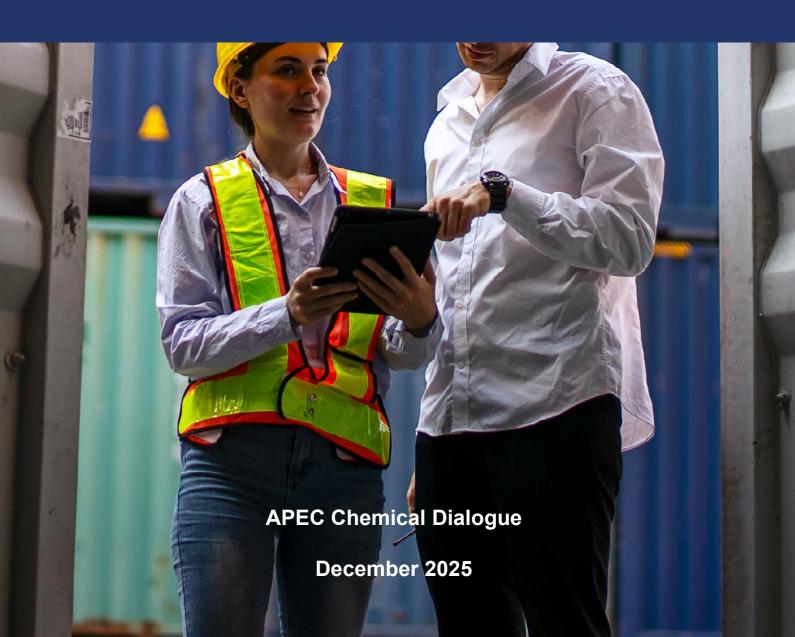


Best Practices:

Effective Management of Confidential Business Information (CBI)
During Inwards Customs Clearance





Best Practices: Effective Management of Confidential Business Information (CBI) During Inwards Customs Clearance

APEC Chemical Dialogue

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Asia-Pacific Economic Cooperation Secretariat

35 Heng Mui Keng Terrace

Singapore 119616

Tel: (65) 68919 600 Fax: (65) 68919 690

Email: info@apec.org
Website: www.apec.org

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1. Executive Summary

APEC economies are increasingly requesting detailed chemical compositional information during the inward goods clearance process. These requests, often targeting Confidential Business Information (CBI), may lack a formal regulatory framework, leading to considerable variability in their nature and scope amongst different economies.

The requested information often includes:

- 100% chemical compositional information for chemicals, materials, formulations and mixtures
- Requests for specific chemical identity, including identification by the chemical abstracts services (CAS) number

However, specific chemical identity and/or the percentage of a substance in a composition are recognized as trade secrets – a category of Confidential Business Information (CBI). CBI and trade secret information do not appear on Safety Data Sheets (SDS), which are public documents accompanying a chemical to provide specific categories of health and safety information and hazard communication. Trade secrets and CBI are competitively valuable property that can lose protection if they become public.

When a chemical identity is recognized as CBI, companies often develop a generic name for the substance that can be disclosed. In APEC, Australia; Canada; China; Korea; Malaysia; Chinese Taipei; and the United States have published guidance on how to develop a generic name. Genericizing typically starts with the CAS or International Union of Pure and Applied Chemistry (IUPAC) name for the substance, then masking some of the following identifiers as appropriate: parent structure; locant of chemical group; multiplicative prefix of a chemical group; identity of a chemical group; identity and number of counter ions.

If it is necessary to disclose CBI to a regulator, there are multiple mechanisms and procedures available to protect the safety and security of the information from inadvertent disclosure, theft, or IT systems breach. Regulators that come into possession of CBI may have strict internal procedures for control purposes, including marked or segregated filing systems, stamping or labelling to mark the CBI, and limiting the number and type of government staff who can handle the information. In some jurisdictions, if the regulator improperly discloses CBI, the company that submitted it may have legal recourse, including the ability to recover damages.

This document aims to outline best practices for managing Confidential Business Information (CBI) effectively and ensure the proper and successful use of Safety Data Sheets (SDS) at the border, mitigating the negative impacts on trade and business confidentiality arising from SDS disclosure requirements in APEC economies, and reducing potential non-tariff trade barriers in the region. The practices reflect the views expressed at the workshop. These practices have not received approval from all economies and should not be considered to reflect consensus among all APEC economies.

The resources from this document include knowledge gained during an in-person workshop on the margins of the 34th Chemical Dialogue in February 2025 and additional feedback from APEC economies regarding their CBI and SDS rules and regulations.

2. Introduction: What is Confidential Business Information and Why Does it Matter?

Confidential Business Information (CBI) is a broad category of property rights that includes information that may provide a business with a competitive advantage. Trade secrets are a subset of CBI. Trade secrets and CBI generally have either current or future economic value; are not generally known or reasonably ascertainable by others; and are managed with reasonable efforts to keep them secret.

Property rights are recognized globally - including intellectual property rights - like trade secrets or CBI. Members of the World Trade Organization (WTO) are also bound by Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Article 39.2 requires undisclosed information, which includes trade secrets and know-how, to benefit from protection. The protection applies to information that is secret, that has commercial value because it is secret and is subject to reasonable efforts to keep it secret. APEC's Joint Statement on the WTO/ TRIPS agreement observed that all APEC member economies recognize the role of the TRIPS agreement "based on the understanding that the extension of adequate protection to intellectual property rights contributes to the economic development of the APEC member economies as well as to the promotion of sound trade and investment in the APEC Region".

Economies have different definitions and regulations for CBI. Australia; Canada; China; Korea; Singapore; the United States; and Viet Nam have specific criteria and processes for protecting CBI, including the type of information considered confidential and the requirements for maintaining its secrecy. It should be noted that CBI, and rules for withholding CBI, may exist under both environmental and health regulations and separate worker protection/hazard communication regulations that govern SDS. This is the case in the United States, for example, where the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard allows a company to claim a trade secret for a chemical name, other specific identification of a hazardous chemical, or the concentration of substances in a mixture. The worker protection agency's rules govern what goes into the SDS, not separate environmental and health rules administered by other agencies.

Because each economy's definition of CBI is different, industry must clearly understand the following criteria for each economy when entering a new market:

- what information can be claimed as confidential,
- whether protection is automatic for some information; whether companies must affirmatively assert CBI; or whether companies must affirmatively approach a regulator to apply for protection,
- whether (and how) confidentiality claims must be substantiated and approved by the authority,
- · application fees, and
- how long protection will be in effect.

Safeguarding CBI at the border is vital for protecting proprietary information from unauthorized disclosure and protecting companies from harm when doing business across borders. Unauthorized exposure of CBI at the border could result in intellectual property theft, noncompliance with international trade laws, reduced investment in new markets, and in some cases, illicit technology transfer or espionage.

3. Policies and Procedures for Submission of CBI to Governments

There are both international standards and domestic standards for managing and protecting confidential business information. This section identifies the standards economies should be aware of regarding submission of CBI to governments.

International Standards and Agreements

The Globally Harmonized System of Classification and Labelling of Chemicals ("GHS Rev. 10, 2023" or "GHS") provides general recommendations for economies to consider what provisions may be appropriate for the protection of CBI. The document notes that "such provisions should not compromise the health and safety of workers or consumers, or the protection of the environment."

A key GHS principle is that CBI may be claimed for specific chemical identity (chemical name or CAS or IUPAC descriptor) and concentrations in mixtures. While provisions for the protection of CBI may differ amongst economies, GHS provides the following general principles:

- For information otherwise required on labels or SDS, CBI claims should be limited to the names of substances, and their concentrations in mixtures. All other information should be disclosed on the label and/or the SDS, as required.
- Where CBI has been withheld, the label or SDS should indicate.
- CBI should be disclosed to the competent authority upon request. The competent authority should protect the confidentiality of the information in accordance with the applicable law and practice.
- Where a medical professional determines that a medical emergency exists due to exposure
 to a hazardous substance or mixture, mechanisms should be in place to promote timely
 disclosure by the supplier or employer or component authority of any specific confidential
 information necessary for treatment. The medical professional should maintain the
 confidentiality of the information.
- For non-emergency situations, the supplier or employer should allow disclosure of confidential
 information to a safety or health professional to the extent necessary to provide medical or
 other safety and health services to exposed workers or consumers, and to workers or
 representatives. People requesting the information should provide specific reasons for the
 disclosure and should agree to use the information only for the purpose of consumer or worker
 protection, and to otherwise maintain its confidentiality.
- Where non-disclosure of confidential business information is challenged, the competent authority should address such challenges or provide for an alternative process for challenges.
 The supplier or employer should be responsible for supporting the assertion that the withheld information qualifies for CBI protection.

To better understand APEC economies' domestic regulations as it relates to CBI chemical management, the APEC Chemical Dialogue conducted a survey to gather more data and better understand current laws and regulations in the Asia-Pacific, current challenges, and potential opportunities for action. 10 economies (including a total of 17 respondents) answered the APEC Chemical Dialogue survey. All respondents indicated they follow GHS guidelines as they relate to SDS. A small handful of respondents indicated that in addition to GHS guidelines, they may also "include specific requirements developed under [their] own legislation."

Domestic Regulations

Each economy may have one or more agencies responsible for implementing regulations that impact CBI and SDS during inwards customs clearance.

The APEC Chemical Dialogue Survey (identified above) requested economies to identify domestic regulations as they relate to chemical importation. The survey responses are below for reference and for future discussion.

	AICIS: Industrial Chemicals Act 2019 (section 113)	
Australia	Model WHS laws: Model Work Health and Safey Regulation (SDS requirements outlined in schedule 8)	
	Decree of the Head of the National Standardization Agency No. 682/KEP/BSN/12/2021	
Indonesia	MOI Director General Regulation No. 4 Year 2014 – The Technical and Monitoring Guidance on the Implementation of GHS on Classification and Labelling of Chemicals	
Malaysia	Customs Act 1967	
Walaysia	Classification, Labelling Safety Sheets Regulation 2013	
Mexico	Chemical Product Inventory: General Law for the Prevention and Comprehensive Management of Waste and the Law of Chemical Substances	
	The Federal Commission for Protection against Health Risks (COFEPRIS) Regulations (Art. 245 General law for health, Regulation 4 General Health Law Control of Chemical Precursors)	
	Registro de productos: Las Normas Oficiales Mexicanas (NOMs), como la NOM-018-STPS-2015 sobre la comunicación de peligros y riesgos por sustancias químicas peligrosas y Ley aduanera y sus reglamentos (capítulo II)	
The Philippin	nes RA 6969 of the Environmental Management Bureau (EMB) (for industrial chemicals)	
Russia	Unified List of Products (Goods) Subject to State Sanitary and Epidemiological Supervision (Control) at the Customs Border and Customs Territory of the Eurasian Economic Union, approved by the Decision of the Customs Union Commission dated May 28, 2010, No. 299. 2)	
	Federal Law "On Information, Information Technologies, and on Information Protection" of July 27, 2006, No. 149-FZ. 3) Federal Law No. 98-FZ "On Commercial Secrets" of July 29, 2004 (as amended on August 8, 2024).	
Singapore	Singapore Standard SS586 : 2022 Part 2 and 3 for GHS SDS, classification, Labelling and training requirement SS 586: 2022 Part 3 Annex A	
	Trade secrets are protected under common law in Singapore. This means that businesses can take legal action against individuals or entities that unlawfully disclose or misuse their confidential information.	
Thailand	Department of Industrial Works Chemical Consultation under Hazardous Substances Act. The consultation result of a restricted product shall be used for product registration and permit licens	
United	Toxic Substances Control Act (TSCA)¹	
States	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	
	OSHA Hazard Communication Standard	
Viet Nam	DECREE No. 113/2017/ND-CP Detailing and guiding the implementation of a number of articles of the Law on Chemicals (Article 25. Chemicals must be declared; Article 29.	
	Confidential information)	

¹ Under TSCA importers must certify that imported chemicals either comply with TSCA (positive certification) or, if not otherwise clearly identified as a chemical excluded from TSCA, are not subject to TSCA (negative certification). A certification must be signed and filed electronically or in writing with U.S. Customs and Border Protection (CBP) by the importer or an authorized agent of the importer. A certification must also include the certifier's name, carrier to the importer of the importance of the importer of the importer of the importer of the importance of the impo

CBI Protection Policies and Procedures

The chemical industry identified that when multiple agencies manage domestic regulations as they relate to chemical importation, it can cause challenges when protecting CBI.

To better understand the methods that economies use to protect CBI, the APEC Chemical Dialogue Survey identified relevant CBI protection policies/procedures within economies during the customs clearance process. APEC economies provided the following feedback (please also see Figure 1):

- 29% of respondents said protection procedures included "information that relates to the composition of the chemical substance being imported, including complete composition data".
- 26% of respondents said protection procedures included "the authority (or authorities) requires the importer to provide information".
- 14% of respondents said protection procedures included "the authority (or authorities) requiring the CBI information be provided by email/online portal".
- 11% of respondents said protection procedures included "the authority (or authorities) allowing overseas suppliers/foreign manufacturers to provide information directly".
- 11% of respondents responded "other" to additional policy/procedures.
- 9% respondents said protection procedures included "the authority (or authorities) allowing overseas suppliers/foreign manufacturers to self-certify."

When asked how often economies update their Standard Operating Procedures (SOPs) for CBI management, only 2 out of the 17 respondents noted that SOPs were updated on an annual basis. All other respondents did not know how often SOPs were updated, or noted they were not updated on a regular basis. This gap may be worth exploring in future capacity building projects within APEC.

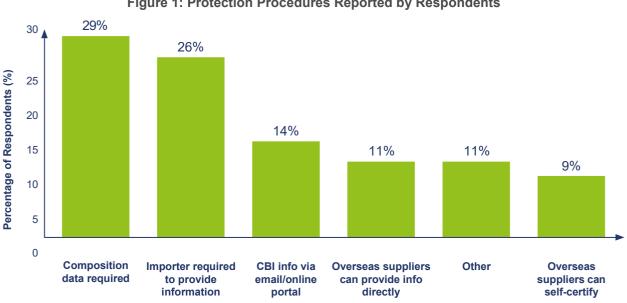


Figure 1: Protection Procedures Reported by Respondents

3. Policies and Procedures for Submission of CBI to Governments

Case Study:

Malaysia

Within the Malaysian economy, CBI is one of the provisions under the CLASS Regulations of 2013. It is a principle where information about a product is protected by intellectual property rights and cannot be accessed by competitors.

Upon request, CBI can be disclosed by the manufacturer or importer to the Director General of The Department of Occupational Safety and Health (DOSH), an Occupational Health Doctor, or any person who uses or handles the imported hazardous chemical. These types of requests for information are made in writing and the information is only used for the health and safety of individuals/employees.

For information otherwise required on chemical inventory or SDSs, CBI claims should be limited to the names of chemicals, and their concentrations in mixtures. All other information should be disclosed in the inventory and SDS, as required; and where CBI has been withheld, the inventory or SDS shall indicate the same. CBI should be disclosed to the Director General of DOSH upon request. The confidentiality of the information received is protected under Sec 67 of OSHA 1994.

4. Purpose of Safety Data Sheets (SDS) under GHS

A Safety Data Sheet (SDS) is a crucial document for hazard communication - identified under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). As described here, it should be noted that the primary purpose of the SDS is not to facilitate border and customs flows; its primary purpose is to inform its audience of the hazards of a substance or mixture and provide information on the safe storage, handling, and disposal of a substance or mixture. The SDS uses a standardized format of 16 sections to provide extensive information on a substance or a mixture, its supplier, and the safe use, handling, storage, transportation, and disposal of such substance or mixture, thereby minimizing risks to human health and the environment by clearly outlining hazard classifications, precautionary measures, protective equipment requirements, and emergency response procedures.

Some key uses of SDS include:

Hazard Identification: SDS list the potential hazards associated with a substance, including health, fire, reactivity, and environmental risks.

Safe Handling Instructions: SDS provide guidelines on how to safely handle, store, and dispose of chemicals to prevent accidents and injuries.

Emergency Procedures: In case of an accident, SDS offer first aid measures, firefighting instructions, and spill response procedures.

Personal Protective Equipment (PPE): SDS specify the necessary PPE to protect workers from exposure to hazardous substances.

Regulatory Compliance: SDS help companies comply with occupational safety and health regulations by providing essential safety information.

The SDS is ultimately designed to communicate hazard related information about a chemical substance or mixture and how to mitigate any issues with handling or storage. According to the UN GHS Purple Book (which provides GHS hazard classification and communication provisions, ensuring the safe use of chemicals throughout their product life), the SDS should be written with the workplace audience in mind. However, it should be considered that all or part of the SDS can be used to inform workers, employers, health and safety professionals, emergency personnel, relevant government agencies, and members of the community.

Key Sections of a Safety Data Sheet

Below are some key sections of safety data sheets for APEC economies' review and reference. More information on the SDS can be found in Appendix 4 of the GHS Purple Book.

Section 1: Identification

Section 1 of an SDS is to ensure that users can quickly identify the product and know who to contact for additional information or in case of an emergency. Details in this section include:

• Product Identifier: The name of the product as it appears on the label, including any synonyms or trade names.

- Manufacturer or Distributor Information: The name, address, phone number, and emergency contact information for the manufacturer or supplier of the product.
- Recommended Use: The intended use of the chemical, such as industrial, laboratory, or consumer use.
- Restrictions on Use: Any specific uses that are not recommended or are restricted.
- Emergency phone number: Any reference to emergency information services, including hours of operation.

Section 2: Hazard(s) Identification

This section allows the handler/user to understand the primary hazards associated with a substance or a mixture and the necessary precautions to take.

Hazard identification includes:

Classification of the Substance or Mixture: This section details the hazard classification according to GHS. It should include any appropriate hazard class and category/subcategory. For example: Flammable liquid – Category 1.

Label Flements:

- Signal Word: A word used to indicate the relative level of severity of the hazard (e.g., Danger or Warning)
- Hazard Statements: Phrases that describe the nature and degree of the hazard (e.g., "Causes skin irritation")
- Precautionary Statements: Recommendations on how to minimize or prevent adverse effects from exposure (e.g., "Wear protective gloves")
- Pictograms: Symbols that visually represent the hazards (e.g., a flame for flammability)
- Other Hazards: Information on any other hazards that do not result in classification but may contribute to the overall risk, such as dust explosion hazards or environmental effects

Section 3: Composition/Information on Ingredients

This section identifies the specific chemicals present in a product and their potential hazards.

Composition on ingredients include:

- Substances: If the product is a single substance, this part will list:
 - o Chemical Name: The systematic name of the substance
 - o Common Name and Synonyms: Any other name the substance is known by
 - o CAS Number: The unique numerical identifier assigned to the substance by the Chemical Abstracts Service (CAS)
 - o Impurities and Stabilizing Additives: Any impurities or additives that contribute to the hazard classification of the substance

- 4. Purpose of Safety Data Sheets (SDS) under GHS
- Mixtures: If the product is a mixture, this part will list:
 - o Chemical Names of Hazardous Ingredients: The names of all ingredients in the mixture that are hazardous to health or the environment under GHS and are present above their cut-off values.
 - o Concentration or Concentration Ranges: The percentage or range of each hazardous ingredient in the mixture
 - o CAS Numbers: The unique numerical identifiers for each hazardous ingredient

It is important to note that under GHS it is recognised that competent authorities may choose to adopt provisions for the protection of CBI. Under section 1.4.8 of the GHS, considerations on the protection of CBI for competent authorities are listed, and include:

- adoption of CBI definition
- adoption of appropriate procedures for the disclosure of CBI
- list of general principles to follow

As a result of these considerations, economies can implement CBI provisions that would allow, in specific cases, the use of generic names, or hide the CAS number of ingredients disclosed in section 3.

Case Study:

Australia's Section 3 of SDS

Australia has the following rules and procedures of Section 3 of SDS – or the composition of ingredients.

- Disclosure of ingredients on a SDS is governed by respective Jurisdictional Work Health and Safety Laws within the Australian economy.
- Disclosure of hazardous chemicals/ingredients on SDS is done to support appropriate risk management and emergency response.
- Australia has a discretionary approach to support commercial protections for ingredient disclosure:
 - o Lower hazardous classification, such as, Acute toxicity 4, can use generic names if commercially confidential.
 - o The proportion of ingredients can be applied in ranges if considered commercially confidential. No need for exact values to protect commercial interests.

The economy does not require 100% disclosure of all ingredients. Only chemicals that drive hazardous end points to support appropriate risk mitigation are required.

Table 1: Cut-off values/concentration limits for each health and environmental hazard class

Hazard class	Cut-off value/concentration limit	
Acute toxicity	≥1.0%	
Skin corrosion/Irritation	≥1.0%	
Serious eye damage/eye irritation	≥1.0%	
Respiratory/Skin sensitization	≥0.1%	
Germ cell mutagenicity (Category 1)	≥0.1%	
Germ cell mutagenicity (Category 2)	≥1.0%	
Carcinogenicity	≥0.1%	
Reproductive toxicity	≥0.1%	
Specific target organ toxicity (single exposure)	≥1.0%	
Specific target organ toxicity (repeated exposure)	≥1.0%	
Aspiration hazard (Category 1)	≥1.0%	
Aspiration hazard (Category 2)	≥1.0%	
Hazardous to the aquatic environment	≥1.0%	

For more information, please visit <u>Safe Work Australia's Code of Practice</u>

4. Purpose of Safety Data Sheets (SDS) under GHS

Section 15: Regulatory Information

This section provides information about the specific regulatory requirements related to a chemical product. This section provides information on all regulatory obligations and how to comply with relevant safety, health, and environmental laws.

Regulatory information in Section 15 includes:

- Safety, Health, and Environmental Regulations/Legislation Specific for the Substance or Mixture. This includes any relevant domestic or international regulations that apply to the chemical, like:
 - o Regulations on substances that deplete the ozone layer.
 - o Requirements for substances that need authorization before use (e.g., REACH Annex XIV).
 - o Restrictions on certain substances (e.g., REACH Annex XVII).
 - o Compliance with directives such as the Chemical Agents Directive (98/24/EC) or the Detergents Regulation (EC No. 648/2004).
- Chemical Safety Assessments: Indicates whether a chemical safety assessment has been conducted for the substance or mixture.

Key Takeaway

SDS is the primary hazard communication tool for a substance or mixture at the border. It informs users or emergency responders about the hazards associated with the use, handling, transport, and disposal of chemicals. For this reason, only hazardous ingredients that present above a certain threshold (cut-off value) should be listed in the composition.

Key Guidelines and Practices: Components of CBI

- General Principles: According to the UN GHS guidelines, CBI claims related to SDS should be limited to the names of substances and their concentrations in mixtures. When CBI is withheld, the SDS and label must indicate this, and the information should be disclosed to competent authorities upon request.
- 2. General Names: Allow the use of generic chemical names.
- 3. Concentration Ranges: Instead of disclosing exact concentrations, companies can use prescribed concentration ranges. For example, in the United States, the Occupational Safety and Health Administration (OSHA) allows the use of specific concentration ranges (e.g., 1% to 5%, 5% to 10%) to protect CBI while still providing necessary hazard information.
- 4. Regulatory Compliance: Different regions have specific requirements for CBI protection. For instance, in the United States, the Hazard Communication Standard (HCS) allows for trade secret claims without prior approval from OSHA, but companies must be prepared to justify these claims if requested.
- 5. Indicating CBI: When CBI is withheld, the SDS should clearly state that certain information is being withheld as a trade secret. This provides transparency while protecting proprietary information.

5. Identifying Common Challenges to Submission of CBI

Challenge: Disclosing CAS numbers

A CAS number, or Chemical Abstracts Service number, is a unique numerical identifier assigned to every chemical substance described in open scientific literature. It is used to provide a standardized way of identifying chemicals.

- Format: A CAS number is typically formatted as a string of numbers divided into three parts by hyphens, such as 123-45-6.
- Purpose: It helps in the precise identification of chemicals, avoiding confusion that might arise from different names or synonyms for the same substance.
- Usage: CAS numbers are widely used in databases, regulatory documents, and safety data sheets (SDS) to provide clear and consistent communication about chemical substances.

Examples of CAS numbers are below:

- 1. Water (H₂O) CAS Number: 7732-18-5; Uses: Essential for life, used in drinking, cooking, cleaning, industrial processes, and as a solvent.
- 2. Benzene (C₆H₆) CAS Number: 71-43-2; Uses: Used as a precursor in the production of plastics, resins, synthetic fibers, and as a solvent.

Common concerns include:

- Trade Secrets: Companies may be reluctant to disclose CAS numbers because they can reveal proprietary formulations or ingredients that are considered trade secrets. This can be a significant concern in competitive industries.
- Regulatory Compliance: Different regulations may have varying requirements for disclosure. For example, the REACH regulation in the EU requires detailed information about chemical substances, including CAS numbers, which can be challenging if suppliers are unwilling to share this information.
- Confidential Business Information (CBI): Companies often need to balance the need for transparency with the protection of confidential business information. Disclosing CAS numbers can sometimes compromise this balance.
- Supplier Cooperation: Obtaining CAS numbers from suppliers can be difficult, especially if they are in regions with different regulatory requirements or if they are concerned about business confidentiality.
- Consumer Trust: On the other hand, not disclosing CAS numbers can lead to a lack of trust among consumers and stakeholders who demand greater transparency about the chemicals used in products.

Challenge: Disclosure of Ingredients

Requesting the 100% disclosure of ingredients of a substance or mixture at the border can lead to the following challenges within the chemicals sector:

- Providing full disclosure of ingredients is difficult, as it can involve multiple suppliers within a product. The introducer may not have all the chemical details.
- Companies invest significant capital in R&D to gain a competitive advantage. Disclosure
 of confidential information can result in a loss to their investment, which can create supply
 chain hesitancy.
- Poor governance on chemical management by economies can lead to older chemistries entering the market and missing on newer technologies.

These challenges can be addressed by balanced and well-considered laws that provide an effective pathway to avoid the need for product disclosure.

Challenge: Personnel Changes

Even if an economy has a clear policy on CBI management or has a robust mechanism to monitor CBI, personnel changes at customs can create challenges, including:

- Loss of Institutional Knowledge: When experienced employees leave, they take with them an understanding of what information is sensitive; how it should be handled; and who is authorized to access it. Additionally, new or temporary personnel may not yet be fully trained in these protocols, increasing the risk of accidental disclosure.
- Inadequate Training or Onboarding: New hires or reassigned staff may not be fully briefed on data protection policies; cross-border data handling procedures; legal and regulatory requirements (e.g., export controls, data localization laws). This can lead to mishandling confidential documents or digital data during inspections or transfers.
- Increased Insider Threat Risk: Departing employees, especially those leaving under negative circumstances, may pose a risk of taking confidential data with them and sharing sensitive information with competitors or foreign entities. This is particularly concerning at borders where data may be more vulnerable to interception or inspection.
- Breakdown in Communication: Personnel changes can disrupt established communication channels, leading to misunderstandings about what information can be shared and delays in responding to border authorities, which may result in unnecessary disclosures.
- Compliance Gaps: Frequent turnover can lead to lapses in compliance with international trade regulations, customs documentation requirements; and data privacy laws (e.g., General Data Protection Regulation (GDPR), California Consumer Privacy Act (CCPA)).
 These gaps can expose the company to legal and financial risks.

Case Study:

CBI Challenges Identified by Malaysia

Confidential Business Information (CBI) protection safeguards trade secrets and preserves suppliers' competitive advantage in global markets. However, in chemical trade and customs enforcement context, misuse or overuse of CBI creates significant challenges with wide-ranging impacts. Malaysia has identified the following challenges, which affect not only regulatory enforcement but also influence trade efficiency, market integrity and domestic economic security.

- Inconsistent range used in SDS. Mostly affecting Sections 3 and 11: SDSs provided during inwards customs clearance often inconsistent composition and toxicological data, making it difficult for customs to determine whether the imported substance falls under hazardous chemical controls or prohibitions.
- Supplier misinterprets the use of CBI causing inaccurate SDS: When suppliers
 misunderstand or incorrectly apply of CBI provisions, SDSs may become
 inaccurate, leading to incorrect tariff code classification of goods under Harmonizes
 System under World Customs Organization (WCO). This can cause customs to
 release goods without applying necessary controls, or conversely, detain goods that
 are not actually regulated.
- Assessor unable to assess exact risk of hazardous chemicals during assessment:
 Without clear information, customs cannot determine the appropriate inspection level, increasing the risk of hazardous substance entering the economy undetected.
- No agency/bodies to monitor accuracy of CBI: Without a central verification authority, Customs rely solely on importer provided document, even the information is questionable.
- Cut and paste manipulation among importers: Some importer manipulate SDS by copying and pasting details to avoid restriction, resulting incorrect tariff code classification of goods and bypassing import controls
- Inaccuracy of determining hazard class will affect organizational/technical control to improve the workplace.
- When information on a chemical substance is claimed CBI, suppliers may not
 disclose any information at all: When information on a chemical substance is
 claimed as CBI, supplier may withhold all details, leaving customs officer with no
 clues about the actual substance being imported. This hinders risk assessment,
 detection of prohibited chemicals, or enforcement of special regulation.
- Suppliers accept SDS from exporting economies without validating the exact ingredients and hazard classification.

6. Recommendations

Participants in the February 2025 CBI workshop identified the following recommendations as "best practices."

1. Develop Strategies to Address Risks (e.g., Harmonizing Standards, Leveraging Technology)

The chemical sector operates globally, often facing inconsistent data protection standards across jurisdictions.

Harmonizing standards—such as through international agreements or industry standards—can reduce compliance complexity and improve data security. Leveraging digital technologies can also enhance traceability and secure data exchange across borders.

2 Implement Risk-Based Approach to CBI Management

Not all data carries the same level of sensitivity. A risk-based approach allows companies to allocate resources more effectively by prioritizing protection for high-value or high-risk information. This approach is aligned with cybersecurity frameworks like the U.S. National Institute of Standards and Technology Risk Management Framework, which emphasizes tailoring controls based on risk assessments.

3. Balance Transparency and Confidentiality Requirements

Chemical companies must comply with customs and regulatory disclosure requirements while protecting trade secrets. This balance can be achieved through:

- developing one CBI policy/rule (or a set of policies) that is applied to all government agencies (including customs) within an economy;
- creating one single electronic portal/database (with good safety and security protection) to keep all chemicals/ mixture information (including those classified as CBI). All authorized regulators (who require access to this database due to their role and responsibilities in the department) should be able to access same data -reducing the re-submission of the same data to different regulators;
- developing a standard procedure to cover CBI component disclosure;
- training and renewal of skills/training to all authorized regulators on the CBI disclosure procedure;
- creating standard procedures to share CBI disclosure policy & requirement procedures and relevant databases with all chemical suppliers, traders, distributors, manufacturers, and additional relevant stakeholders; and
- developing a channel to allow the chemical suppliers (owner of the CBI components) to provide the information directly to regulators within an economy.

Case Study:

The Philippines Polymers and Polymer of Low Concern Exemption from the PMPIN Process²

In 2019 the Department of Environment and Natural Resources issued an administrative order for <u>Polymers and Polymer of Low Concern (PLC) Exemption from the Pre-Manufacture and Pre-Importation Notification (PMPIN) Process.</u> For new polymers which are not listed in the Philippine Inventory of Chemicals & Chemical Substances (PICCS), their importers and manufacturers are exempted from PMPIN requirements if they meet certain conditions. This approach enhances transparency in compliance procedures for suppliers.

4. Encourage Self-Notification Practices

Encouraging companies to proactively provide the required information under international and/ or domestic policies generates trust and accountability. Proactive compliance and transparency can be components of a broader strategy for building a resilient customs clearance process.

Case Study:

Australia's Precursor Chemicals Management at Customs

Australia's precursor chemicals management process follows international Conventions - Single Convention on Narcotic Drugs from 1961- and supports a self-notifying process. Stakeholders must get permission from the Office of Drug Control to import or export controlled substances into or out of Australia. Information for this process is transparent and is based on clear chemical identifiers.

- Guides are available to support the process.
- Managed through Licenses and Permits. Does not require full disclosure.
- Seamless approach when information is transparent and supported by a wellfunctioning IT platform.
- Risk-based approach to compliance (Action taken with non-compliance is based on the intention).
- Monitoring programs in place: Inspections, close relationship with local law enforcement, etc.
- Process does not stifle trade and only impacts those that are regulated through a light-touch approach.

Case Study:

Korea's Self Declaration Letter

In February 2025 Korea's Ministry of Environment and Ministry of Justice announced the launch of a K-REACH "compliance grace period" in which non-compliant companies (manufacturer or Korean importer) may voluntarily declare past violations without threat of penalties. The goal of the self-declaration letter is to improve legal compliance with K-REACH registration obligations and encourage businesses to voluntarily correct past violations by offering temporary exemptions from penalties.

4. Support Public-Private Partnerships

Public-private partnerships foster trust and collaboration, enabling the development of balanced CBI policies that protect proprietary data while providing regulatory transparency. By combining industry expertise with governmental oversight, these partnerships can help create practical procedures that align with both commercial interests and public safety needs. They also facilitate the secure exchange of sensitive information across borders, supporting compliance and innovation in a globally connected regulatory environment.

Case Study:

Public-Private Partnership Mexico

The Integrated Customs Automated System (SAAI) was developed in collaboration with the private sector to modernize and digitize customs processes. In addition, the Single Window for Foreign Trade (VUCEM) digital platform was created in collaboration with technology companies, centralizing and simplifying customs procedures.

7. References and Further Reading

Australia Government Guide to Policy Impact Analysis [March 2023]

This Guide helps policy makers reflect on how policy can affect people, businesses and community as well as its broader economic and competition impacts.



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Produced by

APEC Chemical Dialogue

For

Asia-Pacific Economic Cooperation Secretariat

35 Heng Mui Keng Terrace

Singapore 119616

Tel: (65) 68919 600

Fax: (65) 68919 690

Email: info@apec.org

Website: www.apec.org

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