ASEAN Guidance Document on New Substance Notification

An Initiative of the ASEAN Regulatory Cooperation Project

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Contents

Acknowledgement

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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 Industries Council of Malaysia*

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

Philippines – *Environmental Management Bureau* and *Chemical Industries Association of the 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*

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Introduction

The Virtual Working Group on New Substance Notification (VWG-NSN) has discussed and developed this Guidance Document to capture the key elements of a new substance notification scheme. 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 may, in the future, develop a new substance notification scheme. Or if a regional new substance notification scheme becomes appropriate, this Guidance Document would serve as a sound foundational and technical basis. The separate ASEAN Guidance on Developing a Chemical Inventory should also be referred to, because a new substance notification scheme is usually set up to manage the "new chemical substances" that have not been added to the chemical inventory. And like the chemical inventory, the new substance notification scheme should be developed after sufficient consideration of its overall objectives, resource availability, and consultation with the impacted stakeholders.

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

Section 1: Terms and Definitions

The use of proper terms and definitions is essential to every type of regulation to avoid misunderstanding. Similarly, for New Substance Notification (NSN), terms and definitions are an essential part and should be aligned with international terms and definitions as far as possible.

Table 1: Terms and Definitions used in this ASEAN Guidance Document on NSN

Terminology	Definition
Articles	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*
Chemical Product	A chemical substance or mixture of chemical substances as distributed in commerce; may contain impurities and/or by-products; often marketed under trade names.
Chemical Substance	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
Confidential Business Information (CBI)	**CBI** 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

Terminology	Definition
	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*
Consumer	A **consumer** buys a product and use it outside an industrial/professional setting. *Source:* User of chemicals - ECHA (europa.eu)
Distributor	A **distributor** sources a chemical substance or a mixture within ASEAN, stores it and then places it on the market for someone else (also under own brand without changing its chemical composition in any way) *Source: ECHA* Distributors - ECHA (europa.eu)
Downstream User	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. *Source: ECHA*
Foreign legal entity	Overseas/other country manufacturer, supplier, distributor, company or business entity
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	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 was not intentionally added, nor does it enhance the commercial value of that substance. *Source: OECD ENV/JM/MONO (2007)13*
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*
Incidental reaction products	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. *Source: OECD ENV/JM/MONO (2007)13*
Intermediates	Substance produced and consumed in the course of the manufacture of another substance. *Source: OECD ENV/JM/MONO (2007)13*
Local representative	**Local representative** is a local entity such as a 3rd party consultant, broker or a local business entity designated by the foreign legal entity to comply with the notification scheme

Terminology	Definition
Non-isolated intermediate	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. *Source: OECD ENV/JM/MONO (2007)13*
Site-limited Intermediate	Intermediate that is manufactured and consumed at the site of manufacture. *Source: OECD ENV/JM/MONO (2007)13*
Imported Intermediate	Intermediate that is imported and transported directly to the site where it is consumed. *Source: OECD ENV/JM/MONO (2007)13*
Site	Individual location, which includes one or more different legal entities, to which there is controlled access. *Site includes warehouse, production, assembling, packing facilities.* *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*
Mixture	Mixture, or a solution composed of two or more substances in which they do not react. See also “Preparation”. *Source: OECD ENV/JM/MONO (2007)13*
Notification	Submission of physical, chemical, and simple toxicological data to the competent authority with or without authority’s approval
Notifier	Company or person (entity) responsible for submitting data to authority for substance registration or notification
Only representative	Companies based outside the region/country can appoint an in-country only representative to take over the tasks and responsibilities of importers for complying with the notification scheme. This can simplify access to the region market for their products, secure the supply and reduce the responsibilities for importers. Only representatives must be: • A natural person or legal entity established physically in the region/country • Equipped with sufficient knowledge in the practical handling of the substances and information related to them • Appointed by a mutual agreement with a manufacturer, formulator or Article producer, established outside the region • Responsible for complying with the legal requirements for importers under the notification scheme Only representatives can represent more than one foreign supplier but must keep the information related to each of them separate. The foreign company must inform the importer(s) within the same supply chain of your appointment as an only representative. These importers are then regarded as downstream users for the notification scheme. *Source: ECHA*
Overseas manufacturer	Non-ASEAN Introducer of New Substance-containing products into the ASEAN territory
Polymer	Substance consisting of:

Terminology	Definition
	1) Molecules characterized by the sequence of one or more types of monomers units; 2) A simple weight majority of molecules containing at least three monomer units that are covalently bound to at least one other monomer unit or reactant; 3) Less than a simple weight majority of molecules of the same molecular weight; and 4) Molecules distributed over a range of molecular weights wherein differences in the molecular weights are primarily attributable to differences in the number of monomer units. *Source: OECD ENV/JM/MONO (2007)13*
Preparation	Intentional combination of two or more chemical substances (i.e., all mixtures that do not occur naturally or that are not the result of a chemical reaction). See also "Mixture."
Registration	Submission of physical, chemical, simple and advanced toxicological data to competent authority with authority's approval
Research and development substance	Substance that is undergoing systematic investigation or research, by means of experimentation or analysis, other than test marketing, the primary objective of which is: 1) to create or improve a product or process; or 2) to determine the technical viability or performance characteristics of a product or process; 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*
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*
Substances occurring in nature / Naturally occurring substance	Substances that are unprocessed, processed only by manual, gravitational, or mechanical means, or by dissolution in water, or by flotation, or by heating solely to remove water, or are extracted from air by any means, without chemical change in the Substance. *Source: OECD ENV/JM/MONO (2007)13*
UVCB	(**U**nknown or **V**ariable composition **C**omplex reaction products or of **B**iological material). A UVCB substance is legally defined as meaning any of the following: (a) a chemical of unknown or variable composition; (b) a complex product of a chemical reaction; (c) biological material, other than a whole animal or a whole plant. A UVCB substance is also complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents. *Source: Definition in Australia Industrial Chemicals Act 2019 and Canadian CEPA*

Section 2: Substances that should be considered Excluded or Exempted from notification requirements

2.1 Exclusions

In line with the "ASEAN Guidance Document on Developing a Chemical Inventory", the following categories are excluded from the chemical inventory, thus, not in the scope of chemical notification.

a) Medicines, including human and veterinary drugs
b) Medical devices
c) Food and food additives/Animal feed additives
d) Pesticides – including inert/inactive ingredients
e) Radioactive and nuclear materials
f) Munitions
g) Cosmetic products
h) Gun powder and pyrotechnics
i) Tobacco, tobacco products
j) High pressure gas already regulated by high pressure gas safety law
k) Micro-organisms
l) Mixtures of which the components have already been controlled by chemical inventory legislation
m) Waste
n) 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
o) Non-isolated intermediates
p) Dangerous substances and dangerous mixtures transported by rail, road, in land, waterway and sea or air

2.2 Exemptions

The following are in scope of the chemical inventory; however, exemption should be given for chemical notification.

a) Chemicals to be used for purposes of analysis, measurement of properties or toxicity testing
b) Chemicals to be used exclusively for R&D (Research and Development) purposes – Refer to Section 2.3
c) Impurities in chemicals, chemical by-products, and incidental reaction products
d) Articles, except intentionally released chemicals from the Article
e) Polymers, provided that the monomers and reactants included in the polymer above 2% are listed on the chemical inventory
f) Chemicals which will be sold in quantities of less than, for example, 1,000 kg/year
g) Naturally occurring substances
h) Site limited intermediates

i) Chemicals produced for export purpose only
j) Hydrates of existing chemicals
k) Glass, frit, pottery, ceramic raw material, steel, cement, metal alloy
l) 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 of "ASEAN Guidance Document on Developing a Chemical Inventory")

2.3 Exemption of New Substances Exclusively Used for R&D Purpose

Exemption should be provided for R&D chemical substances, which undergo systematic investigation or research, by means of experimentation or analysis, other than test marketing. Their primary objectives are:

a) To create or improve a product or process; or
b) To determine the technical viability or performance characteristics of a product or process; or
c) To evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials or panelist tests under supervision, other than test marketing, to modify the technical specifications in response to the performance requirements of potential customers.

Regulators in many jurisdictions with comprehensive chemicals legislation recognize the benefit of R&D activities and aim to foster innovation by exempting non-inventory listed R&D substances from normal notification requirements.

The benefits of developing simple measures for R&D substances include:

a) Enhanced development of new chemicals and exploration of new applications of chemicals contributing significantly to innovation and technical development all over the world, including stimulation of new areas of chemistry and new technology.
b) Enhanced opportunities for companies to undertake controlled experiments with a variety of new material options prior to submitting a notification and commercializing the successful candidate.
c) Reduced burden on companies by eliminating costly notifications for research materials that do not move forward into commercial markets from the iterative R&D process.
d) Reduced burden on the government by eliminating countless applications for chemicals that will not be used in commerce and whose use may be entirely discontinued.
e) Reduced government agency resources required to manage this aspect of new substance management without diminishing protection of human health and the environment.

Adoption of an R&D exemption is recommended, which includes the following concepts:

a) Utilize a definition for R&D to eliminate the artificial distinction between "scientific research and development" and "process orientated research and development"; recognize specifically that not all R&D takes place in a lab or pilot plant; and acknowledge that testing of prototype products (including with test panelists) is within the legitimate scope of R&D.

b) Limit the volume of substance permitted for R&D and the duration of the R&D exercise, by the type of the activities that meet the definition of R&D, not by an arbitrary, fixed volume number, nor by a fixed time limit. The amount to be permitted should be restricted only by the amount needed to conduct the R&D work and will vary on a case-by-case basis.

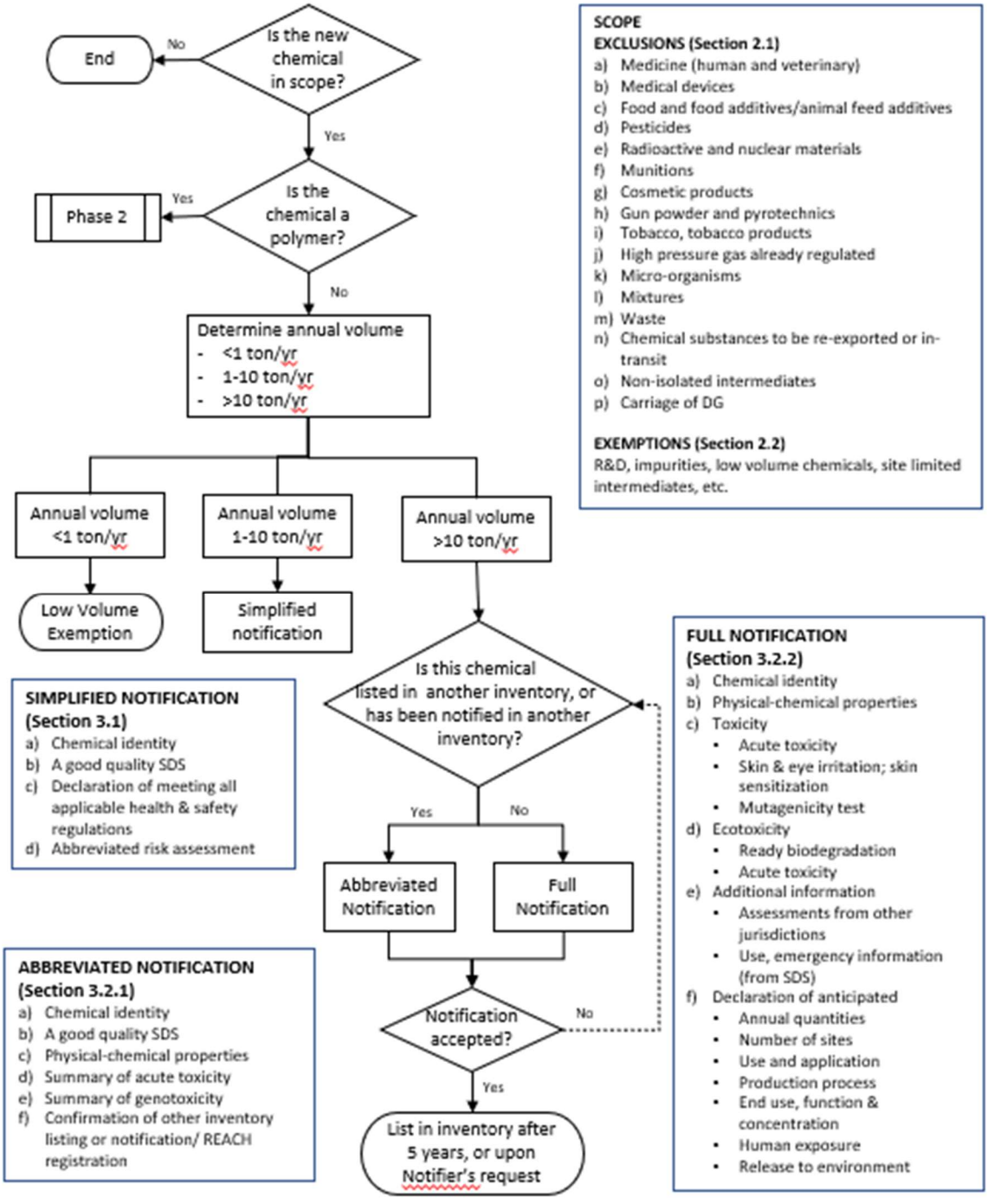
c) Stimulate innovation and minimize administration for both industry and the authorities by not requesting applications to be submitted. Instead concentrate efforts on protection for people and the environment by:

    i. Requiring that R&D activities be conducted under the supervision of persons with appropriate skills, knowledge and experience (e.g., Technically Qualified persons).
    ii. Placing appropriate restrictions (but not prohibitions) on the commercial uses of an R&D substance.
    iii. Mandating appropriate, proportionate evaluation by the manufacturer of the risks associated with the R&D activity, and suitable communication to those involved in the activity of those risks and the R&D status of the substance.
    iv. Requiring maintenance of appropriate records related to the activity that would be available for inspection by a regulatory authority, but not submitted as a notification.

Section 3: New Substance Notification Scheme

Various levels of New Substance Notification (NSN) are defined in this section to correspond with potential risks of the new substances (**Diagram-1**).

Diagram-1: Overview of Proposed NSN Scheme



ASEAN Member States can benefit from adopting simplified measures for new, non-inventory listed, lower volume chemicals. These benefits include:

a) Decreased cost and management burden to domestic and foreign companies to commercialize new specialized chemicals;
b) Stimulation of innovation into new areas of chemistry and new technology;
c) Better alignment with international practice related to new chemical notification; and
d) Less government resources required without diminishing protection of human health and the environment.

In principle, substances manufactured or imported in smaller quantities pose lower risk to human health and the environment. Most other jurisdictions with chemical control legislation in place have *de minimis* quantities as exemptions from their notification processes.
Hence it is proposed that new substances below 1,000 kg/year are exempted from the notification scheme. These notification schemes generally apply to industrial chemicals, typically used in large volumes; therefore, 1,000 kg/year is deemed as a sufficiently low threshold. This threshold is also deemed appropriate to manage the initial load of information associated with new substance notifications, and the threshold can be adjusted in future refinements. As a best practice, industry should keep internal records of low volume new substances for potential future regulatory audits and potential future notification for higher tonnage.

3.1 Simplified Notification for New Chemicals Manufactured or Imported between 1 to less than 10 tons/year

The following requirements are recommended for low volume new substances manufactured or imported at 1 to less than 10 tons/year:

a) Chemical identity – chemical name, CAS number and structure
b) A good quality SDS (Safety Data Sheet)
c) Declaration that the use of the new substance meets all applicable health and safety regulations
d) An abbreviated risk assessment addressing the known hazards of the substance, potential exposure, and environmental release and disposal

The following conditions and monitoring measures will apply to low volume new substances manufactured or imported at 1 to less than 10 tons/year:

a) Company will keep internal records to support its use of 1-10 tons/year of the new substance.
b) Company may be audited, and to demonstrate compliance, must be able to produce records of production or import.
c) Chemical substance will not be added to the inventory unless full notification is completed.

3.2 Notification Scheme for Substances Manufactured/Imported ≥ 10 tons/year

3.2.1 Abbreviated Notification

An abbreviated notification scheme with reduced requirements recognizes the new substance notification schemes of other countries and the assessments made, resulting in a reduced data set required for the new substance notifications.

3.2.1.1 Criteria for the Abbreviated Notification Scheme

An abbreviated notification (like the Philippines Abbreviated PMPIN) applies to new chemical substances that are new in the ASEAN Member State but which are listed or notified on the chemical inventory of other jurisdictions or registered under the EU REACH regulations. These other chemical inventories include:

a) Australian Inventory of Industrial Chemicals (AIIC)
b) Canadian Domestic Substances List (DSL)
c) China – Inventory of Existing Chemical Substances in China (IECSC)
d) Japan Existing and New Chemical Substances (ENCS)
e) Korea Existing Chemicals Inventory (KECI)
f) New Zealand Inventory of Chemicals (NZIoC)
g) Taiwan Chemical Substance Inventory (TCSI)
h) US Toxic Substances Control Act inventory (TSCA)
i) European Inventory of Existing Commercial chemical Substances (EINECS) and European List of Industrial Notified Chemical Substances (ELINCS)
j) ASEAN Member State inventories such as
    i. Philippines Inventory of Chemicals and Chemical Substances (PICCS)
    ii. Thailand Existing Chemical Inventory (when it becomes legally binding)
    iii. Vietnam National Chemical Inventory (when finalized)

To support eligibility for an Abbreviated Notification, the notifier should provide evidence of inventory listing above, or other references for a chemical notified but not yet listed on the inventory. Following are examples of evidence that can be used:

a) US Notice of Commencement
b) US Accession Number (assigned only to confidential materials)
c) Canada Notice of Commencement
d) Europe EINECS and ELINCS (European List of Industrial Notified Chemical Substances) numbers
e) Japan MITI number (Ministry of International Trade and Industry)
f) Australia AIIC number (Australian Industrial Chemicals Introduction Scheme)
g) China IECSC registration number (Regulations on the Management of New Chemical Substances)

3.2.1.2 Data Set for Abbreviated Notification

To be consistent with regulations for similar notifications in other countries, it is recommended that the following data be provided to support an abbreviated notification:

a) Chemical identity – chemical name, CAS number and structure
b) A good quality SDS
c) Physical-chemical properties including melting or boiling point, water solubility, partition co-efficient, vapor pressure, and an assessment of flash point, flammability and explosive properties, if applicable
d) Summary of acute toxicity (oral or dermal); inhalation for volatile liquids, gas, aerosols, dust or mists
e) Summary of genotoxicity - bacterial reverse mutation result (Ames test) or alternative data
f) Confirmation that new chemical substance is on another inventory, or evidence of notification to the inventory as above (for chemicals not yet listed), or registered under EU REACH

3.2.2 Full Notification

The full notification scheme is intended for new-to-the-world chemical substances imported and/or manufactured in the ASEAN Member State and not yet listed or have been reviewed and approved for addition in any of the chemical inventories stated in Section 3.2.1.1

3.2.2.1 Data Set for Full Notification

The data set required in a full notification focuses on allowing a risk-based assessment of the inherent hazard of the new substance and potential for human exposure or environmental release. QSAR, Read Across and public domain information can be used to demonstrate if there are any potential concerns on human health or the environment. The notifier should assure that the use of the substance meets all applicable health and safety regulations.

For new substances imported or manufactured at ≥10 tons/year, the data set shall be commensurate with the inherent hazard and exposure/release potential (risk), with more extensive data being needed for the higher hazard identification and/or exposure potential.

Manufacturers and importers of such chemicals should submit a risk assessment of the new substance that addresses the risk of all intended uses and releases to the environment based on the problem formulation. The dataset below is usually recommended as minimum requirements for a risk assessment. However, it can be adjusted depending on the risk assessor's best knowledge on what data would be sufficient to assess the risk of the substance. It should not be considered as prerequisite data. Addressing these elements may be done by submission of actual test data, information from published scientific literature, or scientific mechanisms such as analog or surrogate information as describe in the following section.

a) Chemical Identity
    i. Chemical name, CAS number
    ii. Molecular formula and structure
    iii. Purity, appearance

b) Physical-Chemical Properties, if applicable
    i. Melting or boiling point
    ii. Water solubility; partition co-efficient
    iii. Vapor pressure
    iv. Assessment of flash point, flammability and explosive properties

c) Toxicity
   i. Acute toxicity to reflect most likely route of human exposure
   ii. Skin and eye irritation; skin sensitization
   iii. Mutagenicity test: In vitro test for gene mutation (or Ames test) and in vitro test for chromosome aberration (followed by other tests if needed)

d) Environmental
   i. Ready biodegradation
   ii. Acute fish or daphnia or algae toxicity test

e) Additional information
   i. Assessments from other regulatory authorities should be considered in an evaluation of a substance
   ii. From an SDS: Use(s), emergency, first-aid measures and storage requirements
   iii. From a self-declaration form or letter, include
      - Quantity to be manufactured and/or imported annually
      - Number of sites manufacturing or using the substance and estimated quantity used or processed
      - Predicted uses and application: Industrial (i.e., manufacture, formulation), commercial (use of the substance or formulations containing the substance), and consumer activities
      - Description of production process including frequency of operation
      - Anticipated end-uses, function and concentration of the substance
      - Possible human exposure to workers and/or public
      - Anticipated release to environment by predicted use

3.3 Data Strategies

Data requirements to comply with the notification and exemption process of new chemical substances should be practical, simplified yet effective to address the safety and health of human and the environment. Clear guidelines on the type and amount of information shall be provided to the Notifiers to ensure that only the appropriate information is submitted.

When fulfilling data requirements for notification, additional information may be needed. This can come from gathering existing data as well as collecting new data using (i) read across, (ii) modelling (including QSAR), (iii) *in vitro* studies and/or (iv) *in vivo* studies, with animal testing only if absolutely needed. Details on this information can be found in Appendix E of this document, as Step 4 Data Gathering of the ARCP Regulatory Chemical Risk Assessment Guidance document.

3.3.1 Read Across and Grouping

These situations can be identified for the notification of new non-Inventory listed chemical substances having similar structures:

a) New chemical substances that are new in the country, but which are of similar structure to the one(s) already listed on the Inventory,
b) A group of new chemical substances, not listed on the Inventory, which have similar structures and/or usage, similar test(s) data and/or other information

To support the notification of these types of chemicals, it is recommended that the ASEAN Member State adopts the principle of "Read Across" of data from one substance to a similar substance (analog approach) or group of chemical substances (category approach). This principle is already recognized in international risk assessment activities, including the OECD HPV (High Production Volume) Chemicals Program.

Properties of individual substances can be established by "reading across" from the properties of substances with similar structural characteristics (i.e., by interpolation and/or extrapolation). This means the grouping of substances whose physico-chemical, toxicological or eco-toxicological properties are likely to be similar or follow a regular pattern because of structural similarity. Therefore, these substances may be considered as a group, or "category" of substances. It will minimize the need to test every substance for every endpoint.

The similarities may be based upon:

1. A common functional group, or/and
2. The common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals, or
3. A constant pattern in the changing of the potency of the properties across the category.

Read across for UVCBs requires specific considerations, for which ECHA has provided guidance (https://www.echa.europa.eu/documents/10162/11395738/advice_uvcb_read-across_en.pdf). Documentation for the similarity of substances from which the data was used (source substances) and the new substance (target substance) for read across is required for justification. Guidance for read across is available from OECD (Guidance on Grouping of Chemicals, Second Edition, OECD Series on Testing and Assessment, OECD 2014) and ECHA (Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals, ECHA 2008;& Read-Across Assessment Framework (RAAF), ECHA 2017).

3.3.2 Computational Modelling

Computational predictive models can provide useful information on hazards of chemical substances when experimental data are not available. For certain endpoints, the relationship between the chemical structure and the biological effect are well defined. Therefore, robust predictions can be made using mathematical models, known as Quantitative Structure-Activity Relationships (QSARs). These models quantitatively relate a numerical measure of chemical structure (e.g. a physical-chemical property) to a biological effect (e.g. a toxicological endpoint). Endpoints of the new substance can be predicted through the chemical structure using the well-defined structure-activity relationships.

QSAR should be associated with a well-defined endpoint and unambiguous structural descriptors. For each endpoint, the model may not apply to all groups of substances. Each model has a defined applicability domain. The new substance must lie within the applicability domain of the model in order to generate valid predictions. Guidance on QSAR models and their validity is available from OECD (Guidance Document on the Validation of (Quantitative) Structure-Activity Relationship [(Q)SAR] Models, OECD 2014; and (Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure − Activity Relationship models, predictions, and results based on multiple predictions, ENV/CBC/MONO(2023)32, OECD 2023). OECD has developed QSAR Toolbox software (OECD QSAR Toolbox | OECD) in close collaboration with

ECHA. Results from this software have been widely used by governments, chemical industry, and other stakeholders for hazard assessment of chemicals.

3.3.3 Testing Recommendations

Intelligent testing strategies can be based upon use of existing data for the substance, in-vitro methods, computational predictions, read-across and chemical categories. Such strategies can be further optimized by considering weight of evidence approaches, optimization of in-vivo tests and exposure-based test waiving. Such integrated approaches can be part of an iterative risk assessment process, and at the same time, reduce costs and animal tests.

To minimize animal testing, the following recommendations are provided:

a) The use of read-across data from chemicals of similar structure as well as modeling (e.g. QSAR)
b) Mutual recognition of new substance approvals by other countries like the US (TSCA), Canada (DSL), Australia (NICNAS/AICIS) and EU REACH. AICIS Australia, for example, provides a complete hazard assessment of products they approve that may support the data set required for an abbreviated notification.

In line with other jurisdictions (e.g., US, Canada), it is recommended that hazard assessments for toxic endpoints be performed by using a tiered approach, i.e., starting with an evaluation of all the data already available. These would include animal in vivo and in vitro data, and human evidence and case reports, as well as data from QSAR or read-across.

In cases where testing is not technically possible, consideration should be given to the omission of a specific endpoint based on the intrinsic properties of the substance and technical limitations of the specific guidelines available at the time of testing.

(Eco)toxicity tests by GLP certified laboratories should be conducted in accordance with OECD, ISO, EU, US EPA or other equivalent guidelines. However, other scientifically sound, relevant data should also be accepted and utilized for the evaluation of a new substance notification. Additionally, it may not always be necessary or practical to determine certain characteristics using GLP (e.g., physical properties testing).

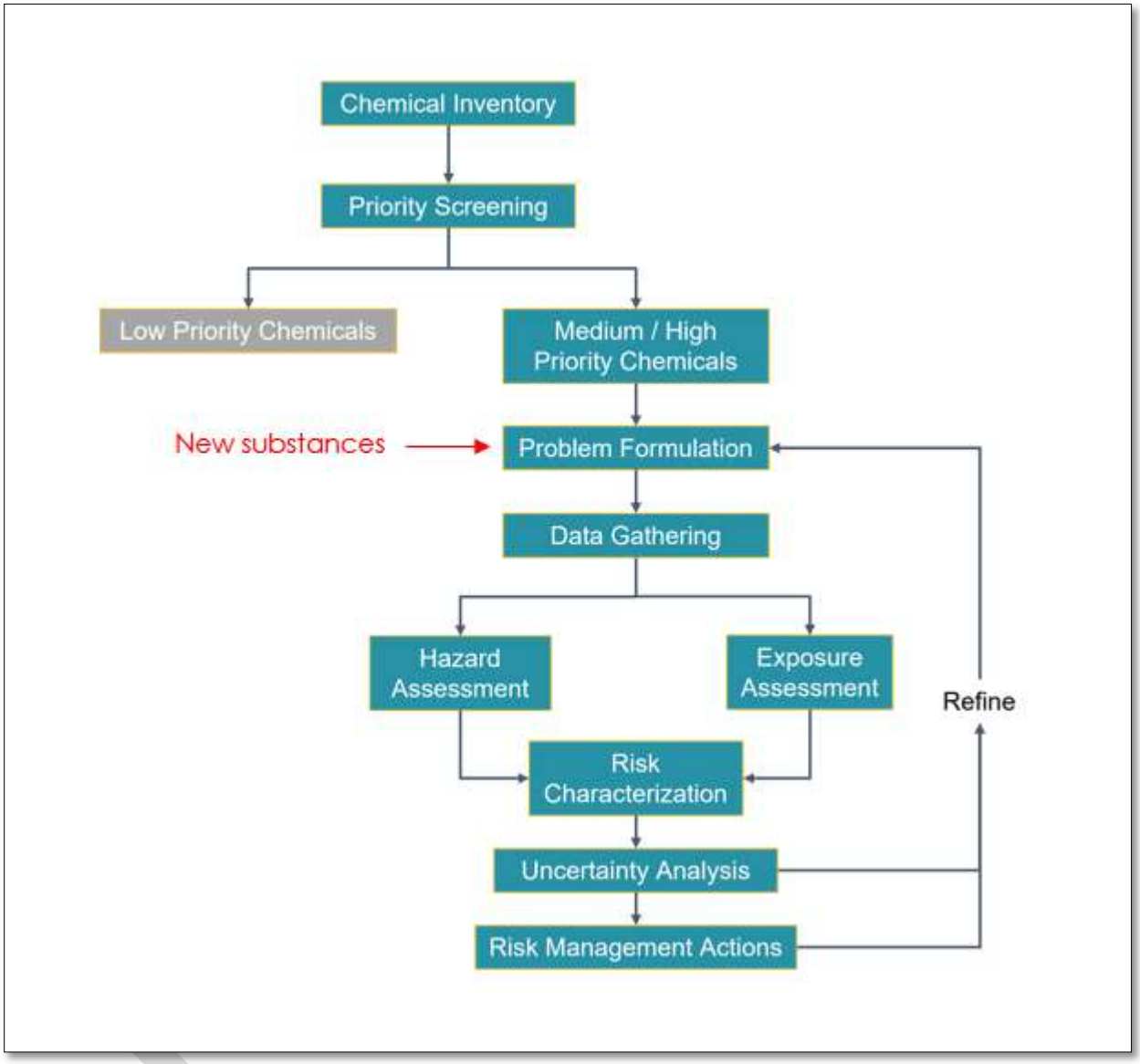
3.4 Risk Assessment of New Chemicals

The overall objective of the new substance notification is to address the risks of new chemical substances based on their identified hazards, production volume as an estimate of potential exposure, and anticipated end uses. Regulatory authorities should therefore define the criteria of acceptance for the Simplified, Abbreviated, and Full Notifications.

For Full Notifications, authorities may request a comprehensive risk assessment for the identified uses. The ASEAN Regulatory Cooperation Project (ARCP) Regulatory Chemical Risk Assessment Guidance document describes how to conduct a risk assessment (Appendix E). Additionally, the document integrates well into the recommended chemical management framework of the ASEAN Regulatory Cooperation Project.

The following Diagram-2 demonstrates where the assessment of new chemicals fits within the broader risk assessment process that is reflected in the ASEAN Guidance Document on Chemical Risk Assessment.

Diagram-2 Simplified Flow Diagram of a Chemical Management Scheme



3.5 New Substance Notification Review Process and Timing

In the submission and review process of notifications outlined in this Section 3, the complexity of data submitted can sometimes require discussions between the notifier and the authority, and this will lengthen the review process. Direct discussions will greatly assist in helping both the notifier and authority to understand and address what data (or waiver) is needed, why it is (or not) needed, how submissions are being interpreted, or other concerns that arise. The following recommendations are made to facilitate timely reviews and responses.

Table-2: Chemical Notification Review Process and Timing Example

Review Process	Lead-Time (Calendar Days)		
	Simplified Notification (1-10 tons/year)	Abbreviated Notification (≥10 tons/year, Inventory Listed)	Full Notification (≥10 tons/year, New-to-the-World)
Authority reviews if submission is complete and informs the Notifier. This is a simple completeness check.	10	10	10
Notifier to respond to Authority with corrections, or to confirm that the submission is complete.	10	15	20
Authority performs technical review on a completed application and communicates with the Notifier for specific requests. • When changes or additional information is required, the Authority shall inform the Notifier. The Authority can specify the time allotted for the Notifier to respond. • Where the Authority proposes significant and/or complex changes/additions to the submission (e.g., significant revision to submission, additional test data required), the Authority shall discuss the issues with the Notifier. • When there are complex changes or additional data requiring more time than specified, the timing can be adjusted/extended based on mutual agreement between the Notifier and the Authority. The review process will be temporarily paused during this response period. The Notifier shall respond within agreed deadline. The Authority may cancel the Notifier's submission if no response is received within the agreed deadline.	30	60	90+ with possible extension of another 30 days

In summary, transparency of technical decisions and the opportunity to discuss complex matters will help both the Notifier and the Authority to better understand complex submissions to facilitate the chemical notification review process.

3.6 ASEAN Approach

In the spirit of the ASEAN Economic Community (AEC) and to reduce non-tariff barriers to trade, notification to one ASEAN Member State should be mutually accepted by other ASEAN Member States as fulfilling the obligation.

Section 4: New Chemical Substance Notification: Proposal for Regulation of Polymers

As stated in the "ASEAN Guidance Document on Developing a Chemical Inventory", polymers are basically recommended to be exempted from the initial chemical inventory. Once non-polymeric 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. With this, it is recommended that polymers are excluded from the chemical substance notification scheme if they are exempted from the chemical inventory.

For jurisdictions which have established inventory containing polymers, specific rules for new non-Inventory listed polymers with reduced requirements compared to non-polymeric substances have been set up. This acknowledges the fact that polymers are generally low hazard substances. Regulatory schemes typically allow for exemptions of certain kinds of polymers and lay down reduced data requirements for polymers which do not qualify for exemptions. As most polymers are non-bioavailable, pose low risks and are of low concern, it is often appropriate to not require notification and animal testing on these substances.

4.1 Polymer Definition

The definition of a polymer was developed by the Organization for Economic Cooperation and Development (OECD) expert work group on polymers in 1970 in Toronto, and was subsequently adopted by the OECD as its formal definition of a polymer:

> *"Polymer" means 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 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. In the context of this definition a "monomer unit" means the reacted form of a monomer in a polymer.*

This definition can be expressed succinctly as three requirements:

a) Molecules must be distributed over a range of molecular weights.
b) More than 50 percent of the molecules must contain at least three monomer units covalently bound to at least one other monomer unit or another reactant.
c) No single molecular weight molecule can be more than 50 percent (w/w) of the total molecules.

This definition has been recommended as well in the "ASEAN Guidance Document on Developing a Chemical Inventory" and adopted by most jurisdictions with chemical control laws including the EU, Canada, Australia, China and South Korea. Japan's definition is slightly different, requiring that the number average molecular weight (Mn) be more than 1,000. While the original US Toxic Substance Control Act (TSCA) does not include an explicit definition of a polymer, the 1995 polymer exemption amendment requires that substances meet the OECD definition of a polymer to qualify for the exemption.

It is recommended to adopt this common polymer definition, which would serve to differentiate between polymers and non-polymers and help ensure that polymeric substances are treated the same in all regulatory controlled regions.

4.2 Polymer Identity (2 Percent Rule)

As a rule, if the weight of a monomer or reactant charged to the reaction vessel or incorporated into the polymer is less than 2% by weight of total polymer reactants, the manufacturer or importer has the option to include or exclude that monomer or reactant from the chemical identity of the polymer. Naming polymers this way, more commonly referred to as the "2 percent rule", is included in most chemical control laws.

Accordingly, polymer manufacturers can use monomers or reactants at less than 2% without changing the chemical identity of an inventory-listed polymer. As stated in Canada's "Guidance document for the New Substances Notification Regulations (Chemicals and Polymers)", "*A polymer on the DSL that is modified by adding reactants, none of which constitutes more than 2% by weight of the polymer, does not require the explicit substance name to be changed and is therefore not subject to notification.* In the US, this rule was adopted because the US EPA and the regulated community agreed that it would be difficult to identify the exact number of monomers or other reactants incorporated in the final polymer at low levels.

As an example, consider a polymer of Monomers A/B/C/D in which monomer D is present at 2% or less. If a jurisdiction uses the 2% rule the new A/B/C/D polymer (D<2%) is considered ALREADY INVENTORY LISTED within the name of A/B/C in the chemical inventory.

It is recommended to include an explicit "2 percent rule" for determining polymer identity as it would harmonize the reporting and inventory searching and listing rules with other jurisdictions that use the "2 percent rule".

4.3 Polymer Exemption from New Chemical Notification

The chemical notification scheme should allow polymer exemptions for the following, when polymers are included in the notification scope:

a) Natural polymers
b) "Polymers consisting of monomers (present at equal or greater than 2%) listed in the existing chemicals inventory."
c) Polymer of Low Concern (PLC), which is a polymer with
    i. Number Average Molecular weight (NAMW) ≥10,000 Da, of which NAMW < 1,000 Da at < 5% and NAMW < 500 Da at < 2%. Or
    ii. NAMW 1,000-10,000 Da, of which NAMW < 1,000 Da at < 25% and NAMW < 500 Da at < 10%. Or
    iii. Polyesters

Note: Certain polymers, for example, cationic polymers and degradable polymers are sometimes not qualified as PLC, or there could be a reactional function group (e.g., heavy

metals, Acrylates, Hydrazines, etc.) restriction for NAMW 1,000-10,000 Da polymers, to fulfill the PLC definition.

These exemption criteria are part of the regulatory schemes in different jurisdictions. Adoption in the ASEAN Member State's existing or future notification scheme would therefore increase international harmonization.

It is critical to include these exemption criteria for polymers, which would further increase international harmonization and reduce animal testing.

In some jurisdictions (e.g. US), exemptions are therefore "self-actuated", meaning, no application for exemptions is required. Industry is held responsible to comply with the exemption requirements and keeps records. Authorities will control compliance with requirements by inspections.

It is recommended to allow exemptions to be self-actuated by industry, to make efficient use of authority and industry resources. No applications or submissions are recommended.

4.4 New Polymer Notifications

For new polymers that do not qualify for the exemptions mentioned in Section 4.3, the basic data required for notification of new polymers should be less than for non-polymeric substances due to the lower hazards associated with polymeric substances. If available, existing data on a similar polymer substance or QSAR data should be accepted. It is recommended that such a polymer data set consist of general physical-chemical properties (usually available from the SDS) and one acute toxicity test or one aquatic toxicity test and one genotoxicity test (e.g. Ames test). A different threshold for annual production volume should apply for polymer vs. non-polymer, and it is recommended to be above 10 tons/year per legal entity as a minimum.

Section 5: Addition of New Substance to Chemical Inventory

5.1 Substances that Should be Listed on the Chemical Inventory

All chemical substances which are manufactured and imported, except those which are in the scope of the exclusions and exemptions (see Section 2), should be considered for inventory listing.

All chemical substances that underwent the process of Abbreviated or Full Notification that were evaluated, approved and have been issued a Notification Certificate, should be listed in the chemical inventory.

5.2 Listing of Proprietary Substances

In some instances, the exact chemical identity of a specific chemical substance may be considered a trade secret by the Notifier. Publication of the exact chemical identity of such a substance could lead to others discovering the notifier's trade secret composition, or the possible loss of patent protection. For such cases, it is recommended that a process be developed for the protection of CBI (see Section 7).

One of the possible approaches of listing a confidential chemical substance to the chemical inventory is to allow the Notifier to list the chemical substance on the inventory by a ***generic chemical name***, visible to the public but which does not reveal the exact chemical identity of the substance. This process may involve the assignment of an ***arbitrary listing number*** for the substance. Another approach is by providing a ***separate list of non-public/ confidential as part of the chemical inventory***, which will only be visible to authorities. Both cases will require a "bona fide confidential chemical inquiry" work process defined, so that a Notifier can determine if its chemical substance of interest is already listed in the confidential inventory. In this instance, the authority may charge the interested party a reasonable fee when conducting a confidential chemical check. Additional information of this kind may be accessed through the links provided in Section 9 (Best Practices) of this ASEAN Guidance Document on NSN.

Certain substances, previously or newly notified as confidential substances, require careful management and suitable precautions to avoid negative impacts, especially for those with existing confidentiality agreements in other regions. Hence, the country needs to establish comparable CBI protection policies.

5.3 Timing of Adding Notified Substance to the Chemical Inventory

Upon successful notification of a chemical substance, its automatic inclusion in the chemical inventory may be recommended after a 5-year period. However, notifiers have the option to expedite this process by formally requesting or applying to the authority for early addition. This premature listing is exclusively applicable to the non-confidential segment of the inventory. If a notifier wishes to maintain confidentiality for their chemical's specifics, they can invoke CBI (Confidential Business Information) provisions, thereby safeguarding certain data from public disclosure. Once listed, any compliant registered entity, whether an importer or manufacturer, is eligible to introduce the chemical into circulation, adhering to the stipulated conditions of the listing.

Section 6: Post Notification Requirements

6.1 Basic Post Notification Guide (for New Chemical Substances)

The owner of the Notification Certificate is responsible for fulfilling post notification requirements. It is recommended to have requirements tiered towards the annual chemical tonnage volume. See Table-3 below for recommended post-notification requirements. Another example is shared in Appendix-C for China post-registration obligations.

Table-3: Recommended Post Notification Requirements

Annual Tonnage	**Volume Monitoring** (Keep Internal Records)	**New Use Notification**
Exempted	Recommended if relevant to volume (e.g. <1t substance)	Not required
1-10 MT	Recommended	Not required
≥10 MT Abbreviated notification	Not required	Required
≥10 MT Full notification	Not required	Required

Volume monitoring of new chemical substances is to ensure compliance for tonnage notification needs and reporting, if the authority requires.

Collection of volume data for new uses of the notified chemical substance for risk management will be addressed in Section 8.2 (Additional Notification Requirements).

6.2 Extension of Trading Rights to Downstream Users of the Notification Certificate Owner

In this section, the recommendation is to enable the authority's effective risk management whilst balancing the industry needs for flexibility to grow business in ASEAN.

The overseas notifier should be able to allow its direct downstream customers to import its notified chemical into the country, provided that the volume is made known to the downstream customers, and the original notifier has written consent. For the case of the Simplified Notification, the total annual import volume should remain within 1-10 MT. An amendment mechanism should be set-up to add the direct downstream customers to the original Notification Certification or record. This does not only reduce the burden from the authority, who will be conducting redundant reviews on the same notified chemical substance, but it will also allow the authority to strategically focus its scarce resources on assessing new chemical substances. Section 9.2.2 (Extension of Chemical Notification Approval Certificate) further explains the best practices on the extension of the Notification Certificate to direct downstream users.

Section 7: Confidential Business Information

7.1 CBI Definition

CBI (Confidential Business Information) is "protected information". There is generally a low level of awareness for the need to protect CBI, but it is extremely important for the industry, and it has an impact to new product development if not properly managed.

CBI broadly encompasses proprietary information that is considered confidential to the notifier. Its release would cause substantial business injury to the owner and innovation. In general, CBI disclosure may be harmful to the business when a competitor or the public can obtain an economic advantage. However, transparency of information may be viewed positively by downstream users and the public. There must be a balance between transparency and protection of CBI.

Businesses often give government and other parties information that, if disclosed, may cause them commercial harm. Businesses can apply for protection under laws. This protection means the business won't publish certain commercially sensitive information. More general information is preferred to be published. No CBI from the notifier of the notified substance will be disclosed to the public without the consent of the notifier, except in conformity with the laws of the jurisdictions.

7.2 CBI Scope

The scope of CBI protection of the chemical's identity or end use shall include the following:

A. New Substance Notification (NSN). The notifier's confidential information shall make a claim for confidentiality when the notification dossier is submitted to specific jurisdictions. Any information exchanged between authorities during NSN cannot be disclosed to the public except in accordance with the laws of those jurisdictions, due to consideration being given to the notifier's claim for confidentiality, if any.

B. Data protection and confidentiality for Customs and other government agencies. There should be freedom of information when providing specific information for Customs and other government agencies. Confidential or commercially sensitive information should not be divulged (i.e., private or sensitive information made public). Furthermore, appropriate freedom of information would enhance transparency and predictability for traders. Most modern government agencies have instituted legislation to promote what is generally referred to as freedom of information. In broad terms, such legislation is aimed at giving people the legal right to view information held by governments nationally, regionally and locally, thereby, making governments more accountable to the public. In such cases, Customs and other agencies administrations should:

    a) Ensure that they do not disclose details of a private or confidential nature affecting third parties unless such disclosure is required or authorized by national legislation.
    b) Allow traders or any interested parties to access the data and information held by Customs and other government agencies regarding confidentiality.
    c) Publish clear criteria on exempted documents or data which cannot be accessed under the freedom of information.

The participating authorities also need to promote an organizational culture of data confidentiality. There should be controls that both enable appropriate access and inhibit inappropriate access, coupled with management actions such as targeted monitoring, response to events, testing, and auditing.

The following information are typically protected as CBI:

a) CAS number/Chemical name
b) Unique chemical name or identifier
c) Detailed use information and substance function
d) Manufacture or import quantities
e) Manufacturing mechanism and process
f) Full toxicology/ecotoxicology study reports
g) Specific downstream user information
h) Other information to be considered – Commercial volume, Spectral data linked to trade name.

The following information typically cannot be claimed under CBI protection:

a) Assessment Statements (chemical name, end use and EHS (Environmental & Health Safety) impact)
b) Inventory listings (chemical name, scope of assessment, which may include end use)
c) Commercial interest (listed chemicals)
d) Public interest (e.g. Information is published to protect humans, health and environment such as harmful information and exposure data available on media, literatures and SDS)

C. Third-party confidential information. In certain circumstances, a notifier may not have access to all information required to notify a chemical substance. This may be because a third party (e.g., overseas manufacturer of the chemical substance) holds this information, considers the information to be confidential information, and is not willing to release it to the notifier. However, if the third party holding this information agreed to authorized authorities to disclose only the mandatory information for new substance notification, then the information can be sent directly to the authorities who are obliged to keep it confidential from the notifier. When the third party provides the information to the authorities, the third party must include a cover letter specifying what information is to be kept confidential. If no information is specified confidential, then the authorities should treat all the information provided as confidential and not disclose any of it without receiving written permission.

7.3 CBI Application

To implement CBI protection, CBI application process is usually applied to secure CBI data.
CBI application step by step is described below (see Diagram-3: CBI Application Flow):
To obtain CBI protection, the notifier should apply for it. Once approved, CBI protection is required and maintained for certain period depending on country facility, for example, maximum of 5 years, 10 years or no limited timeline, after which the applicant must provide further evidence to continue or disclose to the public.

The process whereby the authority reviews the CBI application and weighs the commercial prejudice versus the public interest, including data sufficiency are explained in the following steps when applying for CBI protection.

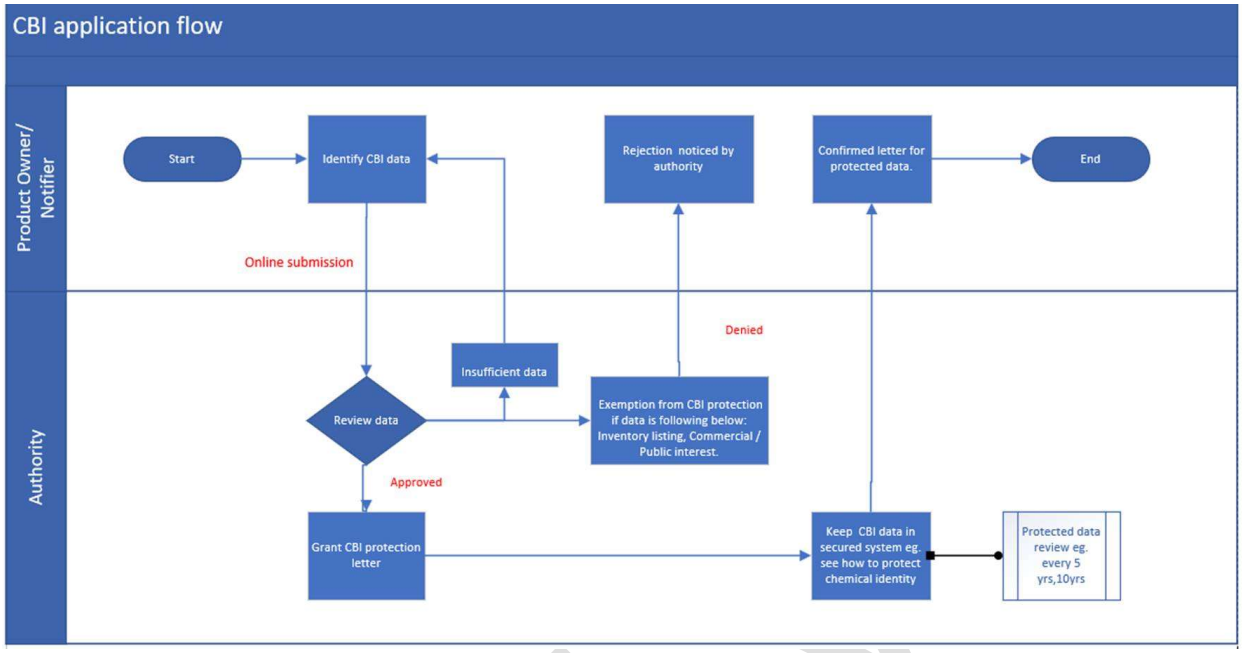
If the CBI application is determined as acceptable, then it is approved. A nominal fee is typically paid to the authority to cover the administrative expenses.

Beside of CBI application process, Self-declaration of Product Conformance or Letter of Confirmation of Chemical Inventory Compliance is one of CBI protection method refer to the information on self-declaration which is mentioned under section 9.2.1

Tips : How to protect chemical identity in CBI application process.

- Instead of the chemical's full name, to protect a chemical's identity, similar systems of generic chemical naming can be used.
- To hide a chemical name by replacing specific parts of the full chemical name with a related generic name that could represent various specific parts that would disclose the chemical's full identity. The way to hide a chemical's name depends on the type of chemical.
- Do not hide the part of the chemical known to cause toxicity or environmental fate concerns.
- Consider scientific or technical factors on appropriate protection of the chemical identity.
- Basing the generic name on a systematic chemical name (such as a CAS name or IUPAC name) keeps some degree of order to the hidden chemical name. This allows a person to understand the "generic" structure of the chemical. This is different to protecting the identity of the chemical by using a trade name. A trade name may not provide any indication of the chemical's structure.

Diagram-3: CBI Application Flow



7.4 When CBI Disclosure is Needed to Protect the Public

Disclosing protected CBI may be necessary to protect the public. Following are the criteria to consider when disclosing CBI:

a) This is under its legislation
b) If ordered by a Court, or for the purpose of law enforcement
c) With the consent of the CBI owner
d) If the information is already (lawfully) public
e) To reduce serious risk to public health or the environment
f) To certain government entities prescribed in legislation

Section 8: Other Appropriate Requirements to Support the Evaluation, Approval and Safe Use of New Chemicals

New Substance Notification is recognized as one part of a risk-based framework for the sound management of chemicals. It addresses new substances introduced into a geography or country and the identified hazards and potential exposure based on annual production volume associated with the intended use/s of the new chemical, as identified by the Notifier. In countries that take this approach to regulate chemicals (i.e., develop and maintain a national chemical inventory, and require notification of new chemical substances), there can be other additional regulatory mechanisms associated with the broader sound management of chemical substances.

8.1 Periodic Report

Periodic reporting of chemical substances is practiced in some countries. The chemical manufacturer and/or importer is typically required to report the substance identity and volumes. The reporting frequency can vary from annual (e.g., Japan CSCL) to once in every 4 years (e.g., US TSCA). There are thresholds set for reporting, e.g., above 1 ton/year.

The benefit of such a reporting scheme is to identify chemicals that are commercially active, hence, targeting regulatory focus on those chemicals versus those that may be on the inventory but have not been commercialized or have been discontinued. Periodic (annual) reporting can also be a tracking tool to ensure that new substances are introduced at the tonnage band that had been stipulated (e.g., for low volume exemptions volume did not exceed 1 ton/year, while for simplified notifications volume did not exceed 10 tons/year) in the Notification.

8.2 Additional Notification Requirements

This mechanism requires the notifier to submit additional data when there are major differences in the notified substance, compared to the conditions of the original notification. Such changes can include 'new' uses or uses not previously evaluated, new hazard information, and/or significant volume increase. The intent is to trigger an additional evaluation based on the 'new' conditions. Following are a few key examples that illustrate this principle:

a) US SNUR. Under the US TSCA, the Significant New Use Rule (SNUR) is a risk management mechanism to prevent the use of chemicals in specific circumstances without additional evaluation. SNURs are usually associated with new chemical substances but can be issued for existing chemical substances as well. SNURs describe very specific circumstances for a Manufacturer and/or Importer to abide by, and they will need to submit a Significant New Use Notice (SNUN) to be allowed to use under those circumstances.

b) Canada SNAc. The Significant New Activity (SNAc) provisions of the Canada CEPA trigger an obligation to provide the authority with information when proposing to use, import or manufacture the substance for a significant new activity. The substance will be assessed for potential risks to human health and/or the environment, and risk management measures may be imposed if appropriate. Significant new activity can be due to a different quantity or concentration or different circumstances that affects the human or environmental exposures to the substance.

c) Australia Inventory Listing with Regulatory Obligations. The AICIS requires the Manufacturer and/or Importer to submit additional information for chemicals listed on the inventory with specific information requirements, conditions of use, or with a defined scope of assessment. A specific information requirement means that the Manufacturer and/or Importer must inform authorities about the introduction of the chemical so that they can determine if there is a need to reassess the chemical. Conditions of introduction or use are restrictions imposed on the importation or manufacturing of the chemical, i.e., how much volume can be imported and/or manufactured and where the chemical is permitted to be introduced or used. A defined scope of assessment describes the parameters of the assessment of a chemical, such as how the chemical is used, volume or quantity and concentration in products.

8.3 Prioritization of All Chemicals in the Inventory (Including New Chemicals) for Further Assessments

Where a regulatory scheme does not include additional notification requirements described in Section 8.2, a new chemical substance could be assessed along with existing chemical substances to ensure any new or unassessed condition is evaluated. However, full risk assessment of chemicals is extremely resource intensive. The ASEAN Prioritization Screening Tool can be utilized to prioritize all chemical substances (new and existing) for further assessment, hence focusing resources on chemical substances with the highest potential risk.

8.4 Simple Notification for Low Volume New Chemicals

In some jurisdictions, a simple notification is required before the manufacture or importation of a new chemical of low volume (1 ton/year). For example, in China, the Notifier of a new substances of less than 1 ton/year needs to submit information on chemical identity, available physical-chemical properties, and available health & environmental toxicity data.

Similarly in Japan, for new substances ≤ 1 ton/year (may be adjusted based on number of Notifiers or end use/ release factor), the Notifier needs to submit information on chemical identity, physical-chemical properties, composition of new substance in the product, and expected uses. The submissions should not lead to an assessment as defined in Section 3 of this ASEAN Guidance Document on NSN for the Simplified, Abbreviated or Full Notification schemes.

Section 9: Best Practices

There are compounding benefits of global and regional harmonization of regulatory requirements such as ensuring ease of trade to support a wide variety of industries and early access of products, reducing unnecessary duplication of testing, and promoting competition and efficiency among businesses. Efforts have been initiated by different organizations and groups in the EU, USA, Asia-Pacific, and ASEAN, as well as in the respective countries, to pursue collaboration and convergence on regulatory harmonization.

For example, the APEC-CD (Asia-Pacific Economic Cooperation Chemical Dialogue) has developed the "Good Regulatory Practices" which serves as an excellent foundation for effective policies and regulations. Countries with advanced chemical management have also established tools and systems that successfully address the concerns from both the regulators and industry stakeholders. Implementation of better regulations may cover IT infrastructure, simplified data requirements and processes, handling of information shared by stakeholders, communication, and post submission processes.

9.1 Information Technology (IT) Infrastructure, Systems and Applications

IT fosters innovation in businesses. It provides accessibility, faster processing of applications, real-time tracking of information and documents, improved data storage and retrieval and wider reach to stakeholders. Online submission of an application is a far more practical process compared to the manual application. Today, regulatory agencies have developed different online platforms to support the need of the chemical industry as in the case of Australia and the Philippines. The IT infrastructure must feature protection from data breaches or unauthorized access to an account or computer system and networks.

9.1.1 Online Chemical Notification and Application

In Australia, the Australian Industrial Chemicals Introduction Scheme (AICIS) provides online chemical notification. The AICIS is a regulatory scheme under the Industrial Chemicals Act 2019, formerly known as the New Australian Chemicals Law. The aim of the AICIS is to make it easier for companies to import low-risk chemicals that are new to the Australian market. Furthermore, to introduce a new industrial chemical in Australia, companies are still required to register their business before import or manufacture, and the chemical being introduced must meet the requirements of a category of introduction based on the level of risk to human health and the environment. More information is available from the following link: https://www.industrialchemicals.gov.au/business/getting-started-registration-importing-and-manufacturing/basics-importing-and-manufacturing-chemicals.

On the other hand, the Philippines under the Environmental Management Bureau (EMB) has utilized the Online Permitting and Monitoring System (OPMS) for the online applications related to notification and exemption of chemicals and chemical substances. More information can be accessed from the following link: https://emb.gov.ph/.

9.1.2 Data Searching Function

The NSN database should be searchable in the official website or other online search engines of chemicals that are being manufactured or imported in the country for industrial use. Below are examples from Australia, US, Europe, and the Philippines.

a) **AIIC (Australia Inventory)**. The Australian Inventory of Industrial Chemicals (Inventory) is a searchable database of around 40,000 chemicals that are being manufactured or imported (introduced) into Australia for industrial use.
   - Link: https://www.industrialchemicals.gov.au/search-inventory

b) **TSCA (US Inventory)** - The non-confidential portion of EPA's Toxic Substances Control Act Chemical Substance Inventory (TSCA Inventory) is updated every six months. It can be searched in multiple ways. There are also ways to download the non-confidential Inventory and instructions on how to use the downloaded files.
   - Link: https://www.epa.gov/tsca-inventory/how-access-tsca-inventory

c) **ECHA** – The European Chemicals Agency implements the EU's chemicals legislation. It has a database that can be searched by the Chemical (Regulated substances) and Articles (Products) in SCIP database, and offers related information of legislation, consultations (feedback from all interested parties and widest possible range of scientific information for the regulatory processes), information on chemicals (hazardous properties, classification and labelling, and instruction of safe usage)
   - Link: https://echa.europa.eu/search-for-chemicals

d) **PICCS** – The Philippine Inventory of Chemicals and Chemical Substances (PICCS) is a searchable database of existing and notified substances in the chemical inventory. Registered Users of the Online Permitting and Monitoring System (OPMS) may also generate the PICCS Certificate for chemical substances and components of mixtures that have already been included in the PICCS list. The Environmental Management Bureau (EMB) has created the Tool for PICCS Validation and RA 6969 Requirements (also known as PICCS Tool) to help importers, distributors, users and manufacturers with regards to clarifying which permit they need to get from the Bureau. With the tool, clients can input the chemical components themselves and generate a certificate.
   - Link: https://chemical.emb.gov.ph/?page_id=138

9.2 Data Requirements, Storage and Protection

Data requirements to comply with the notification and exemption process of new chemical substances should be practical, simplified yet effective to address the safety and health of human and the environment. Clear guidelines on the type and amount of information shall be provided to the Notifiers to ensure that only the appropriate information is submitted.
In addition, transparency on the evaluation, review and approval process should be exercised. As notification process may take time, providing timely updates on the status of application is very important. This will also guide the Notifiers in the management of purchase orders from customers including logistical requirements. Equally important is establishing a process for storage and data protection. Several practices have been adopted on self-declaration, CBI, use of "Only Representative" model as well as the communication post approval.

9.2.1 Self- Declaration of Substance and Product Conformance or Letter of Confirmation of Chemical Inventory Compliance

Self-declaration is the process when a Notifier declares its chemical products comply with a certain regulation or standard without disclosing the 100% composition. This document may be issued by the original Notifier to its direct downstream end-users, e.g., importers, manufacturers, sub-suppliers, or regulatory agencies, who seek confirmation that the chemical substance or mixture is fully compliant, without the need of disclosing 100% confidential composition. The authority may develop a standard self-declaration form for stakeholders to use, to ensure consistency of required information.

In South Korea, a Letter of Confirmation (LoC) is issued. This document contains the required relevant statement "*We confirm that all components of the product… have been listed in the Korea Existing Chemical Inventory*". Alternatively, inventory listing is also included in many suppliers' SDS.

Self-declaration is also being practiced in the US. A TSCA certificate is a self-declaration document to show customs that all chemical substances imported into the United States either comply with the Toxic Substance Control Act (TCSA) at the time of import (positive certification), or not subject to TSCA requirements (negative certification). The self-declaration statement is, *"I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder*", or *"I certify that all chemicals in this shipment are not subject to TSCA"*. The importer can obtain the TSCA compliance statements from the original notifier for positive or negative certification generation without the need for repeated notification and without the need for the original notifier to disclose 100% confidential composition information. More information can be accessed from TSCA Requirements for Importing Chemicals | US EPA.

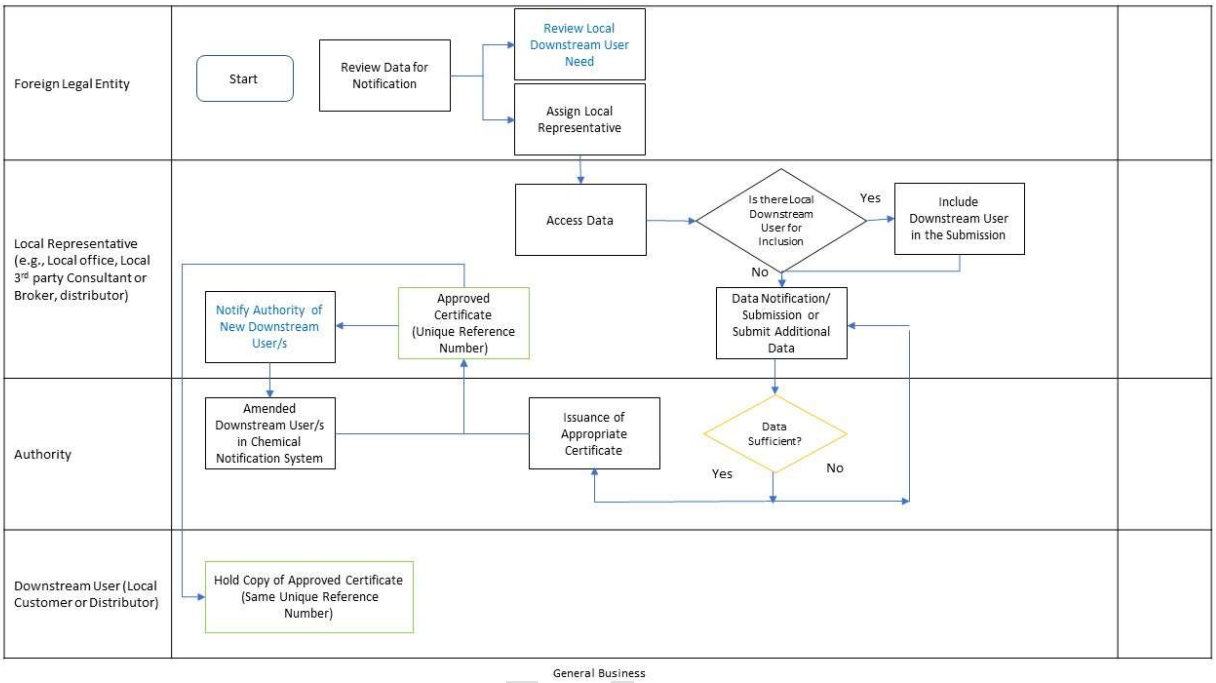
Aside from South Korea and US, Australia is also adopting the self-declaration model. The form is available from this link:https://www.industrialchemicals.gov.au/business/reporting-and-record-keeping-obligations/annual-declaration-all-introducers.

9.2.2 Extension of the Chemical Notification Approval Certificate

The extension of the chemical notification approval certificate to other end-users of the original Notifier's chemical substance will avoid the repeated submission of the same chemical registration data and review and approval process by other end-users. Diagram-4 on the next page provides a simple illustration how this can be undertaken. This means the Foreign Legal Entity, by working through its Local Representative, has the opportunity to include its Downstream Users either (a) at the beginning of its chemical notification submission, or (b) after the issuance of its Approved Certificate. In both cases, the Downstream User does not need to resubmit the same data and undergo another round of review and approval from the Authority. The Approved Certificate has a unique reference number, which is recorded in the Authority's Chemical Notification System. The identity of each Downstream User is also recorded in this System, and the Downstream User is linked to the unique Approved Certificate reference number. In the event other competent authorities (e.g., Customs) require proof of compliance from the Downstream User, a copy of the Approved Certificate will be sufficient because relevant information can be retrieved from the Authority's Chemical Notification System. Stakeholders' roles, responsibilities, and accountabilities must be clearly defined, properly consulted and informed. This can be shown

in the Roles, Responsibilities, Accountability, Consulted, and Informed (RACI) Matrix below (Table-4). Furthermore, other government agencies who are responsible for other aspects of chemical management, for example in case of spill emergency or security concerns, shall also be informed.

Diagram-4 Foreign Entity Extending Chemical Notification Approval Certificate to its Downstream User



General Business

Table-4: Roles, Responsibilities, Accountability, Consulted, and Informed (RACI) Matrix for Extending the Chemical Notification Approval Certificate to the Downstream User

Stakeholder	Responsible	Accountable	Consulted	Informed
Foreign legal entity	X		X	X
Local representative (local office, local 3rd party consultant, broker)	X	X	X	X
Authority			X	X
Downstream user (local distributor or customer)	X	X	X	X
Other government agencies				X

Notes:
A RACI Matrix is a type of responsibility assignment matrix (RAM) used in project management. It stands for **R**esponsible, **A**ccountable, **C**onsulted and **I**nformed. This method is adopted to describe the responsibility assignment of the stakeholders in the Extension of Chemical Notification Approval Certificate process. The stakeholders in this process include the foreign legal entity, local representative (local office, local 3rd party consultant, broker), authority, downstream user (local distributor or customer), and other government agencies.

Responsible designates the task as assigned directly to the person or group of people. The responsible person performs the work to complete the task or create the deliverables. In the case of the RACI Matrix, there are specific responsibilities entrusted to the foreign legal entity, local representative (local office, local 3rd party consultant, broker), and to the downstream user (local distributor or customer).

On the other hand, the **accountable** person or entity delegates and reviews the work in a project. Their job is to make sure the responsible person or team knows the expectations of the project. Certain accountabilities are delegated or transferred to the local representative (local office, local 3rd party consultant, broker), and the downstream user (local distributor or customer) once extension of the chemical notification is approved.

The process of **consultation** is a critical component of the chemical notification process. This ensures that stakeholders are able to provide input and feedback on the work being done. The people consulted have a stake because it could affect their current or future work or business. In Table-4, foreign legal entity, local representative (local office, local 3rd party consultant, broker), authority, and downstream user (local distributor or customer) should be consulted in the process.

Informed stakeholders need to be included in the chemical notification process, however, in some cases, they are not necessarily consulted. These stakeholders just need to know what is going on with the project, but they are not decision makers in the process. For example, in the RACI Matrix other government agencies not involved in the chemical notification or extension of chemical notification approved certificate process may be informed but not consulted.

Australia and Japan have adopted a similar scheme of extending an existing chemical license certificate from the original notifier to its downstream users.

In Australia, extending the certificate allows for addition of a person or company to a certificate for an assessed substance. This avoids repeating and resubmitting the notification dossier to AICIS. This could be done only if there is consent from the certificate holder, who performed the notification which requires submission of toxicity data including all costs associated with its introduction. For further guidance on this process, the link can be accessed through

a. https://www.industrialchemicals.gov.au/business/apply-change-existing-certificate-or-authorisation/apply-add-or-remove-person-be-covered-certificate; and

b. https://www.industrialchemicals.gov.au/business/getting-started-registration-importing-and-manufacturing/role-assessment-certificate-holder-or-person-covered-assessment-certificate

Japan allows for "piggy-back" registration of a new chemical substance with consent from the original notifier. A piggy-back registration does not require the re-submission of all the toxicity reports. Only Form-1, which captures the brief information about the chemical substance identification and a copy of the Approval Letter shared by the original notifier, is needed. See the official guidance in Japanese from "Notification of new chemical substances based on the Chemical Substances Control Law": https://www.nite.go.jp/data/000100515.pdf. Refer to Appendix-D for the English translation of this Japanese guidance.

In addition, the approval timing of piggy-back registration is shortened to less than half of the original registration approval lead-time.

9.2.3 Confidential Business Information (CBI)

The protection of CBI is a process that allows certain information not to be disclosed by the manufacturer or supplier of chemicals to their client. It also provides a certain competitive advantage and have some commercial value. A mechanism should be developed to warrant the protection of information as they are shared to the regulators such as composition of CBI or who may have the access to the confidential listing of a chemical with the competent authority to determine if there is a need for further chemical notification. For example, US allows bona fide enquiry for a substance listed on confidential portion of the inventory. Below are useful references in implementing the CBI:

a. https://www.law.cornell.edu/cfr/text/40/720.25.

b. US TSCA's inventory and process of inquiry to the confidential inventory https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory

c. https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol31/pdf/CFR-2011-title40-vol31-sec720-25.pdf

Per 40 CFR 720.25(b)(6), if during the inquiry process a chemical substance is found on the confidential inventory, US EPA will notify the original notifier. If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical

substance that another person has demonstrated a bona fide intent to manufacture or import the substance and therefore was told that the chemical substance is on the Inventory – 40 CFR 720.25(b)(6)

On the other hand, under Australia's Industrial Chemical Law 2019, importers may apply online to check if the chemical is listed on the inventory due to confidentiality. If the chemical is on the Inventory, the chemical can be introduced into Australia without notifying AICIS, provided that the company is registered with AICIS and the introducer complies with any conditions and obligations (set out in the chemical's terms of listing). More information can be accessed from https://www.industrialchemicals.gov.au/chemical-information/i-cant-find-my-chemical-inventory/apply-search-confidentially-listed-chemicals-inventory.

In addition to South Korea's implementation of CBI, KE Numbers can be used to mask confidential submissions. Once approval is obtained, a KE No. is assigned, a generic chemical name is shown, and the CAS No. will not appear publicly. The KE No. can then be shared with downstream users as proof of inventory listing and the downstream user can search the KE No. on NIER's website. More information is available from https://kreach.me.go.kr/repwrt/index.do.

9.2.4 Impurities

Varying policies and regulations including differences in definitions on impurities may also pose challenges on the Notifiers. In some jurisdictions, impurities are still required to be notified while some do not. In the US for example, no registration is required if the substance is an impurity in a product and the impurity substance must not provide any commercial advantage or benefit to the formulation or product. More information is available from Section 5 of TSCA, which requires anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose to provide EPA with notice before initiating the activity. https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-sec710-4.pdf

Similarly, Australia's implementation of impurities does not require categorization and registration if it conforms with the definition of an impurity. Under the AICIS, an impurity is an ***"****incidentally introduced chemical"* and it is defined as *"A chemical by product or impurity that remains in a mixture with an industrial chemical as a result of manufacture, offering no commercial value separate from that industrial chemical, and being uneconomical to remove as part of manufacture or before importation of that industrial chemical*". [Reference link: Introductions that don't require categorization and registration | Australian Industrial Chemicals Introduction Scheme (AICIS)]: https://www.industrialchemicals.gov.au/business/getting-started-registration-importing-and-manufacturing/introductions-dont-require-categorisation-and-registration

Under the EU REACH, impurities are defined as *"all the unintentional constituents coming from the manufacturing process or from the starting material(s). These could be the result of secondary or incomplete reactions occurring during the production and are present in the final substance even if not sought by the manufacturer".* [Reference link: Global document template (europa.eu)]: https://www.echa.europa.eu/documents/10162/983772/bpd_guid_tnsg-technical-equivalence_en.pdf/ed4cdf86-7ce1-47f6-9335-14c65bb271c6

In Canada, no registration is required if the substance is an impurity in a product. Impurities and contaminants are substances that are normally found in minimal concentration in the starting materials or are the result of secondary reactions that occur during the manufacturing process. These substances and partially unreacted starting materials that are present in the final product are the direct result of the preparation; are not necessary to the end use of the product; have not been intentionally added to the substance; and do not enhance the value of the substance. Refer to Section 3.2.6 of Guidance document for the *New Substances Notification Regulations: https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/chemicals-polymers/guidance.html#toc43*

Impurities which are regarded as by-products are also exempted from PMPIN / listing in PICCS in the Philippines under the EMB's Orientation Manual.

9.2.5 Only Representative (OR) Model or Similar Practice

An Only Representative (OR) according to Article 8 of the REACH regulation 1907/2006 is a "natural or legal person established outside the community who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported in the Community to fulfill, as his only representative, the obligations on importers under this Title". In other words, the OR performs compliance tasks on behalf of the overseas manufacturer.

EU, South Korea, and other jurisdictions have an Only Representative (OR) system in place for overseas manufacturers. EU and South Korea's systems are very similar. The EU Guideline of Only Representative can cover multiple importers. Therefore, all the EU importers covered in the OR registration do not need to file their own separate registrations. For proper guidance on the work of the OR in the EU, information can be accessed through https://echa.europa.eu/support/getting-started/only-representative while for South Korea, the link is Article 38 of Korea's Act on Registration, Evaluation, etc. of Chemicals (AREC): ACT ON REGISTRATION AND EVALUATION OF CHEMICAL SUBSTANCES.

Furthermore, Australia allows registration by foreign companies via an agent. The appointed agent is considered the introducer (as importer of the chemical) and the foreign companies as the chemical data provider. Chemical data providers do not need to register with the authorities, but they do need to have an account with AICIS Business Services to submit the data directly. This is one of the concepts that the chemical industry has promoted for a while to Philippines EMB, and this would also remove the need to make multiple applications for different importers. More information can be accessed through: https://www.industrialchemicals.gov.au/foreign%20companies.

9.3 Digital Solution for Post Notification Declarations and Reports

A digital solution for post-notification declarations and reporting is very useful for the transmission of information from the notifier to the relevant multiple authorities. That prevents repetitive action on validating data. One example is the Philippines EMB Online Permitting and Monitoring System (OPMS). There is a "My Importation" section in the OPMS that allows users to facilitate the submission of importation-related documents only for chemical substances that have already been notified to the OPMS. This convenient feature allows notifiers to upload the required files. A NOC must also be submitted to the EMB through OPMS for the notified chemical substance. Most chemicals after the successful NOC process are listed in PICCS in a span of 1 year or until the issuance of a circular or administrative order. Such integration streamlines regulatory processes and coordination between government agencies

9.4 Communication after Notification Submission

Transparency in the review and approval process should also be maintained. Communication should be timely to provide the update on the application status of the new substance notification application to the Notifier. This may be done through emails, SMS or any communication applications of the regulatory agency. The OPMS of the Philippines EMB, for example, has a self-checking feature that allows the Notifier or authorized person to access the application and track the status of the application. Authorized persons are provided with the required username and password.

9.5 Other NSN Functions

Chemical databases are useful references for Notifiers about the hazards or risk posed by a chemical substance. Some of these are readily available through their respective websites. On

the other hand, some databases will require registration for user verification. Below is a list of international databases:

a) AICIS - Several guidelines included international assessment is available on the AICS website
   - https://www.industrialchemicals.gov.au/help-and-guides/guide-categorising-internationally-assessed-introductions

b) European Chemicals Agency (information about chemicals in Europe)
   - https://echa.europa.eu/information-on-chemicals

c) United States Environment Protection Agency Aggregated Computational Toxicology Resource
   - https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=209598&Lab=NCCT

d) Common Chemistry (from Chemical Abstracts Service) introductions
   - Link: https://www.cas.org/about/cas-history

e) eChemPortal – OECD database for information on properties of chemicals
   - https://www.echemportal.org/echemportal/

Other databases also offer results of hazard evaluations, GHS classification or risk assessment about a chemical substance. Following are few examples:

a) AICIS - User can search the assessment or evaluation by CAS number for Chemical Information
   - Link: https://www.industrialchemicals.gov.au/chemical-information.

b) ECHA - User can search and see Overall progress, Dossier evaluation and Substance evaluation on website.
   - Link: https://echa.europa.eu/progress-in-substance-evaluation.

c) ASEAN-Japan Chemical Safety Database. The ASEAN – Japan Chemical Safety Database (AJCSD) is developed by ASEAN countries and Japan under AMEICC Working Group on Chemical Industry which consists of representatives from ASEAN countries and JAPAN. The AJCSD is a free database and includes chemical regulatory information, GHS classification results, risk and hazard information, etc. The purpose of AJCSD is to enhance transparency and to reduce compliance risk on chemical safety among those countries.
   - Link: https://www.ajcsd.org/chrip_search/html/AjcsdTop.html

Appendices

Appendix-A: ASEAN Guidance Document on Developing a Chemical Inventory

(Final) Chemical Inventory Working [

Appendix-B: Philippines Notice of Commencement (NoC)

PH_NOC

Appendix-C: China Post-Registration Obligations

CH_RGN_Obligations

Appendix-D: Google English Translation of “Notification of new chemical substances based on the Japan Chemical Substances Control Law”

JP_CCL_Notification

Appendix-E: ARCP CRA guidance document (draft final)

DraftFinal ARCP VWG CRA guidance docum