

# Global Chemical Disclosure Challenges and CBI

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# Outline

- Confidential business information (CBI) and trade secrets
- CBI in substance notifications/registrations
- CBI in hazard communication
- Beyond hazard communication to ingredient communication
- Management of global CBI requirements

# Confidential Business Information Defined

- Confidential business information (CBI) is a broad category that includes information that may confer a competitive advantage or involve personal information
- Examples:
  - Strategic plans
  - Manufacturing process information
  - Customer lists
  - Employee home addresses
  - Correspondence about legal advice

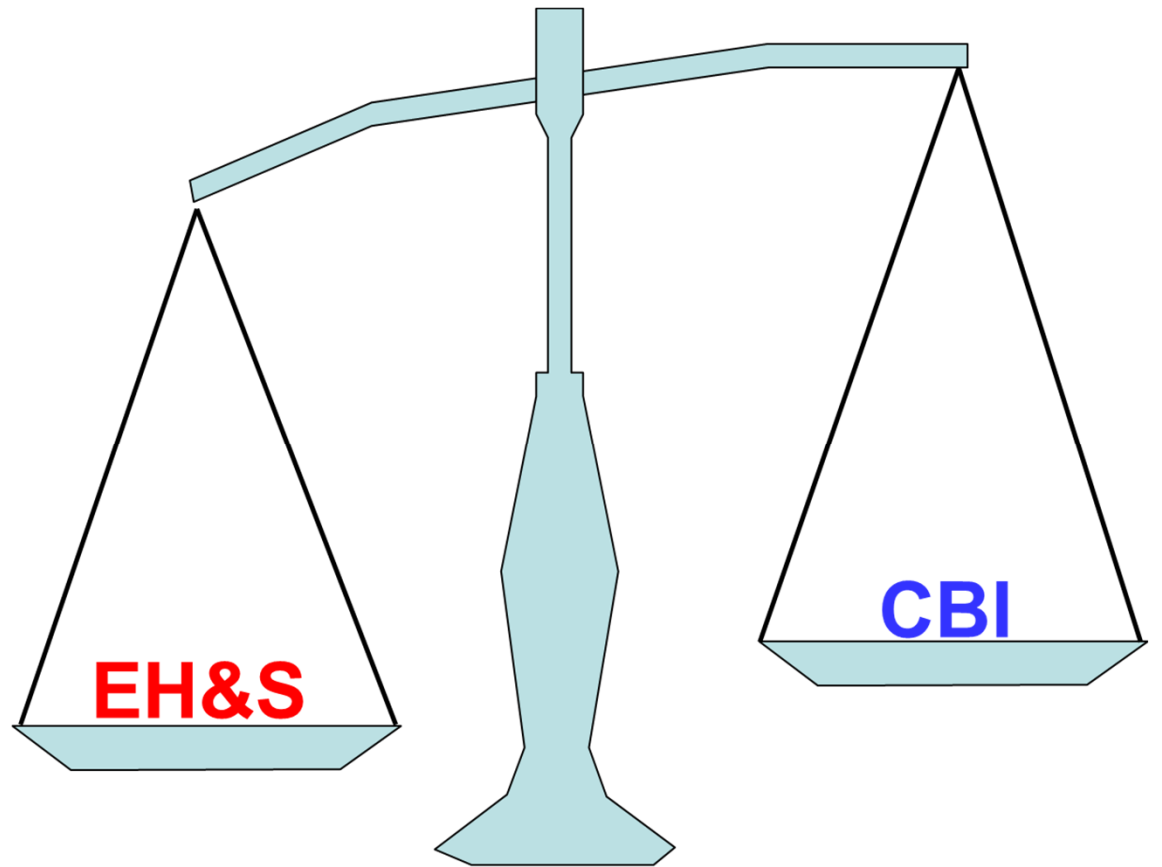
# Trade Secrets Defined

- Trade secrets are a subset of CBI
- In general, a trade secret:
  - Has current or future economic value;
  - Is not generally known or readily ascertainable by others; and
  - Is subject to reasonable efforts to keep it secret.

# Trade Secrets, Continued

- Trade secrets are often some of a company's most valuable assets
- Trade secrets can be valuable for a long time
- Trade secrets are legally protectable until they are no longer secret

# The Essential Balance



# Common Approaches in Global Regulations

- Required disclosure:
  - Lists or categories of substances that must be disclosed
  - Disclosure to first responders, health care professionals, etc.
  - Generic naming rules
  - Health and safety information
- Procedural requirements:
  - Asserting specific claims
  - Substantiation of claims
  - Approval of claims by a government authority
  - Expiration dates for CBI
- Greater publication of information



**U.S. FEDERAL  
REQUIREMENTS**

OSHA HCS TSCA  
FIFRA FHSA FFDCA

**PERMITTING AND  
ENVIRONMENTAL  
REPORTING  
REQUIREMENTS**

NPDES TRI  
GHG Reporting

**U.S. STATE  
REQUIREMENTS**

CA Prop 65 PA RTK  
NJTSRN CCPRTKA

**CUSTOMER AND  
INDUSTRY  
REQUIREMENTS**

**VOLUNTARY  
INITIATIVES**



...and then think global!

# CBI in Substance Notifications/Registrations

# Generic Naming of CBI Substances

- When chemical identity is CBI, need to develop disclosable “generic name”
  - Guidance published in United States, Canada, EU, China, Korea, and Taiwan
- In general, start with CAS or IUPAC name, and “mask” one or more of the following:
  - Parent structure
  - Locant of a chemical group
  - Multiplicative prefix of a chemical group
  - Identity of a chemical group
  - Identity and number of counter ions

## Generic name example – Substance with a well-defined structure

### *Fully Defined Name*

3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane

Single Masking	Acceptable Masked Name
Number of fluorine atoms	3-ethoxy- <u>polyfluoro</u> -2-( <u>polyfluoromethyl</u> )hexane
Fluorine atoms	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodeca <u>halo</u> -2-( <u>trihalomethyl</u> )hexane
Ethoxy group	3-( <u>alkoxy</u> )-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane
Hexane parent	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl) <u>alkane</u>

Double Masking	Acceptable Masked Name
Hexane parent (plus parent locants)	<u>Ethoxydodecafluoro(trifluoromethyl)alkane</u>

Generic name example – Substance without a well-defined structure

Specific chemical name: “*Zinc ores, concs., preleached*”

Appropriate generic names:

- “*ores, concs., preleached*” masks the identity of the zinc ores
- “*zinc ores, concs., modified*” masks that the zinc ores are preleached

## United States – Toxic Substances Control Act (TSCA)



- 2016 TSCA amendments significantly changed CBI requirements and processes
- “Three-bucket” approach to CBI
  1. Information not eligible for protection
  2. Information protected if claimed CBI
  3. Information protected if claimed CBI and substantiated
- EPA must review all CBI claims for chemical identity, and at least 25% of other CBI claims

# United States – Toxic Substances Control Act (TSCA)



- Excluded from protection:
  - General information
  - Information from health and safety studies, with limited exceptions
  - Information on Safety Data Sheets (SDSs) is treated as health and safety information
- Duration of protection:
  - Up to 10 years for substantiated claims
  - Can be renewed
- Fees:
  - None

# United States – Toxic Substances Control Act (TSCA)



- Specific CBI certification is required for all claims:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.



# United States – Toxic Substances Control Act (TSCA)



- EPA has a recommended substantiation template for new substance notifications:

<p>% in Formulation (Part I Section C.2.a.6)</p>	<input type="checkbox"/>	<p>Exempt – No substantiation required for this specific data element claim</p>
<p>% of Substance Expected Per Use (Part I Section C.2.a.8)</p>	<input type="checkbox"/>	<p>Exempt – No substantiation required for this specific data element claim</p>
<p><b>Part II Section A Industrial Sites Controlled by the Submitter</b></p>	<p><b>CBI Claim</b></p>	<p><b>Substantiation</b> <i>(Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position.)</i></p>
<p>Site Identity (Part II Section A.1.a) <i>Provide a detailed substantiation explaining how/why the release of this data element information will substantially harm your company.</i></p>	<input type="checkbox"/>	<p><b>Click or tap here to enter text.</b></p>

## United States – Toxic Substances Control Act (TSCA)



- Careful review and substantiation of CBI before submittal is critical
  - Information that is not claimed CBI is rapidly posted to the public ChemView database
  - EPA has discontinued a practice of sending “Notices of Deficiency” to submitters
  - “Notice of Determination” that a CBI claim has been denied results in disclosure within 30 days unless an injunction is obtained
  - Increased focus on addressing reverse engineering in substantiation, due to recent litigation
- Assignment of “unique identifiers” to link CBI information together

# European Union - REACH



- Uses the “three bucket” approach to CBI
- Excluded from protection:
  - Results from health and safety studies
  - Classification and labeling
  - Guidance on safe use
  - Chemical identity for phase-in substances classified as dangerous
  - Limited exceptions for R&D and intermediates

# European Union - REACH



- Duration of protection:
  - Indefinite for most CBI claims
  - 6 years for new substances classified as dangerous
  - No renewals
- Fees:
  - €114 – 4500, depending on information type, company size, and use of the substance

# Australia – Australian Industrial Chemicals Introduction Scheme (AICIS)



- Excluded from protection:
  - General uses
  - Precautions and restrictions on handling
  - Data on health and environmental effects
  - Degradation products for perfluorinated substances
- Substantiation required for all CBI claims
- Director weighs potential commercial harm against public interest

# Australia – Australian Industrial Chemicals Introduction Scheme (AICIS)



- Protection of CBI claims is granted on a case-by-case basis
- Examples of factors taken into consideration:
  - Has sufficient information been provided to demonstrate a potential commercial loss if the information is disclosed?
  - Is the substance publicly listed on other countries' inventories?
  - What are the hazards of and potential exposure to the substance?
  - Is enough information available to allow for tracking of the substance in the environment?

# Australia – Australian Industrial Chemicals Introduction Scheme (AICIS)



- Duration of protection:
  - 5 years for chemical identity, can be renewed
- Fees:
  - \$1,807 AUD for substance “proper name”
  - \$554 AUD for end use
  - \$1,063 for other CBI
  - \$4,587 for renewal of protection

# Japan – Chemical Substances Control Law (CSCL) and Industrial Safety and Health Law (ISHL)



- No confidential sections on these inventories
  - Categorical listings for some substances may protect chemical identity
- Duration of protection:
  - 5 years from notification to publication on CSCL inventory (ENCS/MITI/METI)
  - 1 year from notification to publication in ISHL



# Selected CBI Requirements in Other Countries

- Limitations for certain hazardous substances
  - China, South Korea
- Limitations on duration of protection
  - Canada, China, South Korea, Taiwan
- Fees
  - Canada
- Substantiation requirements
  - Canada, China, New Zealand, South Korea, Taiwan

# CBI in Hazard Communication

# United States – Hazard Communication Standard



- OSHA's Hazard Communication Standard allows specific chemical identity and/or the percentage of a substance in a composition to be withheld as a trade secret
- No government review or substantiation requirement
- Companies have a general duty to ensure that their CBI claims can be supported
- Proposed addition of prescribed concentration ranges for trade secret components

## Canada – Hazardous Materials Information Review Act (HMIRA)



- Companies must obtain approval from Health Canada to claim chemical identity of a hazardous ingredient CBI on an SDS
- Substantiation may be required, including the estimated value of a financial loss associated with disclosure or gain associated with protection
- If approved, the SDS must include the HMIRA Registry Number for the CBI claim

# South Korea – Occupational Safety and Health Act (K-OSHA)



- Companies must apply to the Ministry of Employment and Labor (MoEL) for CBI protection for hazardous substances on the SDS
  - Requirement took effect January 16, 2021, for new SDSs
  - Requirements are being phased in through 2026 for existing SDSs, based on tonnage band



- Review and approval process takes one month for most SDSs; 2 weeks for R&D SDSs

## South Korea – Occupational Safety and Health Act (K-OSHA)



- Application is not required for non-hazardous mixtures or materials that are regulated under certain other statutes, *e.g.*, the Medical Device Act
- CBI cannot be claimed for certain hazardous substances:
  - K-REACH toxic, restricted, prohibited substances
  - Carcinogens, mutagens, reproductive toxicants (CMRs) present at classification thresholds

# South Korea – Occupational Safety and Health Act (K-OSHA)



- Required information:
  - 100% disclosure to MoEL
  - Alternative names for CBI substances
  - Substantiation of CBI claims
  - Name of supplier
  - Use category
- Foreign companies can use an Only Representative

## South Korea – Occupational Safety and Health Act (K-OSHA)



- If approved, CBI substances must be listed with specific concentration ranges
  - $\pm 20\%$  if substance is present at 25% or more
  - $\pm 10\%$  if substance is present at  $<25\%$
- Protection from disclosure lasts for 5 years, may be renewed once



# Taiwan – Regulations for the Labeling and Hazard Communication of Hazardous Chemicals



- SDSs for toxic chemicals are also regulated by the Measures on the Management of Toxic Chemical Substances Labeling and Safety Data Sheets
- Companies must apply online to the Ministry of Labor (MOL) for trade secret protection
- Application must include substantiation of CBI claims and supporting documents for hazard classifications

# Taiwan – Regulations for the Labeling and Hazard Communication of Hazardous Chemicals



- Substances with the following hazard classifications are not eligible for protection:
  - Acute Toxicity, Categories 1, 2, or 3
  - Skin Corrosion/Irritation, Category 1
  - Serious Eye Damage/Eye Irritation, Category 1
  - Respiratory/Skin sensitization
  - Germ Cell Mutagenicity
  - Carcinogenicity
  - Reproductive Toxicity
  - Specific Target Organ Toxicity - Single Exposure, Category 1
  - Specific Target Organ Toxicity - Repeated Exposure, Category 1

# Beyond Hazard Communication to Ingredient Communication

# California Cleaning Product Right to Know Act of 2017



- Applies to:
  - Air care products
  - Automotive products
  - General cleaning products
  - Polish or floor maintenance products
  - Workplace products are included
- Does not apply to:
  - Foods, drugs, cosmetics
  - Industrial products manufactured for and exclusively used in certain industry sectors

# California Cleaning Product Right to Know Act of 2017



- On-website requirements (required starting January 1, 2020)
  - All intentionally-added ingredients in descending concentration; components present at <1% can be listed in any order
  - Non-functional components at 100 ppm, with certain exceptions
  - Fragrance ingredients on designated lists or present at 100 ppm
  - CAS Registry Numbers
  - Functional purpose of each ingredient
  - Links to designated lists
  - Link to product SDS

# California Cleaning Product Right to Know Act of 2017



- On-label requirements (required starting January 1, 2021)
  - All intentionally-added ingredients that appear on a designated list (no CBI, no concentration threshold)
  - Fragrance allergens
  - Link to additional information on website

OR

- All intentionally-added ingredients (limited CBI, no concentration threshold)
- “Contains fragrance allergens” statement, if applicable

# California Cleaning Product Right to Know Act of 2017



- CBI requirements
  - CBI not allowed for substances on “Chemical of Concern” list or designated nonfunctional ingredients
  - CBI substantiation is required
  - CBI substances must follow nomenclature protocols, e.g., aligning with generic name on the TSCA Inventory

# Customer Requirements

- Customers may have their own disclosure requirements for their suppliers
  - May facilitate their regulatory compliance or advancement of corporate initiatives
- There is an increasing focus on disclosure of chemical composition of article products



# Management of Global CBI Requirements

# Conclusion

- CBI requirements are present in many global regulations, and the requirements are growing increasingly complex
- CBI management requires a multidisciplinary approach
  - Laboratory: What is the information that holds trade secret value?
  - Regulatory and legal: What are the CBI requirements?
  - Business and supply chain: How do we obtain necessary information from suppliers? What information can be disclosed to end markets and customers?
- Prepare to defend CBI claims with robust substantiation

# Acronyms

- AICIS: Australian Industrial Chemicals Introduction Scheme
- CAS: Chemical Abstracts Service
- CBI: Confidential Business Information
- CCPRTKA: California Cleaning Product Right to Know Act
- CMR: Carcinogen, Mutagen, and/or Reproductive toxicant
- CSCL: Chemical Substances Control Law
- EH&S: Environment, Health, and Safety
- EU: European Union
- FFDCa: Federal Food, Drug, and Cosmetics Act
- FHSA: Federal Hazardous Substances Act
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- GHG: Greenhouse Gas

# Acronyms

- HCS: Hazard Communication Standard
- HMIRA: Hazardous Materials Information Review Act
- ISHL: Industrial Safety and Health Law
- IUPAC: International Union of Pure and Applied Chemistry
- MoEL: Ministry of Employment and Labor
- MOL: Ministry of Labor
- NJTSRN: New Jersey Trade Secret Registry Number
- NPDES: National Pollutant Discharge Elimination System
- OSHA: Occupational Health and Safety Administration/Act
- PA RTK: Pennsylvania Right to Know
- R&D: Research and Development
- TRI: Toxic Releases Inventory
- TSCA: Toxic Substances Control Act

Thank you!