U.S. and EU Assessment of Existing Chemicals

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Dr. Hill is a toxicologist and Supervising Health Scientist with Cardno ChemRisk. She is a product stewardship and regulatory specialist with experience in the specialty chemicals industry, working with global, midsize, and small businesses. She helps business meet global regulatory obligations related to hazard classification, risk assessment, and hazard communication for new and existing chemicals. Dr. Hill supports compliance efforts concerning U.S. and international chemical control initiatives such as TSCA, country-specific adoption of GHS, CLP and REACH, and has extensive experience with "greener" product chemistry and alternatives assessment.

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Today’s Agenda

- Specific Examples of the Two Approaches in Practice.
- How Are the Same Chemicals Likely to Be Treated in the Two Jurisdictions?
Review of Existing Chemicals Under TSCA

- Under the new TSCA, EPA now has the Authority to Conduct Safety Reviews of All Chemicals in the Marketplace.
- The first ten chemicals planned for evaluation are taken from EPA’s 2014 Work Plan. These are:
  1,4-Dioxane; 1-Bromopropane; Asbestos; Carbon Tetrachloride; Cyclic Aliphatic Bromide Cluster; Methylene Chloride; N-methylpyrrolidone; Pigment Violet 29; Perchloroethylene; and Trichloroethylene.
- After publishing this list in the Federal Register EPA generally will have 3 years to complete its evaluations.
- This evaluation will determine whether the chemicals present an unreasonable risk to humans and the environment.
- If it is determined that a chemical presents an unreasonable risk, EPA must mitigate that risk within two years.
- Mitigation may involve Bans and Phase-outs.
Review of Existing Chemicals Under TSCA (2)

- EPA Must Identify the Hazard(s), Exposure(s), Conditions of Use, and the Potentially Exposed or Susceptible Subpopulation(s) that EPA Plans to Consider in the Evaluation.
- Additional Chemicals will be Designated for Evaluation, and all of the remaining 2014 Work Plan Chemicals will be Reviewed.
- For each Evaluation that EPA Completes, EPA is Required to Begin Another.
- By the End of 2019, EPA Must have at least 20 Evaluations Ongoing at Any Given Time.
- Industry is expected to nominate at least 25% of the chemicals and pay for the assessments.
- EPA assessments are supposed to use best available science and weight of the evidence.
Review of Existing Chemicals Under EU REACH

- The “E” in REACH Stands for Evaluation.
- There are Two Types: (1) Dossier Evaluation, and (2) Substance Evaluation.
- Under Substance Evaluation the EU Member States can Nominate Chemicals for an In-depth Assessment Based on an “Identified Concern”.
- The List of Nominated Substances is called the “Community Rolling Action Plan (CoRAP)”.
- There are Currently 319 Substances on the CoRAP List and Substances are Added to the List Bi-annually.


- 49 Evaluations have Completed to-date.
- Evaluation can Result in: (1) a Change of Labeling; (2) Authorisation; (3) Community-wide Restrictions; or (4) National Measures.
RA of Existing/High Risk Chemicals under TSCA

- Currently, no explicit guidance
  - No specific approach to RA is provided for Work Plan chemicals
  - EPA procedural rule to evaluate risk of high priority chemicals was anticipated to be published in mid-December 2016

- Nonetheless, recently completed Work Plan Chemical Risk Assessments **may be largely predictive of future RA approaches for existing chemicals,**
  - Especially given that the Agency has indicated their internal approach to RA changed in advance of TSCA reform
  - “For chemicals with risk assessments completed prior to the date of enactment, section 26(l)(4) allows EPA to publish proposed and final rules consistent with the scope of those risk assessments, even if they do not cover all conditions of use.”
  - “EPA will also continue to use its TSCA information collection, testing, and subpoena authorities, including sections 4, 8, and 11(c) of TSCA, to develop needed information on additional chemicals that currently have less robust hazard or exposure data.”
TSCA Example: Work Plan Chemical Risk Assessment

- Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses
  - Targeted assessment for these stated uses
  - Significant effort was review of non-cancer toxicity endpoints using rodent and human PBPK models
  - Extensive detail is provided regarding workplace and task-specific information used in development of the risk assessment
CoRAP Example: Substance Evaluation

- **p-Cresol: (2015, United Kingdom)**
  - A significant proportion of the text is focused on hazard characterization
  - In this case, improved hazard characterization resulted in a decision that there was not need for regulatory follow-up at the EU level
  - “The hazard assessment of p-cresol was targeted to human health (carcinogenicity and, because of its use in consumer products, endocrine disruption). In addition, the approach taken for the human exposure assessment was examined, because it was not clear to the eMSCA how the exposure values used for the risk characterisation were derived in all cases.”

- **Diethyl phthalate (2014, Germany)**
  - The bulk of the report focuses on hazard characterization
How Are the Same Chemicals Likely to Be Treated in the Two Jurisdictions?

- Potentially significant differences in institutional power and ability to elicit engagement by stakeholders may emerge.
- Any differences in review of chemicals identified as high concern may be related to the differences in the initial hazard and risk assessment obligations under the original TSCA as compared to REACH registration; if so, this is likely to change.

- EPA approach appears to have strong focus on, and technical capability in, exposure assessment.
- CoRAP approach appears to have a relatively stronger focus on chemical hazard evaluation.
What You Should Do

- Take every opportunity available to interact with EPA during the assessment process.
- Work hard to fill data gaps particularly with respect to exposure to ensure that EPA’s assessment is solid and science based.
- Look for opportunities to use a favorable EPA assessment to defend your products against blacklisting in other countries.
The Next TSCA 30/30:  
Wednesday, February 8th

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THANK YOU

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