The New TSCA – Webinar 3:
Inventory, CDR, and CBI (Sections 8 & 14)

12 September 2016, 4pm BST
Today’s webinar aims

To provide an overview on the changes to the US’s information and reporting requirements, under the Lautenberg Chemical Safety Act. The areas of discussion will include:

- reporting & record keeping obligations
- confidential business information (CBI) considerations
- nomenclature
- the ‘reset’ of the TSCA inventory
- obligations for processors
Speakers

- **Lynn L. Bergeson** – Ms. Bergeson is Managing Partner and owner of Bergson & Campbell, P.C. (B&C). She has earned an international reputation for expansive understanding of areas such as TSCA, FIFRA, REACH and other emerging transformative technologies.

- **Kathleen Roberts** – is Vice President of B&C® Consortia Management, L.L.C. (BCCM). In her role at BCCM, Ms. Roberts is an essential resource for industry groups, in areas such as cost effective management support, services for industry consortia engaged in advocacy and public outreach, amongst others.

- **Richard E. Engler, Ph.D** – is a Senior Chemist with Bergeson & Campbell, P.C. (B&C) and is also a 17-year veteran of the U.S. Environmental Protection Agency. He is one of the most widely recognized experts in the field of green chemistry.

- **Charles Auer** – Senior Regulatory & Policy Advisor at Bergeson & Campbell, P.C. He has with broad and detailed experience in chemical assessment and management issues concerning U.S. domestic (TSCA), foreign (EU REACH, Canada CEPA, etc.), and intergovernmental (UNEP, OECD, etc.) programs.

- **Chair: Kelly Franklin** - Chemical Watch
Questions

- Please submit questions during the webinar using your chat box.

- Any unanswered questions can be raised in the Chemical Watch LinkedIn group following the webinar:
  
  www.chemicalwatch.com/linkedin
Chemical Watch Webinar Series

Webinar 3: Inventory, CDR, and CBI

The New TSCA: What You Need to Know

September 12, 2016
Toxic Substances Control Act (TSCA) Reform Is a Reality

- The new TSCA was signed by President Obama on June 22, 2016 (P.L. 114-182)
- The new law was effective immediately
Overview of TSCA Sections 8 and 14

Amended TSCA significantly changes provisions in these core sections of the law

- **Section 8**
  - Update small manufacturer definition
  - “Reset” TSCA Inventory
  - Nomenclature
  - Mercury inventory

- **Section 14**
  - Requires more substantiation of confidential business information (CBI)
  - Many CBI claims sunset after ten years
  - Broadens who may access TSCA CBI
  - Clarifies when submitters must be notified of loss of CBI protection
Section 8: Reporting and Retention of Information
### Section 8 -- Provisions with Important vs. Conforming Changes

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<td>Section 8(a) Chemical Data Reporting (CDR)</td>
<td>Section 8(a)(2) existing “information” vs. “data”</td>
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Section 8 -- Reporting and Retention of Information

- Section 8(a) -- Largely retained, with key changes. The U.S. Environmental Protection Agency (EPA):
  - Must reconsider small business criteria
  - May impose different information requirements on manufacturers and processors
  - Must enter into negotiated rulemaking for CDR reporting of inorganic byproducts

- Section 8(b) -- Significant changes
  - Nomenclature
  - Inventory “reset” with CBI substantiation
  - Mercury inventory
Section 8(a) -- Small Manufacturer Definition

- Section 8(a)(3)(C) requires EPA to consult with Small Business Administration (SBA) on “adequacy” of the small manufacturer standards
  - Allow for opportunity for public comment
- Make a determination if revision is warranted by December 19, 2016 (180 days after enactment)
  - Review adequacy at least every ten years thereafter
Section 8(a) -- Small Manufacturer Definition Update

- Current definition in place since 1986 Inventory Update Rule (IUR) guidance
- $4 million in 1986 = $8.7+ million in 2016
  - Seems likely that a decision to revise the small manufacturer standard forthcoming
- Not in time for 2016 CDR cycle, but likely before 2020
Section 8(a) -- Reporting by Processors

- EPA retains authority to apply Section 8(a) reporting (e.g., CDR) to processors as well as manufacturers

- EPA may impose different reporting/recordkeeping requirements on manufacturers and processors (Section 8(a)(4))

- Section 8(a)(5) directs EPA to:
  - Avoid unnecessary or duplicative reporting
  - Minimize the cost of reporting and compliance for small manufacturers and processors, and
  - Impose reporting requirements on those entities “likely” to have relevant information
Section 8(a) -- Possible Impacts of Processor Reporting

- Likely to trigger significant changes for 2020 CDR
- May impose significant new burden on processors
  - EPA will have to balance carefully obligations to meet the “likely to have” relevant information standard, minimize unnecessary or duplicative reporting, and minimize costs to small businesses
Section 8(a)(6) -- Inorganic Byproduct Rulemaking

- No later than June 22, 2019 (three years after enactment), EPA must enter into a “negotiated rulemaking” to propose a rule to limit CDR reporting requirements on manufacturers of inorganic byproducts
  - When byproducts are subsequently recycled, reused, or reprocessed
- Final rule must be issued by December 22, 2019 (three and a half years after enactment)
- Given schedule, rulemaking likely to begin significantly before June 22, 2019
Section 8(a) -- Byproduct Reporting

- Recognizes that CDR reporting for byproducts is a barrier to beneficial recycling, reprocessing, or reuse
  - Byproduct exemption only applies if byproduct is burned as fuel, disposed of as waste, or used to extract a component already present
  - Inorganic recycling or reprocessing often requires chemical transformation, voiding the exemption
- Does not provide relief from listing the byproduct on the TSCA Inventory
Section 8(b) -- TSCA Inventory

- Section 8(b)(1) and Section 8(b)(2) unchanged
- Adds Section 8(b)(3) on nomenclature
- Adds Section 8(b)(4) through (9) on Inventory “reset”
- Adds Section 8(b)(10) on mercury and mercury compounds
Section 8(b)(3) -- Nomenclature Provisions

- **Section 8(b)(3)(A) -- EPA must:**
  - Maintain the use of Class 2 nomenclature
  - Maintain the use of the Soap and Detergent Association (SDA) Nomenclature System
  - Treat “individual members of the categories of chemical substances identified [by EPA] as statutory mixtures [as defined by EPA] as being included on the [Inventory]”

- **Section 8(b)(3)(B)**
  - If a manufacturer “demonstrates to [EPA] that a substance appears multiple times on the [Inventory,]” EPA may “recognize the multiple listings as a single chemical substance”
Section 8(b)(3) -- Statutory Mixtures

- Section 8(b)(3)(A)(iii) -- Statutory mixtures -- EPA must treat individual members of the categories of chemical substances identified by EPA as statutory mixtures as being on the Inventory.

- There are six categories identified for statutory mixtures:
  - Cement, Portland, Chemicals
  - Cement, Alumina, Chemicals
  - Glass, Oxide, Chemicals
  - Frits, Chemicals
  - Steel Manufacture, Chemicals
  - Ceramic Materials and Wares

- Seems to obviate the need for notification under Section 5(a) for the individual chemical components of the subject statutory mixture.

- Unclear how it will impact CDR reporting obligations.
Section 8(b)(3) -- Substance of Unknown or Variable Composition, Complex Reaction Products, or Biological Materials (UVCB) Nomenclature

- Section 8(b)(3)(A)(i) -- EPA must maintain use of Class 2 nomenclature

- Section 8(b)(3)(A)(ii) -- EPA must maintain use of the SDA Nomenclature System

- Section 8(b)(3)(B) -- If manufacturer or processor “demonstrates to” EPA that a substance appears multiple times on the Inventory under different Chemical Abstracts Service (CAS) numbers, EPA may recognize the multiple listings as a single substance
Section 8(b)(4) -- Inventory Reset

- By June 22, 2017, EPA must promulgate a rule to “reset” the Inventory

- Manufacturers required to notify; processors may be required
  - Substances on Inventory manufactured or processed in the ten years prior to enactment (June 22, 2006, through June 21, 2016)
  - Notifications required no later than 180 days after final rule published
Section 8(b)(4) -- Inventory Reset (cont’d)

- If a notice is received, substance is designated as “active”
- If no notice is received, substance is designated as “inactive”
  - Inactive substances stay on the Inventory
- Section 8(b)(6) -- EPA must designate the 2016 CDR chemicals as “interim” list of active substances
Section 8(b)(4) -- CBI Claims

- Active notice submitter cannot claim identity of a substance as CBI for any substance not already listed as CBI
- CBI claims must be asserted and substantiated in active substance notices
- If EPA receives no substantiated CBI claims for an active substance, substance is deemed non-CBI
- Inactive CBI substances remain CBI
Section 8(b)(4)(C) -- CBI Review

- Within one year of compiling active substance list, EPA must promulgate a rule with a plan to review all CBI claims for identity of active chemicals
- EPA must determine if CBI claim qualifies and approve or deny claim
  - Can approve part and deny part
- CBI review to be completed five years after Inventory reset
  - Extension of two additional years if “necessary”
Section 8(b)(5) -- Change to Active Status

- After Inventory reset, if an entity intends to manufacture, import, or process an inactive substance, entity must notify EPA prior to the activity
  - No mechanism specified for notification
  - Notification is not a premanufacture notice (PMN)
  - No timeframe specified except before the date that commercial activities occur

- In activation notice, submitter must assert CBI claim for chemical identity and substantiate the CBI claim within 30 days
  - Or else substance will be activated as a non-CBI substance

- Upon activation, EPA designates the substance as active and “promptly” reviews the CBI claim and associated substantiation

- After activation, EPA may review the priority of the substance (for Section 6 review) as necessary
Preparing for Inventory Reset

- Companies advised to assess supply chain to identify active substances
- 2016 CDR compilation is a good start
  - Retain records of all CDR exempt substances in supply chain, including polymers and low volume substances
  - Ten-year window for the reset much longer than four-year CDR reporting cycle
  - Careful review of historical records necessary to ensure all chemicals potentially eligible for the active list are identified and considered
- There is no volume threshold for reporting chemicals as active
- Not clear if substantiation of activity will be required or what would constitute substantiation
Processors Reporting for Inventory Reset

- Processors may not have to notify, but it may be in their best interest to do so
- Work closely with suppliers to ensure that reporting requirements are satisfied
Section 8(b)(10) -- Mercury Inventory

- EPA must create an inventory of supply, use, and trade of mercury and mercury compounds in the U.S.
  - By April 1, 2017
  - Update every three years thereafter

- Gives EPA relevant information on continued use of mercury in the U.S.; allows identifying opportunities for further reductions

- Deadline: Rule must be promulgated two years after enactment (June 22, 2018)

- Entities generating, handling, or managing mercury-containing waste will not be required to report unless they manufacture or recover mercury in the management of that waste
Section 8(b)(10) -- Definition of Mercury

- Section 8(b)(10)(A) -- Definition of mercury states (emphasis added):

  In this paragraph, *notwithstanding section 3(2)(B)*, the term “mercury” means (i) elemental mercury; and (ii) a mercury compound

- Section 3(2)(B) = Chemicals excluded from TSCA
  - Regulated under other Federal statutes, such as drugs, pesticides, tobacco, and food or food additives

- Substances usually excluded from TSCA will be *included* in the mercury inventory and reporting provisions
Section 8(b)(10) -- Mercury Inventory (cont’d)

- Lack of definitional detail for “mercury compound” may be problematic
  - Mercury can and does occur naturally at low levels
  - Need to avoid capturing minerals or metals with naturally occurring mercury
  - Section 8(10)(C)(i) requires EPA to identify any manufacturing processes or products that intentionally add mercury

- Reporting timeline: Three-year cycle
  - Expect periodic mercury manufacture/use reporting to be separate from the four-year cycle of CDR
Discussion of Section 8

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Section 14: Confidential Business Information
## Section 14 -- Provisions with Important vs. Conforming Changes

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<td>Section 14(a)</td>
<td>Former Section 14(e), now Section 14(j)</td>
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Section 14 -- CBI

- Section 14 is nearly entirely new, but CBI protection is not lost
- Section 14(a) makes it clear: CBI received or obtained that meets requirements under Section 14(c) (substantiation) is protected (e.g., from the Freedom of Information Act (FOIA))
- Amended TSCA includes changes as to what information will be protected, for how long, and under what circumstances
- Companies will have to do more to protect less under new TSCA
Section 14(b) -- Information Not Protected

Section 14(b)(1) -- Mixed confidential and non-confidential information

- Now explicit authority: Information protected from disclosure does not lose that protection if it is mixed with information that is not protected from disclosure
Section 14(b) -- Information Not Protected (cont’d)

- Section 14(b)(2) -- Health and safety studies (HSS) are not protected:
  - For chemicals offered for commercial distribution (pre-commercial information may be protected)
  - If testing required under TSCA Section 4 or required in Section 5 notice

- Some information in HSS may be CBI
  - Processes used in the manufacture or processing of the substance, including chemical identity that may disclose process (e.g., name, molecular formulas, structures)
  - Proportions of substances in a mixture
Section 14(b) -- Information Not Protected (cont’d)

- Section 14(b)(3): Now explicit authority -- CBI protection does not apply to:
  - General information describing the manufacture
  - Aggregate volumes or ranges of aggregate volumes
  - General descriptions of processes used in manufacture or processing, functions, and use
  - Information specific to a certain sector that would customarily be shared with the general public
Section 14(b) -- Information Not Protected (cont’d)

Section 14(b)(4) -- Bans and phase-outs

- CBI protection no longer applies for chemicals subject to final Section 6(a) ban or phase-out
  - Unless disclosure would not be in the public interest per Section 14(g)(1)(E)

- CBI protection is lost unless:
  - EPA approves a request submitted by the manufacturer or processor that CBI should not be disclosed or disclosure should be delayed
  - Request must be submitted with supporting documentation within 30 days after notification per Section 14(g)(2)(A)
Section 14(b) -- Information Not Protected (cont’d)

Section 14(b)(4) -- Bans and phase-outs (cont’d)

- CBI related to other uses still protected
  - Uses not subject to ban/phase-out
  - Critical use exemption to ban/phase-out per Section 6(g)
  - Export only under Section 12(a)(1), unless EPA makes unreasonable risk finding under Section 12(a)(2)
Section 14(c)(1) -- Asserting CBI

- CBI claim must be submitted concurrent with information claimed as confidential
  - In conformance with rules 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
Section 14(c)(1) -- Generic Names of CBI Chemicals

Section 14(c)(1)(C) -- Chemical identity

- If chemical identity is claimed CBI, company must provide a structurally descriptive, generic name for the chemical
  - EPA will disclose generic chemical name to the public

- Generic name shall:
  - Be consistent with EPA guidance (Appendix B of 1985 Inventory Guidance is operative until superseded under Section 14(c)(4)(A))
  - 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”
Section 14(c)(2) -- Presumptive CBI

Section 14(c)(2) -- Information generally not subject to substantiation requirements

- Specific information describing manufacturing or processing
- Sales and marketing information
- Information that identifies suppliers or customers
- Composition details and percentages of components in mixtures
- Specific information on use, function, or application of 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
Section 14(c) -- Requirements for CBI Claims

Section 14(c)(3) -- Substantiation requirements

- Assertion of CBI claims to be substantiated in accordance with rules EPA has or may promulgate

Section 14(c)(4) Guidance

- EPA shall develop guidance on generic names
- EPA shall develop guidance on statements to be provided by state government or medical personnel requesting access to CBI

Section 14(c)(5) -- Certification

- Authorized official of submitting company must certify CBI assertion and substantiation as true and correct
  - EPA has already changed the wording of the CBI certification statement for the 2016 CDR cycle to be consistent with amended TSCA requirements
Section 14(d) -- Exemptions to Protection from Disclosure

Circumstances in which EPA must disclose CBI (*italics denote changes*):

- 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 health or the environment against an unreasonable risk of injury to health or the environment

- Upon written request, 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)
  - The entity ensures CBI is protected in accordance with procedures comparable to the procedures used by EPA
Section 14(d) -- Exemptions to Protection from Disclosure (cont’d)

Circumstances in which EPA must disclose CBI (italics denote changes) (cont’d)

- Treating physician or nurse in nonemergency situation with a written statement of need and agreement to sign confidentiality agreement with EPA Administrator

- In the case of an emergency, 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 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

- If EPA determines disclosure is relevant in a proceeding under this Act, 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
Section 14(e) -- Duration of Protection from Disclosure

- 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
- Presumptive CBI claims do not sunset
- Reassertion Process
  - EPA to inform claimant 60 days before the 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 to deny request or grant extension of ten years
- No limits to the number of extensions that may be granted
Section 14(f) -- Review and Resubstantiation

- 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
Section 14(f) -- Review and Resubstantiation (cont’d)

EPA must review a CBI claim and may require resubstantiation if:

- 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
Section 14(g)(1) -- CBI Claim Review

- 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
Section 14(g)(2) -- Notifications to CBI Claimant

- Notification via means that allows verification of the fact and date of receipt

- 30-Day advanced notification
  - EPA denies a CBI claim
  - Determines CBI not eligible
  - Promulgates a ban or phase-out

- 15-Day advanced notification prior to disclosure
  - Section 14(d)(3) (protect against unreasonable risk)
  - Section 14(d)(4) (State or tribal governments)
  - Section 14(d)(5) (non-emergency medical)
  - Section 14(j) (access by Congress)
Section 14(g)(2) -- Notifications to CBI Claimant (cont’d)

- Notification as soon as practicable
  - Section 14(d)(6) (emergency medical)

- No notification for disclosure
  - Section 14(d)(1) (U.S. employees protecting health and the environment)
  - Section 14(d)(2) (contractors)
  - Section 14(d)(7) (relevant for proceeding with Act)
  - Section 14(d)(8) (required to be disclosed under other Federal law)
  - 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
Section 14(g)(2) -- 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) (State or tribal governments)
    - Section 14(j) (access by Congress)
Section 14(g)(3) -- Request and Notification System

- EPA must develop a system for “expedient and swift access” to CBI to be disclosed under emergency and non-emergency medical situations

- EPA must consult with Centers for Disease Control and Prevention in developing the system
Section 14(g)(4) -- Unique Identifiers

- EPA to 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 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 CAS number)
Section 14(h) -- Penalties for Wrongful Disclosure

- Changes largely conforming
- 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
Section 14(i) -- Limits to 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

- 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 Section 14
Questions and Discussion
Thank You

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Questions

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- **Chair: Kelly Franklin** - Chemical Watch
Thank you for attending

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If you have any questions, please contact Jacob: jacob.ward@chemicalwatch.com

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