Keller & Heckman

Whole Chemical Approach - the revised HBCD Risk Evaluation

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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 advises 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). In addition, he has extensive 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), the 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. Having held senior level positions with the US Environmental Protection Agency (EPA) and the American Chemistry Council (ACC), clients look to David for his insight and perspective when navigating the myriad of complex environmental regulations.

- Prior to joining Keller and Heckman, David was the Deputy Assistant Administrator (DAA) for the Office of Chemical Safety and Pollution Prevention (OCSPP). During his tenure as DAA, he was deeply involved in TSCA implementation, with a particular focus on risk evaluation and risk management of existing chemicals, and all aspects of FIFRA implementation.

- During his tenure at the American Chemistry Council, David co-managed the Chemical Products and Technology Division (CPTD) where he led the implementation of the Lautenberg Chemical Safety Act.

Eric Gotting

- Eric Gotting represents Keller and Heckman's clients in litigation and related matters, specializing in complex civil and appellate matters, internal investigations, and regulatory compliance. With an extensive background in environmental law, he has expanded his practice over the years to cover many of Keller and Heckman's industry sectors and regulatory areas. Eric is a former Am Law 50 litigation partner and US Department of Justice, Civil Division, Trial Attorney.

- Eric's practice spans a broad range of legal issues, including administrative and constitutional law, agency enforcement actions, toxic torts, product liability, general business litigation, and regulatory advice. He works with a diverse set of industries, including chemicals, plastics, pesticides, fuels and pipelines, food and packaging, consumer goods, telecommunications, and e-cigarettes.

- As a litigator, Eric has tried cases to verdict and argued appeals before federal and state courts across the country. His experience includes class actions, mass tort litigation, AAA arbitrations, and agency proceedings. Eric has also litigated challenges to federal and state statutes, regulations, and orders. He has particular expertise involving the Administrative Procedure Act (APA), the Dormant Commerce Clause, the First Amendment, the Due Process Clause, and federal preemption. He has also filed amicus briefs in litigation involving regulatory issues facing a variety of industry sectors.

- For his toxic tort clients, Eric has defended claims involving all environmental media, including drinking water, soil, groundwater, and air. He has worked with, and defended against, experts in numerous scientific and business-related fields, including toxicology, geochemistry, hydrogeology, structural engineering, neuropsychology, health physics, survey techniques, statistics, real estate appraisal, and environmental remediation. He has extensive experience litigating toxic tort cases involving claims of personal injury and property damage from alleged exposures to volatile and semi-volatile compounds, specialty chemicals, pesticides, gasoline, radioactive waste, and heavy metals.

Biden EPA Revisits Trump-era Risk Evaluations

- Application of Biden administration TSCA policy changes to the first ten TSCA risk evaluations:
  - No longer relying on assumed use of PPE
  - Whole chemical approach vs individual conditions of use
- Response to NGO lawsuits challenging no unreasonable risk findings for specific categories of use
- The flame retardant Hexabromocyclododecane (HBCD) was first at bat

Draft Revised HBCD Risk Evaluation (1)

- Recall the Trump-era risk assessment concluded that six conditions of use presented an unreasonable risk and six did not
- EPA now concludes that the same six problem conditions of use “drive” the unreasonable risk determination under the chemical as a whole approach
- Although certain uses were only of concern for environmental risk the deletion of assumed PPE use now raises human health concerns for these uses as well
- EPA proposes to rescind the no significant risk orders for the six other conditions of uses

Draft Revised HBCD Risk Evaluation (2)

- EPA says something potentially important - That it's:

"**not limited** to **regulating** the **specific activities** found to **drive unreasonable risk** and **may select** from among **a suite of risk management options** related to manufacture, processing, distribution in commerce, commercial use, and disposal in order **to address the unreasonable risk**."

  - EPA gives as an example that it may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., use) even if the upstream activities are not unreasonable risk drivers

Impacts of a whole chemical risk determination approach (1)

- EPA procedures for manufacturer requests for risk evaluations (MRREs) are described in 40 CFR §702.37
  - "EPA will conduct these assessments and make proposed determinations based on the **same considerations applied in the same manner** as it would for a risk evaluation for a high-priority substance." (emphasis added)

Impacts of a whole chemical risk determination approach (2)

- EPA will no longer determine that certain conditions of use in an MRRE do not present an unreasonable risk
  - Disincentivizes the submission of future MRREs
  - Highly unlikely for EPA to conclude that a whole chemical does not present unreasonable risk

Impacts of a whole chemical risk determination approach (3)

- Scope of Preemption will be limited
  - Generally, under TSCA section 18(c)(3), federal preemption applies to "the hazards, exposures, risks, and uses or conditions of use" included in:
    - EPA's order regarding no unreasonable risk determinations or
    - TSCA 6(a) risk management rules to address unreasonable risks

Impacts of a whole chemical risk determination approach (4)

- If EPA no longer issues orders for certain conditions of use that do not present unreasonable risk, preemption can only be triggered through issuance of a risk management rule
- But will a risk management rule include conditions of use that don't present unreasonable risk?

Can EPA give framework rule a new interpretation without a new rulemaking?

- TSCA requires notice and comment rulemaking for risk evaluation rules
- Administrative Procedure Act requires same for amended rules
- So what's all this talk in the HBCD preamble about "ambiguity"?
  - EPA is setting-up "Auer" deference (*Auer v. Robbins*, 519 US 452 (1997))
  - A court will defer to agency's new interpretation unless "plainly erroneous or inconsistent with the regulation" and will do so without requiring a new notice and comment rulemaking proceeding

Auer Deference Revisited

- Kisor factors (*Kisor v. Wilkie*, 139 S. Ct. 2400 (2019))
  - Is existing regulation "genuinely ambiguous"?
  - If so, is agency's new interpretation "reasonable"?
  - Does interpretation come from authoritative source within agency?
  - Does interpretation implicate agency's expertise?
  - Does interpretation reflect agency's fair and considered judgment?

Does the Biden EPA face an uphill battle?

Unreasonable Risk Determination

"As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation, either in a single decision document or in multiple decision documents"

40 CFR 702.47

Application of Kisor factors 1 and 2

- Is 702.47 “genuinely ambiguous”?
  - Plain language of 702.47
  - Other statements in framework rule preamble
  - Other regulations in framework rule
  - 702.47’s purpose
- Is the whole chemical approach a “reasonable” interpretation?

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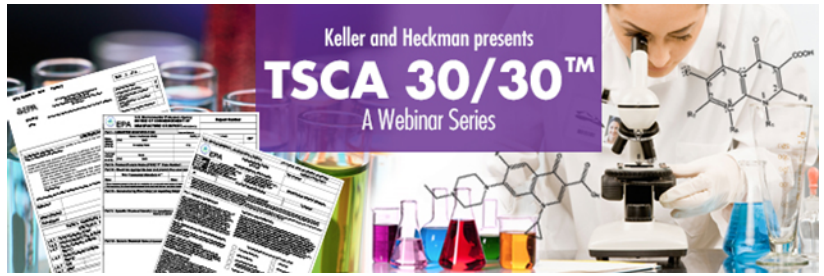

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Thank You

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