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New Chemicals Program: Proposed Changes to Part 720

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Herb Estreicher

- 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 Ph.D. 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 an 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.

Proposed Changes to Part 720 (1)

- A coalition of chemical companies with significant business interest in the manufacturing and use of new chemicals and new uses of existing chemicals submitted a petition requesting that EPA amend 40 C.F.R. Part 720 regulations governing Premanufacture Notices under Section 5 of the Toxic Substances Control Act
- The petition was submitted on November 11, 2022, pursuant to section 553 of the Administrative Procedure Act **not** TSCA section 21
  - TSCA section 21 does not govern TSCA section 5 rulemaking

Proposed Changes to Part 720 (2)

- Fit for Purpose Review
- Timely Communication Between EPA and the Submitter throughout the Review Period
- Reliance on Analogs
- Reliance on Data over Models
- Constructive Withdrawal
- Pre- and Post-Submission Meetings
- Administrative Appeal

Fit for Purpose Reviews of New Chemical Substances (1)

- Risk assessment components should be commensurate with the conditions of use specific and relevant to the chemical substance undergoing review
- Reviews should be consistent with the risk characterization TCCR principles, as described in EPA's Risk Characterization Handbook (Dec. 2000):
  - Transparency: ensures that any reader understands all the steps, logic, key assumptions, limitations, and decisions in the risk assessment, and comprehends the supporting rationale that leads to the outcome
  - Clarity: making the product clear makes the assessment free from obscurity and easy to understand

Fit for Purpose Reviews of New Chemical Substances (2)

- Consistency: the conclusions of the risk assessment are characterized in harmony with relevant policy, procedural guidance, and scientific rationales
- Reasonableness: demonstrates that the risk assessment process followed an acceptable, overt logic path and retained common sense in applying relevant guidance
- The assessment is based on sound judgment and the best available science

- Although the Handbook calls for the TCCR principles in the risk characterization, the principles of TCCR should be fully applied throughout the risk assessment process
- EPA staff and EPA contractors engaged in reviewing new chemical substances should possess the requisite expertise and knowledge to proficiently conduct reviews

Timely Communication Between EPA and the Submitter Throughout the Review Period

- Communications between the submitter and EPA should serve to advance EPA's review of the new chemical substance
- Non-CBI information provided to the submitter via CDX should include, but is not limited to:
  - Analogs and models relied upon by EPA
  - The conditions of use EPA has identified are relevant to the submission
  - Reports or assessments developed by EPA pertaining to the submission
- The submitter should have the opportunity to provide timely feedback to EPA

Reliance on Analogs to Assess the New Chemical Substance

- A submitter may submit any relevant data pertaining to an analog chemical that is structurally similar to the new chemical substance, and which will facilitate the review of the new chemical substance
- EPA should rely on the analog information provided by the submitter unless EPA can clearly demonstrate that the best available science supports the use of another analog
- If the analog identity is CBI, EPA should provide to the submitter redacted copies of studies, reports, or other information on the analog EPA relies upon to clearly demonstrate that EPA's choice of an analog represents the best available science

Reliance on Data Over Models

- In conducting reviews of new chemical substances, EPA should rely on data rather than models, unless EPA can demonstrate why the use of models in place of data represents the best available science
  - EPA should rely on data provided by the submitter unless EPA can clearly demonstrate that it does not represent the best available science
  - To the extent EPA relies on conservative assumptions to assess either hazard or exposure during the review of a new chemical substance, such conservative assumptions shall be grounded in TCCR principles

Constructive Withdrawal

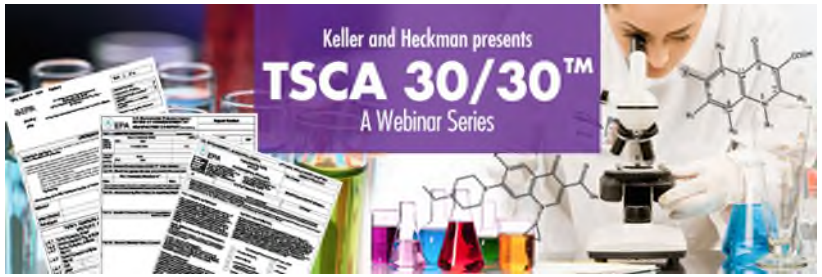
- Moving a new chemical submission through the review process relies on timely input by both EPA and the submitter
- EPA should deem a submitter to have constructively withdrawn the notice if the submitter fails to provide a response to any EPA request within 30 days of EPA having sent the request, unless the submitter made a good faith effort to respond within 30 days

Pre- and Post-Submission Meetings

- Meetings between the submitter and EPA serve to advance EPA's review of the new chemical substance
- During the pre-submission meeting, EPA should, to the extent practicable and consistent with the TCCR principles, address the issues raised by the submitter
- Clearly convey the anticipated data needs to facilitate EPA's review of the submission
- Post-submission meetings also may be useful to advance the disposition of the submission

Administrative Appeal

- For submitters who disagree with an EPA final determination, an administrative appeal process may be a useful next step
- The appeal would be directed to the Senior Science Advisor (SSA) within the Office of Chemical Safety and Pollution Prevention
- The appeal would provide the scientific rationale for the submitter's disagreement and the rationale for an alternative determination
- The SSA would convene a panel of three EPA senior scientists who can objectively conduct a de novo review of the new chemical substance considering all the information provided by the submitter and EPA, and based on a simple majority vote, render a determination



Please join us at 1:00 PM Eastern U.S.
Wednesday, January 11, 2023
www.khlaw.com/OSHA3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, January 18, 2023
www.khlaw.com/TSCA-3030

Please join us at 10:00 AM Eastern U.S.
Wednesday, February 8, 2023
www.khlaw.com/REACH-3030

Thank You

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