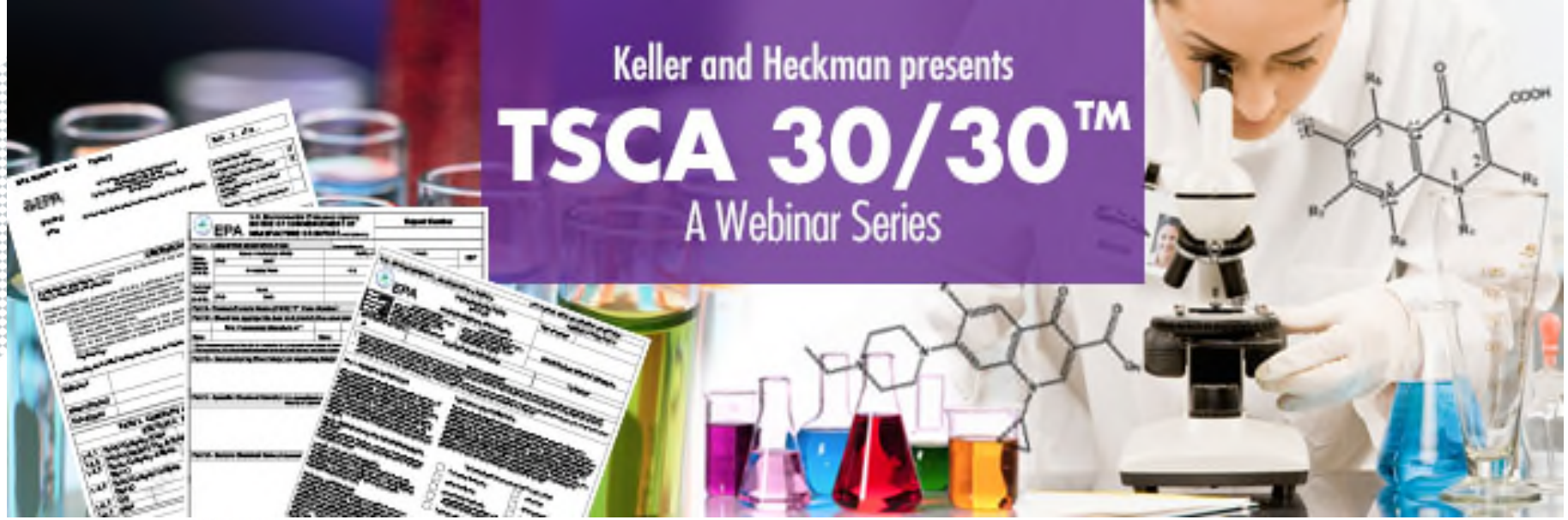


Keller & Heckman

BIDEN EPA INITIATIVES

March 23, 2022

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.

Tom Berger

- Tom Berger assists clients in bringing forth new products and maintaining the ability to market them in a cost-effective manner using an interdisciplinary approach that combines law and science, with an emphasis on emerging technologies in the industrial chemicals area

- Tom helps clients navigate the TSCA premanufacture notification (PMN) review process and negotiates the terms and conditions of TSCA section 5(e) orders and significant new use rules (SNUR). He also counsels clients on US Environmental Protection Agency (EPA) enforcement matters and assists companies in preparing for Agency inspections, responding to information requests and subpoenas, and defending enforcement actions. Tom is a recognized leader in designing and conducting extensive voluntary TSCA compliance audits (often as part of corporate mergers and acquisitions) and assisting clients in managing liability under EPA's “Audit Policy” and other available penalty mitigation policies

- Tom's practice is based on an in-depth understanding of the chemicals, plastics, and electronics industries, with over 25 years of experience counseling clients on the regulation and approval of new and existing chemicals under the Toxic Substances Control Act (TSCA) and TSCA’s international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. His technical background allows him to frequently undertake matters that involve polymers, inorganic chemistry, and complex chemistry and chemical nomenclature issues

- As an active member of the environmental and chemical industries, Tom was heavily involved in efforts to "reform" TSCA and works extensively on all aspects of TSCA, including TSCA Inventory, Inventory "reset," Chemical Data Reporting (CDR), and section 6 "fee" rule issues, as well as confidential business information (CBI), section 8 recordkeeping and reporting, and import/export issues

- Tom has a chemical engineering background and, prior to joining Keller and Heckman, worked as an engineer for a major international chemical manufacturer

James Votaw

- James Votaw has an extensive practice focusing on environmental and health and safety regulation. Within that arena, he concentrates on the regulation of conventional and nanoscale chemicals, pesticides, consumer and industrial products, and industrial processes and wastes.

- For his clients, James obtains pre-market product approvals and exemptions, including the first U.S. approval of a nanoscale pesticide. He negotiates testing orders, defends enforcement actions, advises on restrictions and disclosures associated with the chemical content of products, counsels on release and other environmental reporting, and supports environmental regulatory and liability aspects of commercial transactions (including, but not limited to regulatory due diligence and private label distribution arrangements). Further, he participates in technical rulemaking proceedings, provides strategic and regulatory compliance counseling within existing and emerging industries, initiates compliance training, conducts internal investigations, performs compliance auditing, offers facility permitting services, and develops product compliance plans and systems.

- James represents clients before State and Federal regulatory agencies and federal courts. He has extensive experience in compliance counseling on matters related to the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Clean Air (CAA) and Clean Water Acts (CWA); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); the Consumer Product Safety Commission (CPSC); California's Proposition 65; Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH); Restriction of Hazardous Substances (RoHS); and Waste Electrical and Electronics Equipment (WEEE).

Agenda

- Rescinding the 40-year-old Inventory Correction Process
- Biofuels Initiatives
- New Approach Methods (NAMs) toxicity and exposure testing

Closing the Window on TSCA Inventory Corrections

TSCA Inventory, Compilation Thereof

- Section 8(b) requires EPA to "*compile, keep current and publish a list of each chemical substance which is manufactured or processed in the United States*"
  - "Inventory" first issued in 1979 ("initial Inventory"), amended and reissued several times, now on EPA website and updated every year or so
- Initial Inventory compiled from reports submitted by industry for substances in commerce from 1/1/1975 to 6/30/1979
  - Depending on substance, certain forms, e.g., a "C form," used
    - "C forms" used for substances with no known CASRN and not on "Candidate List," or to assert chemical identity CBI
- Completed reporting forms contained little more than submitter identity, whether manufactured *vs*. imported, and information on chemical identity

Inventory Correction Policy

- On July 29, 1980, EPA issued procedures for correcting Inventory reporting errors (45 FR 50544)
  - Corrections must fall into one of three categories, be adequately documented
- Corrections described in fourth subsection of first category most common
- First category includes:
  - Corrections of typographical or transcriptional errors
  - Refinement of identity of reported substance (e.g., specifying location of substituent originally described as unspecified or unknown)
  - Identification of previously unidentified substance produced in association with material already reported (e.g., isomer)
  - Discovery that substance different from reported, e.g., determining that substance reported as "A" is "C," or that substance reported as "D" is mixture of "E" and "F."
- If/when correction request granted, corrected substance becomes retroactively added to Inventory

February 2022 Policy Revocation

- Feb. 25, 2022 (87 FR 10781), EPA publishes revocation of 1980 policy
  - EPA:
    - Companies have had ample opportunity to correct
    - Passage of time has made provision of substantiating records difficult
    - Possibility of ineligible correction requests being processed(?)
- Companies only have until **April 26, 2022** to make final requests to submit correction requests ("effective May 31")
  - Incomplete submissions "will be rejected"
  - PMN corrections cannot be made (after review period expires)
- After April 26, must submit PMN rather than remain on the market
- Agency reserving right to initiate corrections at its discretion

Issues – At Least *Some* of Them…

- No notice/comment, reliance
- No apparent consideration of alternatives (e.g., monomer acid, activated phosphor approach)
  - Will risk assessment be conducted?
- Insufficient time to prepare/submit requests
- Exclusion of PMN substances
  - What if PMN substance made from corrected initial Inventory substance?
- Process should be improved (perhaps even streamlined), not abolished
- Why now…?
  - Could have been part of reset
- Creates enormous litigation/enforcement risks

Biofuels Initiative: Streamlining TSCA New Chemicals Review

Streamlining Biofuels PMN Process

- EPA's New Chemicals Division (NCD) has implemented an initiative to streamline the PMN review of biofuel substitutes to petroleum-based fuels and fuel additives
- Supports goals under EPA's Renewable Fuel Standard (RFS) program, which aims to replace or reduce reliance on petroleum-based fuels
- NCD has assembled a dedicated team to collaborate on the review of PMNs for biobased or waste-derived feedstocks, developed a standardized process to review biofuel PMNs, and the same dedicated team will be conducting reviews for all biofuels
- NCD will generate one report for biofuels PMNs that combines the six different risk assessments typically conducted for PMNs
- NCD will use standardized 5 (e) Consent Orders and SNURs

Outreach and Training

- NCD is launching outreach and training for interested stakeholders in the biofuels sector
- The training will review TSCA requirements, outline the streamlined approaches for risk assessments and risk management actions, and provide information on how to navigate the new chemicals PMN process
- Kick-off meeting held on February 9, 2022. Two other meetings were held
- Next meetings March 23, 2022, and April 6, 2022

Mixed Reaction from NGOs

- EDF comments
- EDF has a strong interest in climate change mitigation
- Encouraged by EPA's plans to streamline reviews for biofuel PMNs
- However, important that these efforts not ignore the environmental consequences of sourcing certain biomass or come at the expense of chemical safety

Impediments to Achieving the Objective

- Narrowness of the Naturally Occurring Exemption
- Nomenclature Challenges
- Distillation cuts issue
- Biofuels containing trace toxicants found in petroleum-based fuels

New Approach Methods (NAMs) Toxicity and Exposure Testing

NAMs Definition

- **“New Approach Methods” (NAMs)**
  - Any technology, methodology, or approach that can be used to provide information on chemical hazard and risk that avoids the use of intact animals
- **Examples**
  - In vitro tests assays (use human or animal cells)
  - Computational predictive tools (quantitative structural activity relationships)(QSARs)
  - “Read across” methods using info from structurally similar chemicals
  - Waivers – skip test where the result not needed to reach a regulatory decision

Policy to Reduce Vertebrate Animal Testing

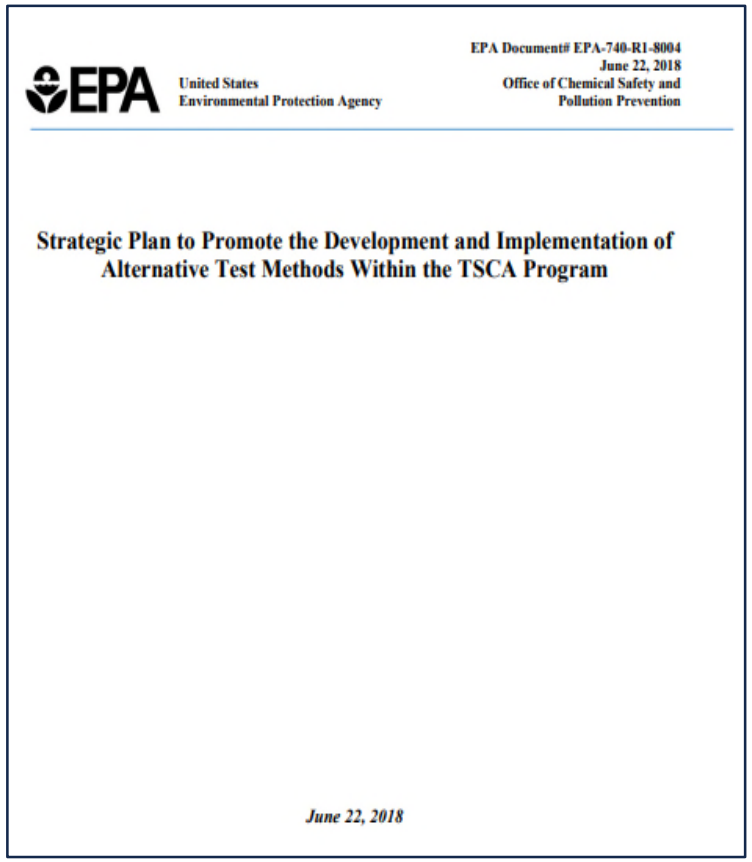
- **Several concerns drive the policy**
  - Vertebrate animal welfare
  - Long data development time frames relative to decision-making needs
  - Cost
  - Uncertain predictive value (variable results, relevance to humans)
- **Some key issues**
  - Validation – reliably predictive, relevant to humans
  - Drop-in replacements may not be available
  - Extent of acceptable uncertainty
  - Public/Scientific Confidence/Acceptance

TSCA § 4(h): Reduce Vertebrate Animal Testing

- **2016 Lautenberg Act Amendments Directive**
  - EPA "shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures…"

1. **Must consider sufficiency of non-animal testing options before ordering vertebrate animal testing**
   - Existing toxicity information (e.g., read across),
   - Computational toxicology and bioinformatics, and
   - High-throughput screening methods and prediction tools
2. **Encourage use of valid methods equivalent or better scientific quality and relevance that will support regulatory decisions**
3. **Prepare strategic plan to develop NAMs & put into practice**

Strategic Plan: Reduce Vertebrate Animal Testing



EPA Document# EPA-740-R1-8004
June 22, 2018
Office of Chemical Safety and Pollution Prevention

United States Environmental Protection Agency

Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program

June 22, 2018

- **2018 Initial Strategic Plan**
  - Maintain and regularly update a list of NAMs
  - Identify most needed study types for TSCA
  - Identify and curate available existing TSCA information on NAMs
  - Develop Scientific Information Technology Platforms
  - Identify NAMs for further development
  - Identify appropriate NAMs research needs of importance to TSCA
  - Outreach & education – encourage us and acceptance
- **2019 Admn. Wheeler Directive:**
  - 2025: Reduce mammal study requests/funding by 30%
  - 2035: Eliminate them

December 2021 – Updated NAMs Work Plan

- **Update to 2020 Work Plan**
  - Consistent substantive milestones/deliverables
  - Eliminate 2025/2035 deadlines of Wheeler Directive
  - Generally, extend ETA of individual deliverables by 1-2 years

December 2021 – Updated NAMs Work Plan

Determine legal/regulatory /policy restraints on use of NAMs for decision-making	2022
Inventory traditional animal testing as baseline for measuring progress	Q4 2022
Establish Scientific confidence in NAMs and demonstrate applicability to regulatory decisions • NAS study comparing variability/relevance of existing animal methods vs NAMS validation frameworks • Validation framework for NAMs • Standard reporting templates for NAMs • Case studies	2023-24
Develop NAMS to fill important information gaps: Step 1 Strategic Research Plans	Q1 2023
Engage and communicate with stake holders: Pilot training program	Q4 2023

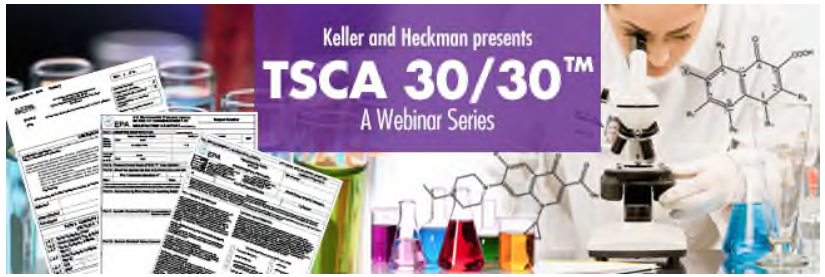
New Chemicals Collaborative Research Program

- **Problem**: How to conduct quality, fit-for-purpose, new chemical risk reviews for chemicals before they enter commerce:
  - In a data poor evaluation environment
  - Completed within short statutory deadlines (90 days)
- **New Collaboration: EPA Office of R&D + EPA New Chemicals Division**
  - Multi year research program
  - More & better NAMs are important part of the answer
  - Action Plan for public comment
    - 87 FR 10784 (Feb.25, 2022)
    - Public meeting April 20-21
    - Comments due April 26

Action Plan for Public Comment

- Update and Refine Chemical Categories
- Develop and Expand Databases Containing TSCA Chemical Information
- Develop and Refine QSAR and Predictive Models:
  - Physical-Chemical Properties,
  - Environmental Fate/Transport,
  - Hazard,
  - Exposure, and
  - Toxicokinetics
- Methods to integrate and Apply NAMs in New Chemical Assessments
- Develop a TSCA New Chemicals Decision Support Tool to integrate data streams

Please join us at 1:35 PM Eastern US
Wednesday, June 8, 2022
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern US
Wednesday, May 11, 2022
www.khlaw.com/TSCA-3030

Please join us at 1:00 PM Eastern US
Wednesday, April 20, 2022
www.khlaw.com/OSHA3030

Thank You

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