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## **Society for Chemical Hazard Communications Spring Meeting**

**Protecting Trade Secrets Around the World**

**Part 1: Comparing CBI Requirements under New  
TSCA and OSHA HCS 2012**

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## Overview

- The Toxic Substances Control Act (TSCA) originally became law in 1976
- Frank R. Lautenberg Chemical Safety for the 21st Century Act (New TSCA) -- signed on June 22, 2016
- Under New TSCA:
  - Confidential business information (CBI) protection remains a priority
  - Section 14 has been extensively rewritten and expanded
  - CBI claims under much closer scrutiny
  - Burden on regulated entities to be active curators of their CBI
- Communicate and coordinate consistently to curate CBI carefully

## Overview (cont'd)

- TSCA requires regulated entities to submit CBI to the U.S. Environmental Protection Agency (EPA)
- Mandatory submission of CBI to EPA does not void its CBI status -- as long as it is managed correctly
- Topics for today's presentation
  - What is and is not protected
  - How to protect CBI in an EPA submission
  - When protected information must be disclosed (exemptions to CBI protection)
  - Duration of protection
  - Review and resubstantiation of currently protected CBI and limits
  - CBI claims review and protection process, appeals, and penalties for disclosure
- How these requirements dovetail with trade secret protection under Hazard Communication Standard (HCS) 2012

## What Is Protected

- TSCA: “Trade secrets and commercial or financial information” that meet the substantiation requirements set out under TSCA [Section 14(a)]
- Occupational Safety and Health Administration (OSHA) HCS: “A trade secret may consist of any formula, pattern, device or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. ...” [29 C.F.R. § 1910.1200, Appendix E]
- Under TSCA, we will have a broader discussion because a greater variety of information is subject to disclosure
- TSCA-protected information does not lose its protected status if it is mixed with non-protected information, but it must be clearly marked as CBI [Section 14(b)(1)]

## What is Protected (cont'd)

### Under HCS 2012

- Must disclose information about hazardous chemicals
- For Safety Data Sheets (SDS), may assert trade secret status for:
  - Specific chemical identity
  - Specific composition (% concentration) [1910.1200(i)]
- Labels
  - Must identify product by “product identifier” linked to SDS
  - Specific chemical identity or % composition not required

## Information Not Protected under TSCA [Section 14(b)]

- Health and safety studies
  - For chemicals offered for commercial distribution (pre-commercial information may be protected)
  - If testing is required under Section 4, or as part of a Section 5 notice, or disclosed under Section 8
  - BUT some information in the health and safety study may be protected
    - Manufacturing processes
    - Chemical identity information that discloses processes
    - For mixtures/formulations, percentages of components
- Aggregate manufacturing volumes or ranges of aggregated volumes
- General descriptions of processes used in manufacture or processing

## Information Not Protected under TSCA [Section 14(b)] (cont'd)

- General descriptions of industrial, commercial, or consumer functions or use of a chemical substance or mixture
- Information specific to an industry or industry sector that customarily would be shared with the general public or within that industry/sector
- If EPA has promulgated a rule under TSCA Section 6(a) to ban or phase out a chemical substance or mixture, then CBI protection is lost unless:
  - The person asserting the claim submits a request with supporting information within 30 days of EPA's notification
  - EPA decides based on the request that disclosure would not be in the public interest

## Asserting CBI Status [Section 14(c)]

- CBI claim **MUST** be made at the time the information claimed as confidential is submitted
  - In conformance with rules that EPA has or may promulgate
- Company must provide a statement that it has:
  - Taken reasonable measures to protect the confidentiality
  - Determined that CBI is not required to be disclosed to the public under any other federal law
  - A reasonable basis to conclude that disclosure is likely to cause substantial harm to the competitive position
  - A reasonable basis to believe that CBI is not readily discoverable through reverse engineering



## Generic Names for CBI Chemical Identity

- If the chemical identity is claimed as CBI, the company must provide a structurally descriptive, generic name for the chemical
  - EPA will disclose the generic chemical name to the public
- Generic name must:
  - Be consistent with current EPA guidance (1985 Inventory Guidance, Appendix B, until replaced)
  - Describe the chemical structure of the substance as specifically as practicable
  - Protect features of CBI chemical structure, the disclosure of which “would likely cause substantial competitive harm”
- EPA must develop new guidance on generic chemical names [Section 14(c)(4)]

## Protecting Trade Secrets under HCS 2012

- Must include an affirmative statement that information has been withheld as trade secret [29 C.F.R. § 1910.1200(i) and Appendix D]
- Considerable discretion on how to identify trade secret chemical substance
- For % composition, substitute a range for the specific percentage

## Unique Identifiers [Section 14(g)(4)]

- EPA must develop system to assign a unique identifier (UI) to CBI chemical identities
  - UI will not be chemical identity or structurally descriptive generic term
- EPA to use identifier consistently to link all information relevant to the applicable chemical substance
- Annually, EPA must update and publish a list of chemical substances (identified by UI) and the expiration date of CBI claims
- For listed chemicals that lose CBI protection, EPA must clearly link the specific chemical identity to CBI identified by the UI (e.g., link UI to Chemical Abstracts Service (CAS) number)



## Presumptive CBI

TSCA identifies information generally NOT subject to substantiation requirements

- Specific information describing manufacturing or processing
- Sales and marketing information
- Supplier or customer identities
- Percentage of components in mixtures and other compositional details
- Specific information on use, function, or application of a substance in a process, mixture, or article
- Specific production (including import) volumes
- Specific identity of a chemical substance in a Section 5 notice prior to commercialization

## Substantiating CBI Claims -- TSCA

- CBI claims must be substantiated in accordance with rules EPA has or may promulgate
- Authorized official of submitting company must certify that the CBI assertion and the substantiation is true and correct
- Current status: January 19, 2017, Notice (82 Fed. Reg. 6522)
  - Upfront substantiation effective March 20, 2017
  - Until September 19, 2017, to backfill substantiations since June 22, 2016
  - Existing substantiation requirements: 40 C.F.R. §§ 711.30, 720.85, and 720.90

## Substantiating Trade Secret Claims -- HCS 2012

- Trade secret claims must be supported [29 C.F.R. § 1910.1200(i)]
- 29 C.F.R. § 1910.1200 Appendix E incorporates an excerpt from the Restatement of Torts with factors for assessing trade secret claim validity:
  - Extent that information is known outside business
  - Extent information is known by employees
  - Measures taken to guard secrecy
  - Value to the business and to competitors
  - Effort and money spent to develop information
  - Effort required to obtain information properly

## Exemptions to Protection from Disclosure -- TSCA

EPA must disclose CBI in the following circumstances:

- U.S. employees in connection with official duties under a law for the protection of health or the environment, for a specific law enforcement purpose
  - Including U.S. government contractors if EPA believes such disclosure is needed for the performance of the contract
- If EPA determines that disclosure is necessary to protect human health or the environment against an unreasonable risk of injury to health or the environment
- Upon written request to state, political subdivision of a state, or tribal government if:
  - The information is needed to administer or enforce a law
  - The entity has at least one agreement with EPA consistent with guidance issued under Section 14(c)(4)(B) (regarding types of required safeguards)
  - The entity ensures CBI is protected in accordance with procedures comparable to the procedures used by EPA

## Exemptions to Protection from Disclosure -- TSCA (cont'd)

- Treating physician or nurse in non-emergency situation with a written statement of need and agreement to sign confidentiality agreement with EPA
- In the case of an emergency
  - To treating doctor, nurse, agent of a poison control center, public health or environmental official of a state, political subdivision of a state, or tribal government, or first responder, upon request
  - If that person has a reasonable basis to suspect information is necessary to address existing emergency, and
  - Provides a written statement as soon as practicable, but not necessarily before the information is disclosed
- EPA must develop a system for “expedient and swift access” to and disclosure of CBI in emergency and non-emergency medical situations [Section 14(g)(3)]
- EPA must consult with the Centers for Disease Control and Prevention in developing the system



## Exemptions to Protection from Disclosure -- TSCA (cont'd)

- If EPA determines disclosure is relevant in a proceeding under TSCA, if disclosure is made as to preserve confidentiality to the maximum extent practicable
- If required to be made public under any other provision of federal law
- As required pursuant to discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable federal or state law
- EPA must develop guidance on statements that must be provided by state government or medical personnel requesting access to CBI [Section 14(c)(4)]

## Exemptions to Protection from Disclosure -- HCS 2012

HCS 2012 addresses disclosure of trade secrets to medical personnel [29 C.F.R. § 1910.1200(i)]

- In a medical emergency:
  - Chemical manufacturer, importer, or employer must disclose specific chemical identity or % composition to treating doctor or nurse if needed for treatment
  - Must disclose regardless of written statement of need or confidentiality statement
  - May require written statement after the fact

## Exemption to Protection from Disclosure -- HCS 2012 (cont'd)

- In a non-emergency medical situation, a manufacturer, importer or employer shall disclose specific chemical identity or % composition to a health professional IF:
  - Written request
  - Describes in reasonable detail the occupational health need
  - Explains why specific identity or % composition is essential and other information would not suffice
  - Describes procedures for safeguarding confidentiality
  - Agreement to use only for health need and not disclose except to OSHA
- Process information given absolute protection

## Exemption to Protection from Disclosure -- HCS 2012 (cont'd)

- Denial of written request for disclosure must:
  - Be in writing
  - Be provided within 30 days of the request
  - Include evidence to support trade secret claim
  - State specifically why request is denied
  - Explain in detail why other information meets health professional's need without trade secret disclosure
- Health professional may refer denial to OSHA
  - If OSHA decides no bona fide trade secret OR that health professional has legitimate need for trade secret information, OSHA may issue citation

## Duration of Protection from Disclosure [Section 14(e)]

- CBI will no longer be protected if:
  - Submitter withdraws CBI claim
  - EPA becomes aware that the CBI no longer qualifies for protection
- CBI sunsets after ten years unless reassertion
- Presumptive CBI claims do not sunset
- Reassertion process
  - EPA will inform claimant 60 days before CBI expiration date
  - Claimant can reassert CBI claim, but must do so no later than 30 days before the CBI expiration date
  - EPA must review the reassertion submission before the CBI expiration date
  - EPA must grant or deny extension of another ten years
- No limits to the number of extensions that may be granted

## Review and Resubstantiation [Section 14(f)]

- EPA can require reassertion, substantiation, or resubstantiation of CBI claims
  - For chemicals designated as a high-priority substance under Section 6(b)
  - In Section 8(b)(4)(B) active substance notices
  - For inactive chemicals being notified as active chemicals [Section 8(b)(5)(B)(iii)]
  - If EPA determines that the CBI disclosure would be important within Section 6 risk evaluations or rulemakings
- If EPA requires a reassertion, substantiation, or resubstantiation, the party submitting the initial CBI claim can:
  - Proceed with the reassertion/resubstantiation
  - Withdraw the claim

## Review and Resubstantiation [Section 14(f)] (cont'd)

- EPA must review a CBI claim and may require resubstantiation if:
  - Information is subject to a Freedom of Information Act (FOIA) request
  - EPA has a reasonable basis to believe that the CBI does not qualify for protection
  - EPA has made a determination under Section 6(b)(4)(A) that the substance presents an unreasonable risk of injury to health or the environment

## EPA Review of CBI Claims

- EPA must review initial CBI claims (excluding presumptive CBI) within 90 days and requests for CBI extensions within 30 days
- If claim denied, EPA shall provide written statement of the reasons
- EPA must review all CBI chemical identity claims (except pre-commercialized chemicals)
- EPA must review at least 25 percent of all other CBI claims
- EPA failure to make a decision on CBI claim shall not have the effect of denying the claim
- In addressing requests to maintain CBI protection after ban/phase-out, EPA shall determine whether justification rebuts the presumption that:
  - Public interest in the disclosure of the information outweighs the public or proprietary interest in maintaining the protection
  - Keeping in mind the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the extent practicable



## Notifications to CBI Claimant

- Notification by means that allows verification of the fact and date of receipt
- 30-Day advanced notification prior to disclosure
  - EPA denies a CBI claim
  - Determines CBI not eligible
  - Promulgates a ban or phase-out
- 15-Day advanced notification prior to disclosure
  - If necessary to protect against unreasonable risk [Section 14(d)(3)]
  - To state, local, or tribal governments [Section 14(d)(4)]
  - In non-emergency medical situations [Section 14(d)(5)]
  - To Congress [Section 14(j)]

## Notifications to CBI Claimant (cont'd)

- Notification as soon as practicable
  - In emergency medical situations [Section 14(d)(6)]
- No notification for disclosure
  - To U.S. employees protecting health and the environment [Section 14(d)(1)]
  - To U.S. government contractors [Section 14(d)(2)]
  - If relevant to any proceeding under TSCA [Section 14(d)(7)]
  - If required to be disclosed under other federal law [Section 14(d)(8)]
  - EPA determines disclosure is necessary to protect against an imminent and substantial harm to health or the environment
- EPA will also not provide notifications for parties that do not respond within the prescribed deadlines for reassertions

## Appeals after Notification

- CBI submitter may bring action to restrain disclosure before the date on which the information is to be disclosed
- EPA shall not disclose information that is the subject of an appeal before the date on which the applicable court rules on the action, unless the disclosure was under:
  - Section 14(d)(4) (to state or tribal governments)
  - Section 14(j) (upon written request by Congress)

## Penalties for Wrongful Disclosure

- Individuals are subject to criminal penalties if they:
  - Obtain or have access to CBI;
  - Know that it is protected; and
  - Willfully disclose CBI to any person not entitled to receive it
- Does not apply to medical professional who discloses CBI obtained pursuant to Section 14(d)(5) or Section 14(d)(6) to a patient (or person authorized to make medical decisions on behalf of the patient) treated by said medical professional, as needed for the diagnosis or treatment of the patient

## Limits on EPA to Requiring Substantiation

- EPA cannot require the substantiation or resubstantiation of a CBI claim made under Old TSCA with some exceptions [Section 14(f)]:
  - Chemicals designated as high-priority substances under Section 6(b)
  - For any substance designated as active chemicals [Section 8(b)(5)(B)(iii)]
  - If EPA determines that the CBI disclosure would be important in conducting risk evaluations or rulemakings under Section 6
  - Information is subject to a FOIA request
  - EPA has a reasonable basis to believe that the CBI does not qualify for protection
  - EPA has made a determination under Section 6(b)(4)(A) that the substance presents an unreasonable risk of injury to health or the environment

## Limits on EPA to Requiring Substantiation (cont'd)

- EPA can review and require substantiation of CBI claims made in response to rules proposed before but promulgated after the date of enactment
- Substantiation or resubstantiation requirements cannot be made more extensive than as provided in New TSCA's Section 14



## Practical Implications for the Intersection of TSCA and HCS 2012 CBI

- Coordinate and communicate consistently ...
  - Does everyone within the organization agree on what is CBI?
  - How is CBI protected?
    - Ranges consistent on Premanufacture Notice (PMN) and Safety Data Sheet (SDS)?
    - Trade secret chemical identities?
- TSCA authorized official's obligations
- Global markets
- ...to curate CBI carefully

## Thank You

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