(1) Existing Chemicals Exposure Limits (ECELs)
(2) Ruminations on Full Study Reports and Data Templates

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Herb Estreicher

- Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his US law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few US-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.
- Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.
- Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.

David B. Fischer

- David Fischer counsels clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Having served as the Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention as well as having held senior level positions at the American Chemistry Council, David advocates for clients before the U.S. EPA and provides strategic advice to them regarding issues before Congress.
- In addition to TSCA and FIFRA, he has experience with numerous other statutes including the Clean Air Act (CAA), Clean Water Act (CWA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), Emergency Planning and Community Right-to-Know Act (EPCRA), and the Food Quality Protection Act (FQPA).
- David's clients include domestic and international industrial and specialty chemical manufacturers, and the trade associations which represent them. Clients seek his assistance on new chemical approvals, and chemical and pesticide risk evaluations and risk management rulemakings because of his deep understanding of EPA, its internal science policy apparatus, and its many organizational pieces that collectively are responsible for all aspects of TSCA and FIFRA.

ECELs (1)

- In the risk evaluations and in the final risk evaluation procedural rule, unreasonable risk is not defined
  - No "bright line" was defined as unreasonable risk
- Instead, unreasonable risk is based on a number of "considerations"
  - "Consistent with EPA's human health evaluations, the RQ is not treated as a bright line and other risk-based factors may be considered (e.g., confidence in the hazard and exposure characterization, duration, magnitude, uncertainty) for purposes of making an unreasonable risk determination" (emphasis added)
    - "EPA did take public comment on this approach and the public agreed that a definition was not appropriate, but appreciated EPA's approach to including considerations"

ECELs (2)

- In the proposed risk management rule, however, exposure above the ECEL **is** unreasonable risk
- So, the ECEL is the bright line for unreasonable risk
- EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health

ECELs (3)

- "The ECEL represents the concentration at or below which an adult human, including a member of a potentially exposed or susceptible subpopulation [e.g., workers] would be unlikely to suffer adverse effects if exposure for a working lifetime [i.e., 40 years]"
  - Should EPA provide more clarity as to what is unreasonable risk when it proposes changes to the rule on procedures for chemical risk evaluation?
  - Is unreasonable risk the absence of nearly any potential risk of adverse effects?

Proposed Risk Management Rule for Methylene Chloride (1)

- How does EPA derive an ECEL?

$$\mathrm{EC}_{\mathrm{MOEchronic\ 8hrTWA}} = \frac{\mathrm{HEC}_{\mathrm{1st\ \%ile}}}{MOE_{benchmk\_chronic}} * \frac{\mathrm{AT}_{\mathrm{MOE\ chronic}}}{ED * EF * WY}$$

$$= \frac{17.2\,\frac{\mathrm{mg}}{\mathrm{m}^3}}{10} * \frac{24h/d * 365d/y * 40\ y}{8h/d * 250d/y * 40\ y}$$

$$= 7.5\,\frac{\mathrm{mg}}{\mathrm{m}^3} = 2.2\ \mathrm{ppm}$$

- Based on chronic liver toxicity, which eliminate unreasonable risks from acute, chronic non-cancer and cancer endpoints from methylene chloride exposure
- EPA is soliciting comments on its methodology

Proposed Risk Management Rule for Methylene Chloride (2)

- EPA rounded 2.2 ppm down to 2.0 ppm, about a 10% decrease in the derived ECEL
- Only a single ECEL is derived for all the COUs to which it applies, regardless of whether there are differences in potential hours/days/years of exposure
- But TSCA requires that EPA apply risk management requirements "to the extent necessary so that the chemical substance no longer present [unreasonable] risk"

Workplace Chemical Protection Program (WCPP) (1)

- In general, the WCCP is analogous to the OSHA standard (29 CFR 1910.1052)
- ECEL, ECEL action level, and STEL (short-term exposure limit)
- Exposure monitoring requirements (with some exceptions)
  - Initial (and every 5 years, in contrast to OSHA)
  - Periodic
  - If workplace changes may cause increases in exposure levels

Workplace Chemical Protection Program (WCPP) (2)

- Exposure Control Plan (analogous to OSHA requirements)
  - Demarcate any area of the workplace expected to exceed the ECEL or STEL
  - Require to the extent feasible the hierarchy of controls before using PPE
    - Respiratory protection (APF) dependent on methylene chloride concentrations
  - No rotation of work schedules to comply with ECEL
  - Use of chemically resistant gloves
- Recordkeeping (retention of records for at least 5 years)

Full Study Reports and Data Templates

Definition Health and Safety Study (1)

- Health and safety (H&S) studies can not be claimed CBI
- Not everything in a study report is part of an H&S study
- 40 C.F.R. 703.3 clarifies what is NOT part of an H&S study, namely:
  1) The name, address, or other identifying information for the submitting company, including identification of the laboratory that conducted the study in cases where the laboratory is part of or closely affiliated with the submitting company

Definition Health and Safety Study (2)

2) Internal product codes
3) Names and contact details for testing laboratory personnel and names and other private information for health and safety study participants or persons involved in chemical incidents such as would typically be withheld under 5 U.S.C. 552(b)(6) or under other privacy laws
4) Information pertaining to test substance product development, advertising, or marketing plans, or to cost and other financial data

- Why is this important?
  - Has to do with Data Compensation under REACH and REACH-like programs and possession of full study reports

IUCLID Data Templates

- New 40 CFR 703.5(g) requires that OECD Harmonized templates, if available, accompany the e-submission of H&S information
- This requirement is in addition to the existing requirements to provide full study reports when reporting is by CDX, for example, in PMNs, Sec. 4 Test rules and Orders & 8(d) reporting rules
- Template requirement does not turn on whether a CBI claim is made
- You can find the OECD Harmonized templates at https://www.oecd.org/ehs/templates

Please join us at 1:00 PM Eastern U.S.
Wednesday, July 12, 2023
www.khlaw.com/TSCA-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, July 19, 2023
www.khlaw.com/OSHA3030

Please join us at 10:00 AM Eastern U.S.
Wednesday, August 23, 2023
www.khlaw.com/REACH-3030

Thank You

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