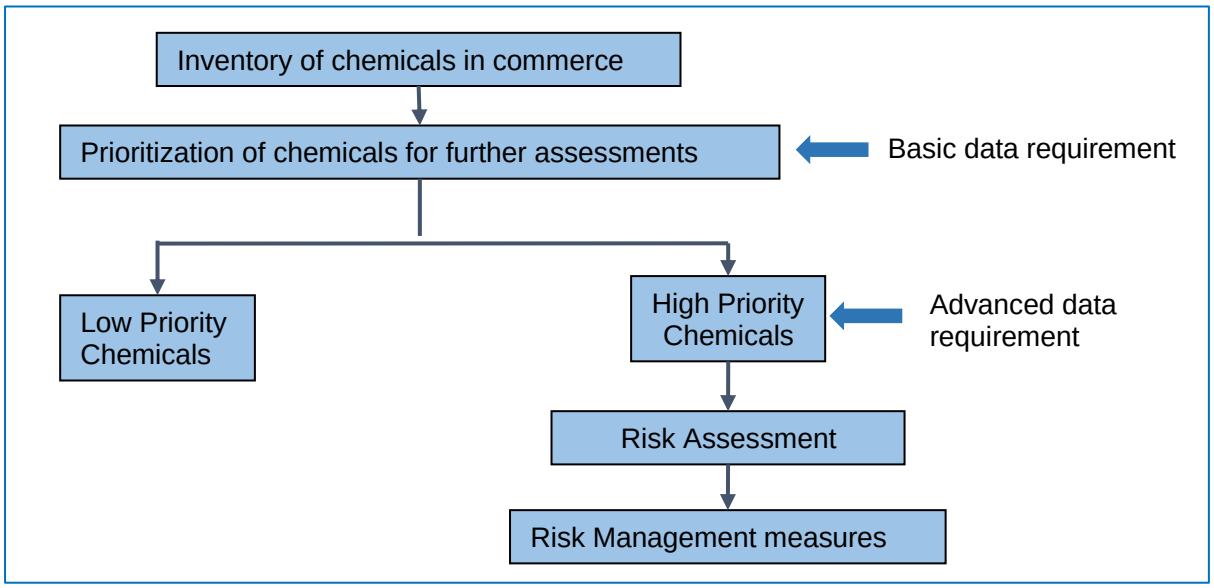
As a first approach to cover polymers, it is recommended that only its composing monomers and reactants, present above 2%, are included in a chemical inventory.

The above implies that, a substance, not fulfilling the above definition of a polymer, cannot be considered as a polymer and are subject to the rules for any other substance, requiring inclusion in the chemical inventory.

Various analytical considerations and techniques are available to demonstrate the compliance with the polymer definition. (See Appendix C)

9. Data requirements

As stated in Section 2 of this document, the data collection should be proportionate to the specific regulatory purpose of the Chemical Inventory. A tiered approach is recommended for managing the chemical inventory by identifying the priority first, and then focusing on high priority chemicals for risk assessment and risk management, as shown in below chart. Considering current ASEAN situation, we recommend focusing on the first step of prioritization first.



Data requirements:

For the purpose of fulfilling the need of prioritization, the following basic data requirements are recommended:

I. Identity of the chemical substance, according to the name in the Chemical Abstracts Service (CAS) or International Union of Pure and Applied Chemistry (IUPAC), and CAS registry number. Some alternative chemical identities, e.g. INCI name for cosmetic ingredient, HSPA substance name for hydrocarbons, etc. can also be collected in the absence of CAS name and/or CAS name/IUPAC name;
II. Manufacturing or importation quantity of the chemical per year per legal entity;
III. Recommended uses of the chemical substance (a simple use pattern, e.g. consumer, workplace, intermediates, etc.); and
IV. Hazard classification based on GHS, in accordance with available national standard.

To note, Persistency (P) and Bioaccumulation (B) data collection is not recommended at current stage due to the complexity and challenges to the industry, especially for SMEs (Small Medium Enterprises), when they are already busy with the implementation of GHS classification. However, if P and/or B are identified as a local priority in certain jurisdictions, then the data could still be collected.

For the purpose of evaluating high priority chemicals, the following advanced data are recommended:

I. Detailed data collection for hazard of concern; and
II. Refined human exposure data and detailed environmental fate and exposure data of the chemical.

Data source:

As a guiding principle, a Weight of Evidence (WoE) approach should be adopted, such that multiple sources of data could be accepted, for example, in-vivo or in-vitro testing data, QSAR or Read Across, scientific literature, and/or expert judgement, while not limiting to only testing data. This principle applies to the hazard classification (GHS classification) purpose and the detailed risk assessment.

The data could be sourced from either the industry, government or academia, and leveraging the use of available global databases (e.g. EU REACH dissemination, OECD eChemPortal)

During the data collection, close engagement between government and industry is recommended, to ensure an efficient and successful data mining, quality assessment, and chemical classification and categorization.

10. Mutual Recognition

Trade plays a vital part in today's international economic platform. When an ASEAN member state plans to set up a chemical inventory, looking beyond the individual country is essential. An effective and efficient chemical management system once established should facilitate and reduce complexity in trade among within and outside ASEAN countries.

Some established chemical management systems adopt certain degree of mutual recognition principle. The mutual recognition principle allows extension of product authorization to other markets without going through the complete evaluation processes. Examples include mutual recognition of registered chemical substances between USA and Canada, simplified evaluation in the Philippines. There are also existing data recognition mechanisms for OECD members. The mechanism allows sharing of expertise and data among members.

Once a country has established a Chemical Inventory, one of the next primary chemical management measures will be the addition of "new" chemicals in the existing inventory. This process may involve data generation, hazard identification, exposure and risk assessment of the chemical substance, which can prove to be an expensive, resource-intensive, and time-consuming investment, not only from the industry but also the government. Therefore, in principle, it is recommended, for the purpose of regulatory efficiency, that when a country reviews a new chemical substance, that it accepts some level of recognition of the available data and assessment done on the same chemical substance from another country with an established chemical inventory. More of the practice will be discussed in the next section on "Inclusion of New Chemical Substances in the Existing Inventory".

Even though each ASEAN member state has a different economic profile and an inevitably different focus when setting up its chemical management system, they all share the same fundamental goal to protect human health and the environment. While it may not be possible and logical to accept registered chemical substances in all existing chemical inventories, it is recommended to review and evaluate the chemical management system of major trading partners of the country. The acceptance or simplified evaluation process of registered chemical substances in these trading partners and within ASEAN member states will not only enhance existing trade activities but also open opportunities for the country innovation and research institutes to access latest development available.

Inclusion of New Chemical Substances in the Existing Inventory

Following are three (3) excellent examples that illustrate how a country can minimize its budget, resource, and time investments by accepting some level of recognition on the available data and assessment done on the same chemical substance from another country with an established chemical inventory.

I. Philippines

Philippines has two (2) types of new chemical notification requirements. The first one is the Full PMPIN (Pre-Manufacture Pre-Import Notification), which is required for completely "new-to-the-world" chemical substance. This means the chemical substance will be first introduced and used in the Philippines. For this type of chemical substances, actual test results on the chemical's physico-chemical properties and toxicological and environmental effects are required, among others.

The second is the Abbreviated PMPIN, which is required for chemical substances that have been listed in the inventory of countries like the US, Europe, Canada, Australia, Japan or Korea. For this type of chemical substances, a summary statement on the chemical's physico-chemical properties and toxicological and environmental effects will be sufficient, among other requirements.

II. Canada

Canada has two (2) chemical inventories, namely: DSL (Domestic Substances List) for chemicals used in Canada commerce and NDSL (Non-Domestic Substances List) for chemicals listed in US TSCA inventory but not in Canada DSL. If an importer or manufacturer plans to introduce a "new" chemical substance that is not in the DSL but listed in the NDSL, then the importer or manufacturer can apply a lower level NSN (New Substance Notification) data requirement.

For example, a 1,000 kg/year NDSL chemical substance can apply the "Schedule 4" 100 kg/year new chemical substance data requirement. Similarly, a 10,000 kg/year NDSL chemical substance can apply the "Schedule 5" 1,000 kg/year new chemical substance data requirement, and so on. This significantly reduces the lead-time for assessment and cost of data generation for a chemical substance in the NDSL. Refer to Appendix D for details.

It is important to note though that chemicals listed in the US TSCA inventory that are subject to special restriction/control will not be listed into NDSL, therefore, not eligible for the above simplified NSN.

III. Australia

Under current NICNAS new chemical notification scheme, there are five arrangements in place for NICNAS to consider overseas assessments conducted elsewhere, as noted below:

a) Approved Foreign Scheme—Canada
b) Modular Notification (Comparable Agency)—Canada
c) Modular Notification (Comparable Agency)—United States
d) Modular Notification (Comparable Agency)—European Union (EU)
e) OECD Parallel Process

Under these arrangements, NICNAS can consider, and use in its assessment report, an overseas health and environment hazard assessment, from one of these countries, for a new chemical. NICNAS must have access to the overseas assessment report/s. The other elements of the risk assessment and recommendations on safe use of the chemical in Australia will still be carried out by NICNAS.

NICNAS has been working on its regulatory reform since 2016 and the above scheme will be further modified as "internationally assessed introduction". If one new chemical has been assessed or evaluated by overseas jurisdiction for the same use and similar volume, etc., the new chemical could go through a reduced simple notification process instead of submitting the full data for authority assessment before introduction. The international bodies currently accepted include Canada CEPA, European Scientific Committee on Consumer Safety, EU REACH evaluation/authorization, EU BPR assessment, and US LCSA.

<u>Mutual Acceptance of Data</u>

As part of establishing a Chemical Inventory, existing or new substances will be subjected to evaluation or assessment. With the recognition or acceptance that the chemical has undergone a similar assessment elsewhere should lead to reduced pre-market requirements and increased efficiency in chemical evaluation. This is an important aspect of a sustainable and integrated chemical management system, where relevant testing data includes, e.g. (eco)toxicological, animal, physical and chemical properties.

Following are the benefits from Mutual Acceptance of Data for both government and industry:

- Saving scientific resources associated with the assessment and notification of new industrial chemicals;
- Providing greater access to external scientific expertise;
- Expanding national perspectives on new industrial chemical notification, assessment and risk management.

- Reducing expenses associated with data generation, and preparing and submitting new industrial chemical notifications;
- Reducing time to introduce or market new industrial chemicals;
- Reducing data submitted for assessment and risk management decision-making;
- Strengthening access to foreign markets in the global commercialization of new industrial chemicals; and
- Fosters a process which is dependable and predictable

To minimize labour-intensive and expensive testing of chemicals, OECD has established a Mutual Acceptance of Data Agreement in 1981. The Mutual Acceptance of Data (MAD) states that test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted on other member countries for assessment purposes. A guideline is available for Adherence of Non-Member countries which allow non-OECD countries to take part as full members in this system. Malaysia and Singapore are currently non-OECD members who adhered to the MAD framework, while Thailand is provisionally adherent to the MAD system.

Following are additional details on the OECD Mutual Acceptance of Data Agreement:

- Test data conducted in any country should be accepted provided that it was generated 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).

More details on OECD MAD can be found via following link
http://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm

Mutual recognition in summary
ASEAN member states that are considering setting up a new chemical inventory will benefit significantly from some form of mutual recognition from other countries with established chemical inventories and most importantly between ASEAN member states. Be it in the form of recognizing another country's listing or evaluation, both government and industry will mutually benefit. Ultimately there could potentially be an ASEAN Chemical Inventory database, driving harmonization and mutual trade benefits. Lastly, as trade within the ASEAN region itself is equally important, mutual recognition between ASEAN member states is encouraged to help facilitate intra-ASEAN trade and reduce regulatory complexity amongst ASEAN trading partners

11. Regulatory Impact Assessment

"*Regulatory Impact Analysis (RIA) is a systemic approach to critically assessing the positive and negative effects of proposed and existing regulations and non-regulatory alternatives… It is an important element of an evidence-based approach to policy making. OECD analysis shows that conducting RIA within an appropriate systematic framework can underpin the capacity of governments to ensure that regulations are efficient and effective in a changing and complex world*[3]".

In the context of developing a Chemical Inventory, a new regulation or a regulatory tool will need to be created. Considering the broad implication of a Chemical Inventory and its subsequent rules, the RIA is clearly an important step to inform decision makers in the development of the Chemical Inventory.

[3] OECD Regulatory Impact Analysis http://www.oecd.org/regreform/regulatory-policy/ria.htm

Within ASEAN, an ASEAN Good Regulatory Practice (GRP) Guideline has been proposed but at this point does not have full endorsement from the 10 Member States yet. Nevertheless, GRP is implemented to varying degrees in most of the Member States, and this is well aligned with the strategic measures to enhance trade in goods, as outlined in the AEC (ASEAN Economic Cooperation) Blueprint 2025.

Regulatory Impact Assessment is a key element of GRP, and it is defined by a series of steps:

1. Defining the problem
2. Setting objectives
3. Assessing all feasible options
4. Analysing the impacts arising from these options
5. Consulting with stakeholders

The element of stakeholder consultation is already widely practiced across ASEAN. The typical stakeholders consulted for chemical regulations are the chemical industry/regulated industry (especially important given the complexity of the value chain and the technical nature of regulations), other impacted regulatory agencies, and academia (especially for the technical content). However in its entirety, RIA can be a complex and tedious process especially the elements of cost-benefit analysis, and proportionate analysis. Extensive training and capacity-building is required to ensure successful implementation of RIA. With practice and over time, RIA will become easier as experience builds up

Key considerations for a successful RIA

- Commitment from highest level of government leadership, including formalization/integration of RIA into the rule making process
- Initiating stakeholder consultation as early as possible (even at brainstorming stage) and continued proactive stakeholder engagement. It is of paramount importance that multiple stakeholders are engaged and given sufficient lead time to provide comments. A regulatory process should be set up to ensure that comments collected will be properly addressed
- Ensuring coordinated effort and open communication amongst government and regulatory agencies as this is usually a multi-agency effort
- Simplifying the RIA as far as possible

A good reference for a RIA checklist is the APEC CD Best Practice Principle Checklist (refer to Appendix E) which outlines the following key principles:

1. Chemical regulations should be the minimum required to achieve their stated objectives;
2. Chemical regulations should adopt a risk management approach to developing and administering regulation;
3. Chemical regulations should minimize the unnecessary impact on competition;
4. Chemical regulations should utilize international standards as appropriate;
5. Chemical regulations should not restrict international trade flows;
6. Chemical regulations should be developed in consultation with stakeholders, subject to public review and comment and periodic review;
7. Chemical regulations should be flexible, not prescriptive, and be compatible with the business operating environment;
8. Chemical regulatory decisions should be science based; and
9. Chemical regulatory decisions should have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms.

12. Resource Requirements

When setting up a chemical inventory, consideration of the required resources (such as manpower, IT systems) and timeline are important aspects to be addressed well before starting any activity.

Budget

A budget would need to be approved and depending on the existing National approval process, this may take time to prepare and to obtain endorsement. Such budget would be required during the implementation phase as well as the maintenance phase. Reference to the timing aspect (see Section 13) as for how many years the budget needs to be made available is essential in the consideration and preparation of the budget.

As discussed in Sections 1-4 of this document, the objective and scope of the chemical inventory need to be determined before anything else, so that a realistic time planning for required resources and funding can be achieved.

Staff

Personnel with various skills will be required for the different phases of the project: initial phase, preparation phase, implementation and maintenance phase. When handled as a project, additional staff may need to be hired to manage the project, set-up of an IT system and handling the many notifications during the implementation period.

This all depends on the earlier discussed objective and scope of the chemical inventory.

For staff resources, a rough general estimate, based on existing work in some of the ASEAN countries, would be about 20 FTE's (Full Time Employees), including IT development. The staff may be reduced once the project has reached full implementation and is moved into a maintenance mode. This number depends highly on the defined objectives and is for setting up an inventory only, not for any further assessment work.

For comparison, developed economies such as the Australia, Canada, EU and USA require resources ranging between 60 to over 600 employees, but do cover a broader scope of activities.

Skills

Those required during project set-up will be IT personnel, skilled personnel with chemistry background, who has good understanding of chemical naming convention, industry subject matter experts, and dedicated legal/departmental staff.

IT System

A robust, well thought through and tested IT system with high specifications on system integrity, stability, and especially security for storing confidential information is a must to handle the many and high load access by notifiers, in particular close to dead-lines.

It is highly recommended to use or start with an existing IT system which is already in use in ASEAN and proven to function well.

By doing so, a common IT platform can be used, which will be easier to implement, and early system bugs will be addressed by then. In addition, a harmonized tool can be advantageous if used across ASEAN member states.

13. Recommended Timeline for Implementation

On average, based on experience elsewhere, the most optimistic time schedule for setting up a chemical inventory (from announcement of the intention until closing date) is at least 4 years.

Many aspects need to be considered, such as the selection of the type of regulatory mechanism and protocol. The more complex the regulatory mechanism in the hierarchy, the more consultation, multi-

government agency alignment, Regulatory Impact Assessment, etc. will be required. This depends on National requirements and are out of the scope of this guidance document. However, it has to be noted that these steps may take a significant amount of time.

Process Steps

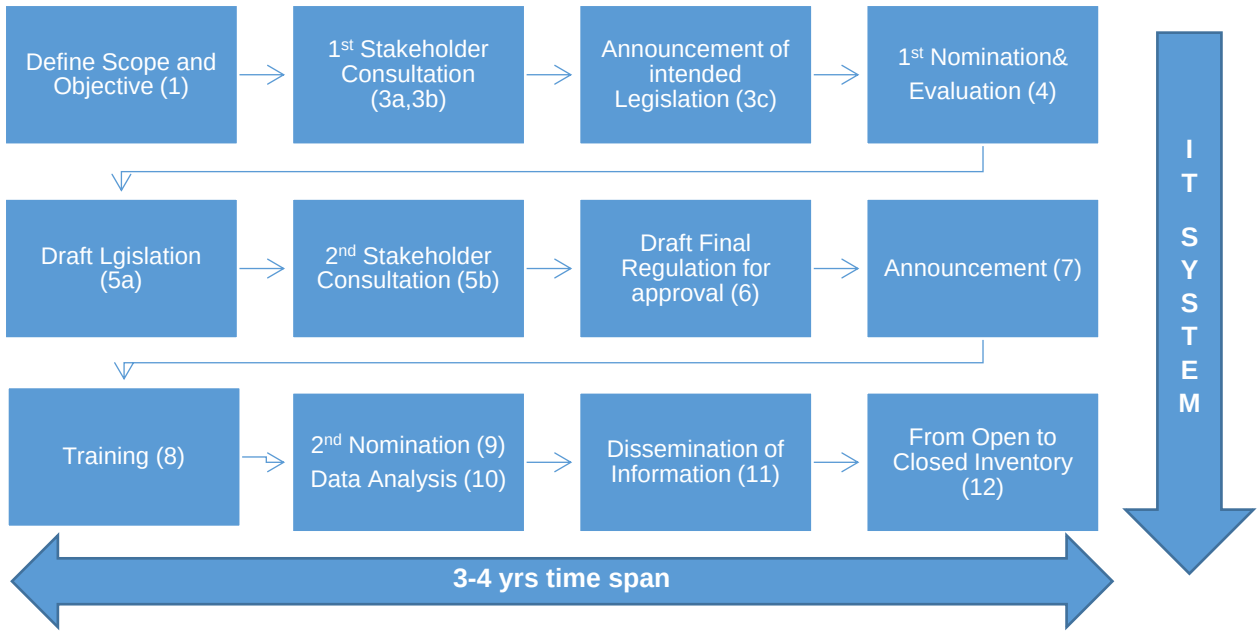
Step	Task	Staff (FTE)	Time (Months)
1	Set Scope and Objectives	3	3-6
2	Set-up IT infrastructure (**parallel process**)	10	6-12
3a	Stakeholder Consultation (National and International)	3	6-12
3b	Review Comments		3-6
3c	Announcement of intended legislation and process		3
4a	First inventory nomination through beta-version IT tool		6
4b	Analyses and feedback*		3
5a	Draft Legislation		
5b	Stakeholder Consultation (National and International)		3-6
6	Final Draft to Legalize		12-36
7	Announcement on legislation and process		3
8	Training on use		6
9	Second inventory nomination with formal IT system*[#]		6 or more
10	Data analysis	10	6
11	Publication of inventory*		3
12	Transition period from open to closed inventory		12
13	Maintenance	5	Continuous
14	Inventory update by including new notified substances		Continuous**

** With opportunity to submit corrections*
*** Continuous but at regular intervals of max 12 months*
[#] *Usually several cycles of inventory nomination are required*

Based on experience elsewhere, it has been suggested to include stakeholder consultation during the implementation process, such a nominated industry subject-matter expert to assist in typical industry related issues, such as clarification of substance identity.

Taking the complexity and time required to set-up such a chemical inventory, a sector specific approach (as referenced in Section 3.3) may be an option for gradual adoption. Same holds for an ASEAN-wide chemical inventory system or mutual acceptance approach (Sections 3.4 and 10).

Time line in diagram



14. Capacity Building and Raising Awareness

Previous sections have highlighted the various considerations and challenges to address when setting up a national chemical inventory. Both stakeholders – government agencies as well as industry (and in particular SME's) – will require knowledge, understanding and skills in various areas, in order to successfully set-up and implement a chemical inventory.

Government agencies

Key considerations include:

- Defining the overall scope and objectives: the "bigger picture"
- Inclusions and exemptions of an inventory
- Industry segments/markets and industry supply chain
- Understanding of chemical nomenclature and substance identity
- Polymer definitions
- Confidential Business Information
- Legal aspects
- Data ownership
- IT System
- Regulatory Impact Assessment
- Training and communication

Some of the above subjects can be addressed as a one-time or short-term event, while some require continuous awareness and training. Some subjects can be covered by external consultants (such as private companies with established track record in the field), foreign government agencies, international agencies and industry. Some items may be best to be developed jointly with industry as key stakeholder and owner of detailed knowledge (such as industry specific chemicals and naming: petrochemical, oleochemicals, resins, metals, etc.) Some of the subjects will require continuous attention; therefore, on-site well trained and knowledgeable staff will be needed.

Some aspects will have an inter-agency impact and require personnel from other agencies to be knowledgeable as well (Regulatory Impact Assessment).

Industry

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The (chemical) industry, as stakeholder of a chemical inventory (manufacturers, importers, formulators), will need to be made aware, understand and be trained on various topics. This holds true for all industry sizes (National, International, large and small). Perhaps, it is even more important for SMEs, who may have significant shortage in skilled resources to handle a new initiative which is complex in nature.

Industry will require the following:

- To understand the objectives of the government
- Training on how to utilize the reporting/nomination tool
- What information is required
- Detailed guidance on 'difficult' areas (such as polymers, in/out scope, etc)
- Training on chemical naming conventions (in particular for SME's)
- Availability of requirements (presentation, guidelines) in both the National language as well as English language

The table below summarizes training requirements for Government Agencies and Industry. It includes suggestions for resource support, and defines level of knowledge needed (overall awareness vs. in-depth understanding of the topic/issue) so that training can be provided as a one-off event (short term) or has to be repeated over time (long term) to refresh/update knowledge.

Subject	**Government**			**Industry**
	Source/ support for subject knowledge	Cross Agency?	Short term (S)/ Long term (L)	Awareness (A)/ Understanding (U)
Overall Scope & Objectives		Yes	S	A
Inclusions & Exclusion/ Exemptions	Foreign Agencies; Industry	Yes	S	U
Industry segments & supply chain	Industry	Yes	L	A
Chemical nomenclature & Substance identity	International agencies; Industry	No	L	U
Polymers	Industry	No	L	U
Legal		Yes	L	A
CBI	Industry; Foreign Agencies	Yes	L	
Data ownership	Industry	Yes	L	
IT System	Consultant; Foreign Agencies	No	L	U *Clear guidance on tools*
Regulatory Impact Assessment	Consultant; Foreign Agencies	Yes	S	
Training and Awareness		No	L	

Appendix A: EXEMPTIONS from Inclusion in the Chemical Inventory

Name/Group	CAS No
D-glucitol $C_6H_{14}O_6$	50-70-4
Ascorbic acid $C_6H_8O_6$	50-81-7
Glucose $C_6H_{12}O_6$	50-99-7
Fructose $C_6H_{12}O_6$	57-48-7
L-lysine $C_6H_{14}N_2O_2$	56-87-1
Sucrose, pure $C_{12}H_{22}O_{11}$	57-50-1
α-tocopheryl acetate $C_{31}H_{52}O_3$	58-95-7
Galactose $C_6H_{12}O_6$	59-23-4
DL-methionine $C_5H_{11}NO_2S$	59-51-8
Lactose $C_{12}H_{22}O_{11}$	63-42-3
D-mannitol $C_6H_{14}O_6$	69-65-8
L-sorbose $C_6H_{12}O_6$	87-79-6
Glycerol stearate, pure $C_{21}H_{42}O_4$	123-94-4
Carbon dioxide CO_2	124-38-9
Calcium pantothenate, D-form $C_9H_{17}NO_{5.1/2}Ca$	137-08-6
DL-phenylalanine $C_9H_{11}NO_2$	150-30-1
Sodium gluconate $C_6H_{12}O_7$.Na	527-07-1
Sorbitan oleate $C_{24}H_{44}O_6$	1338-43-8
Krypton Kr	7439-90-9
Neon Ne	7440-01-9
Argon Ar	7440-37-1
Helium He	7440-59-7
Xenon Xe	7440-63-3
Nitrogen N_2	7727-37-9
Water, distilled, conductivity or of similar purity H_2O	7732-18-5
Lecithins The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid	8002-43-5
Syrups, hydrolyzed starch A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins	8029-43-4
Tallow, hydrogenated	8030-12-4
Dextrin	9004-53-9
Starch High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water	9005-25-8

Maltodextrin	9050-36-6
Sodium D-gluconate $C_6H_{12}O_7$.xNa	14906-97-9
D-glucitol monostearate $C_{24}H_{48}O_7$	26836-47-5
Fatty acids, coco, Me esters	61788-59-8
Cellulose pulp	65996-61-4
Glycerides, C_{16-18} and C_{18}-unsaturated.	67701-30-8
Syrups, corn, dehydrated	68131-37-3
Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3
Glycerides, C_{16-18} and C_{18}-unsaturated, mono- and di-	68424-61-3
Glycerides, C_{10-18}	85665-33-4

Other EXEMPTIONS

The following substances which occur in nature, if they are not chemically modified: Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.

The following substances if they are not chemically modified: Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.

Compost and biogas.

Hydrogen and oxygen.

Appendix B: Additional Information on Protection of Confidential Business Information

General Considerations

Information being classified as CBI should have following features;

a. Not generally known to public
b. Economic benefit to its holder
c. Subject of reasonable efforts by the holder to maintain its secrecy.
d. IP (Intellectual Property)
e. Commercial value
f. Not in the public domain
g. Reasonably protected
h. Communicated to others in confidence

In addition, the types of information that can constitute CBI can vary from company to company. However, for the chemical industry, the following information are commonly considered CBI:

i. Chemical Identity/CAS number/IUPAC names, including chemical structure of the substance
ii. Composition and formulation of chemical products (mixtures)
iii. Information about the manufacturing or processing of a chemical product, including the raw materials
iv. Spectral data which can be used to deduce the specific chemical identity
v. Link of a chemicals to trade name(s)
vi. Information about the specific use of the chemical
vii. Volume of the chemical sold or expected to be sold
viii. Production or import volumes of the manufacturer, processor or importer
ix. List of customers
x. Location of manufacturer, importer or marketer
xi. Name of the submitter, both company name and the responsible individual
xii. Raw toxicity/ecotoxicity study data (including data about the hazards, uses, exposures to and risks of chemicals, although robust summaries can be made publicly available if needed by the European Chemicals Agency (ECHA) by following its guideline on “How to report robust study summaries”).

Items (i) – (iv) can provide a competitor with the knowledge to copy or reverse engineer a chemical, thereby resulting in a loss of competitive advantage of the company who has invested heavily in developing and creating the chemical product. Sometimes the fact that a chemical exists, i.e. Item (v), can provide clues that divulges sufficient information for competitors, especially for specialty chemicals

Items (vi) – (xii) provides commercial information that reveals business strategies. Toxicity data, Item (xii), is usually commissioned at great cost and the raw data should therefore be kept confidential to protect from “free riders”.

CBI Justification

Some information is patented and commercially sensitive that it need not 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:

1. The business has asserted a CBI claim that has not been waived or expired;
2. The business demonstrates it has taken reasonable steps to protect the confidentiality of the information and intends to continue to do so;
3. The information is not reasonably obtainable by other persons;
4. No statute or law requires the disclosure of the information; and

5. 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.

Process and Management of Responsibility

Business and government authorities shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

- Is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- Has commercial value because it is secret; and
- Has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Both electronic and paper CBI processes should be properly secured and clearly described in the managing them. Easy understanding of CBI mechanism is useful and effective when both business and government authorities are aligned on its implementation.

Obligations on the part of Government Agencies to protect CBI submitted for the fulfilment of regulatory requirements

- In order to protect data against unfair commercial use, Agencies holding this data should take steps to ensure the security of the data, including education, training, establishing institutional procedures (e.g. data custody model) for handling documents and data, limiting access to authorized personnel with the need to know, and providing secure storage and protection of physical as well as electronic documents and data;
- Unauthorized disclosures of legitimate CBI should constitute criminal and/or civil offense and should be vigorously prosecuted;
- Trade secrets should not be disclosed to third parties unless there is a critical benefit as articulated by the requestor and it outweighs the harm done to information owner;
- Where CBI is disclosed to third parties contracted by Agencies, those third parties should be under the same obligations to safeguard any CBI that is disclosed to them in the execution of their contract;
- Industries should strongly support the requirement for Agencies to notify information owners of any intent to disclose CBI, the justification, and the party to whom it would be disclosed and giving the information-owner the opportunity to comment on the proposal;
- Agencies who received CBI from another government should be under the same obligations to protect the CBI in question and that any such disclosure occurs only with approval of the CBI owner;
- Working together from regulatory Agencies and industries is critical need to safeguard regulatory data, especially CBI.

CBI Mechanism

A well-designed CBI mechanism is a process wherein both Business and government authorities can easily follow and avoids unnecessary workload.Following are factors that a process owner needs to consider when implementing the CBI process:

- Simple and transparent
- Clear responsibility of parties in process
- Business practical and robust system
- Efficient maintenance and secure CBI document

- Appropriate lead time of validation CBI
- Cost of housekeeping CBI document
- Managing of obsolete CBI document
- Responsibility of improper CBI handling

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Appendix C: Analytical considerations and techniques available to demonstrate the compliance with the polymer definition

Identification of polymer substances

The preferred method to determine whether a substance falls under the definition of a polymer is Gel Permeation Chromatography (GPC). Guidelines on the determination of the number average molecular weight (Mn) and molecular weight distribution using GPC are available in the OECD TG 118 (1996)10. Whenever practical difficulties in using GPC are expected or encountered, alternative methods for the determination of the Mn are also listed in an annex to the OECD guideline.

http://www.oecd.org/env/ehs/testing/

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Appendix D: Canada New Substance Notification Schedules and Data Requirements

	Schedule 4 5 day review period no test requirements	**Schedule 5** 60 day review period ~$75,000 test cost	**Schedule 5+** 75 day review period ~$335,000 test cost	**Schedule 6** 75 day review period ~$415,000 test cost
new **chemicals**	100 kg/yr.	1000 kg/yr.	→	10,000 kg/yr.
NDSL **chemicals**	1000 kg/yr. (30 day review)	10,000 kg/yr.	>50,000 ky/yr + significant exposure	Not required
	Chemical name + synonyms CAS number MSD Sheet Intended use information All other information available in Canada	Structural formula & Mol. Wt. % purity, impurities, additives; Comprehensive exposure info; Spill & handling procedures; Estimated envir. Discharge Melting Point, Boiling Point, Density, Vapor Pressure, Water Solubility, Kow Acute Mammalian LD50 Ames Test Fish Acute LC50 Ready biodegradability test Summary of all other information available Worldwide	<u>Site releases > 3 kg/day</u> Adsorption/Desorption Hydrolysis vs. pH <u>Significant Public Exposure</u> 28-day subchronic test *in vitro* cytogenetics	IR, UV or Mass Spectrum 2nd acute mammalian tox Information to assess skin irritation potential Skin sensitization *in vivo* mutagencity test‡ Daphnia Acute LC50 Acute Algal Toxicity EC50

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Appendix E: APEC Chemical Dialogue Best Practice Principle Checklist (for conducting a Regulatory Impact Assessment)

No	Best Practice Principle	Yes	No	Yes	No
1.	CHEMICAL REGULATIONS SHOULD BE THE MINIMUM REQUIRED TO ACHIEVE THEIR STATED OBJECTIVES			☐	☐

	• Has a problem that justifies regulation been identified?
	• Has a case for regulatory action been made?
	  ○ Have all relevant existing regulations at all levels of government been assessed to demonstrate that they do not adequately address the problem?
	  ○ Is the regulatory action under consideration focused on achieving the objective, and targeted to achieve the objective (eg specifically and significantly mitigate an identified unacceptable risk)?
		☐
		☐
			☐
			☐		

	• Have all of the alternatives to government regulation been assessed, including consideration of existing requirements, self-regulation, co-regulation and non-regulation?	☐	☐		

	• Has a cost benefit analysis been done?
	  ○ Has an appropriate baseline (ie how the world would look in the absence of the proposed action) been used?
	  ○ Have all the benefits and costs of potentially effective and reasonably feasible alternatives been assessed?
	  ○ Have all the impacts on consumers and business, particularly small business been assessed?
	  ○ Have the benefits and costs of the preferred option been quantified and to the extent possible, monetized?
	  ○ Have appropriate discount rates been used for benefits and costs that are expected to occur in the future?
		☐	☐		

2.	CHEMICAL REGULATIONS SHOULD ADOPT A RISK MANAGEMENT APPROACH TO DEVELOPING AND ADMINISTERING REGULATION			☐	☐
	• Has a risk assessment been undertaken? ○ Does the assessment adequately address exposure as well as hazard?	☐	☐		
	• If the problem involves unacceptable risks, have all the risks been properly identified?	☐	☐		
	• Is the level of intervention commensurate with the risk posed?	☐	☐		
	• Is there clear authority to take risk management actions?	☐	☐		
3.	CHEMICAL REGULATIONS SHOULD MINIMIZE THE UNNECESSARY IMPACT ON COMPETITION			☐	☐
	• Will the regulations restrict competition? ○ Has the impact assessment identified impact on incumbent business?	☐	☐		

	○ Will it restrict entry on new business? ○ Has an assessment of prices and production been done? ○ Will quality of goods and services be affected? ○ Will innovation be restricted? ○ Will there be impacts on market growth?				
	• If the regulations restrict competition, ○ Does the regulation maximise net benefits? ○ Can the objectives of the regulation be met any other way which does not restrict competition?	☐	☐		
4.	CHEMICAL REGULATORS SHOULD UTILIZE INTERNATIONAL STANDARDS AS APPROPRIATE			☐	☐
	• Has guidance been developed for assisting regulators in assessing whether a standard being considered was developed in an open, transparent, consensus-based process in line with the WTO TBT Committee Decision (G/TBT/1/Rev1.2, Annex 2)? • Are such existing standards relevant?	☐	☐		
	• Can international standards be adopted instead of unique domestic regulations, as the basis for regulation? • Have unique local conditions been considered when determining the extent to which an international standard can be adopted?	☐	☐		
5.	CHEMICAL REGULATIONS SHOULD NOT RESTRICT INTERNATIONAL TRADE FLOWS			☐	☐
	• Could the regulation act as a barrier to trade? ○ Has the potential impact on trade been assessed as part of the cost-benefit analysis or impact assessment? ○ Is there sufficient time provided between publication of the final regulation and its date of effect so as to allow market participants to adjust to the new requirements (including taking into account the need for translation, changes to manufacturing processes, shipping times, product already in the pipeline)?	☐	☐		
	• Does the regulation discriminate in favour of domestic products?	☐	☐		
	• Have all relevant trade agreements been considered?	☐	☐		
	• Has the WTO been notified? ○ Have comments from importers and foreign stakeholders and trading partners been assessed and reflected as appropriate?	☐	☐		
6.	CHEMICAL REGULATIONS SHOULD BE DEVELOPED IN CONSULTATION WITH STAKEHOLDERS, SUBJECT TO PUBLIC REVIEW AND COMMENT AND PERIODIC REVIEW			☐	☐
	• Were the stakeholders most likely to be impacted identified and consulted early on in the process?	☐	☐		
	• Were all stakeholders, including those outside of the economy, given an equal opportunity to access	☐	☐		

	available documents (including the text of the regulatory proposal and any risk assessment or regulatory impact assessment) and provide timely input?					
	• Have all decisions been explained and feedback provided?	☐	☐			☐
	• Has a timetable for monitoring and review been provided?	☐	☐			☐
	• Is there a mechanism to ensure that all comments on a proposal are adequately addressed before it is finalised?	☐	☐			☐
7.	CHEMICAL REGULATIONS SHOULD BE FLEXIBLE, NOT PRESCRIPTIVE, AND BE COMPATIBLE WITH THE BUSINESS OPERATING ENVIRONMENT				☐	☐
	• Has the regulation been tested with business to ensure ease of implementation?	☐	☐			☐
	• Does the regulation have clearly identifiable outcomes?	☐	☐			☐
	• Has the regulation been drafted in plain easy to understand language?	☐	☐			☐
	• Is the regulation performance based?	☐	☐			☐
8.	CHEMICAL REGULATORY DECISIONS SHOULD BE SCIENCE BASED				☐	☐
	• Is the regulatory action based on relevant and objective scientific and/or technological information and processes?	☐	☐			☐
	• Are there established data and method quality criteria?	☐	☐			☐
	• Does scientific information relied upon meet high standards for quality and meet any applicable data and method quality criteria?	☐	☐			☐
	• Has all the available scientific information been considered in a weight of evidence evaluation?					☐
9.	CHEMICAL REGULATORY DECISIONS SHOULD HAVE A CLEAR DELINEATION OF REGULATORY RESPONSIBILITIES AND EFFECTIVE AND TRANSPARENT ACCOUNTABILITY MECHANISMS				☐	☐
	• Is the regulatory authority clearly identified?	☐	☐			☐
	• Does the regulatory authority have the capacity and resources to effectively implement the requirement?	☐	☐			☐
	• Have all relevant authorities for chemicals management been consulted and notified of changes?	☐	☐			☐
	• Are the compliance requirements clear and unambiguous?	☐	☐			☐
	• Can the regulations be enforced?	☐	☐			☐