Industry Engagement With the New TSCA

August 14, 2019

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KELLER AND HECKMAN LLP
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Herbert Estreicher, Ph.D.

Herbert Estreicher, Ph.D. has a broad practice in international environmental regulatory law.

Dr. Estreicher has an interdisciplinary approach combining law and science. He represents leading manufacturers of chemicals, pesticides, insect repellents, food additives, and consumer products before Federal and State regulatory agencies.

Dr. Estreicher provides advice on product liability risk control and assists clients with crisis management for embattled products, including chlorinated pesticides, wood preservatives, dioxins, and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on responding to the CEPA challenge program, and provides advice on European chemical directives and initiatives, such as the EU Biocidal Products Directive, the Classification, Labelling and Packaging Regulation, the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, and the Prior Informed Consent (PIC) Regulation. Dr. Estreicher also represents clients in the negotiation and development of various international environmental instruments governing persistent organic pollutants (POPs), has been actively involved in the Great Lakes Binational Toxics Strategy, and has participated in the Canadian Strategic Options Process (SOP). He is actively engaged in the areas of TSCA Reform and the California Green Chemistry Initiative. His extensive background in organic chemistry, risk assessment and bioengineering is valued highly by clients in the chemical, nanotechnology, and biotechnology industries.

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Agenda

- Manufacturer-Requested Risk Evaluations under TSCA Section 6
- Prioritization Candidates
- CBI Proposals

Manufacturer-Requested Risk Evaluations under TSCA Section 6

- TSCA section 6(b)(4)(C) directs EPA to establish the “form and manner” and “criteria” that govern manufacturer requests that EPA conduct a risk evaluation on a substance that they manufacture/ import.
- EPA must grant any request if it determines that it complies with EPA's criteria, until the statutory minimum of 25 percent of all on-going high priority risk evaluations has been met.
- Assuming EPA receives requests in excess of this threshold, EPA has discretion to determine whether to grant further requests, up to the maximum 50 percent of all on-going high priority risk evaluations.
- In such circumstances, EPA is directed to give preference to manufacturer requests for which EPA determines that restrictions imposed by one or more states have the potential to significantly impact interstate commerce, or health or the environment.
- Any manufacturer-requested risk evaluations for substances on the 2014 update of the TSCA Work Plan (Ref. 2) is discretionary and exempt from the percentage limitations.

Manufacturer-Requested Risk Evaluations (2)

- The Regulations governing manufacturer-requested risk evaluations are codified at 40 CFR 702.31.
- A manufacturer may request that EPA conduct a risk evaluation for conditions of use of interest to the manufacturer.
- Within 60 days of the receipt of a facially complete request, EPA is required to submit the request for publication in the Federal Register, open a docket, and provide a public comment period of no less than 45 days.
- After the comment period closes the Agency has 60 days to either grant or deny the request.
- It is anticipated that manufacturer-requested risk evaluations will comprise between 1/5th to 1/3rd of all on-going risk evaluations.
- Manufacturers making the request pay a fee of $1.3 MM deposit.
- The fees to be collected from manufacturer-requested risk evaluations are hoped to be a major portion of the funds available to EPA to fund the Risk Evaluation program.

Manufacturer-Requested Risk Evaluations (3)

- The request must include a list of all existing relevant information on the substance and it's uses that are part of the request.
- The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the uses identified by the manufacturer(s).
- The request need not include copies of the information; citations are sufficient, if the information is publicly available.
- The request must include or reference all available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the uses.

Incentives for Manufacturers

- Preemption
- No Preemption Pause

Requests Received

- On May 24, 2019, EPA received a request to conduct a risk evaluation for diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP).
- Both were identified in the 2014 Update to the TSCA Work Plan.

DIDP

- Request that the following uses be evaluated:
  - DIDP Manufacturing
  - DIDP use as a general purpose plasticizer for PVC used in the following applications;
  - Building and construction – electrical wire coating, vinyl tiles, resilient flooring, PVC-backed carpeting, wall coverings, roofing, etc.
  - Automotive – upholstery and interior finishes, window glazing, body-side molding, automotive undercoating, molded interior applications, insulation for wire and cable and wire harnesses.
  - Other consumer applications – flexible tubes, hoses, profiles, etc.
  - Non-PVC applications – inks, adhesives, sealants and paints, synthetic lubricants and engine oils.
  - Use in PVC for children's toys and childcare articles

Existing DIDP Risk Evaluations

- US CPSC's Chronic Hazard Advisory Panel (CHAP) (2014)
- European Union (2003 and 2013)
- Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2015)
- Environment Canada and Health Canada (2015)
- 31 Pages of Citations Submitted

NGO Reaction

- Two US NGOs have called the request for EPA risk evaluation of DINP and DIDP an attempt to “circumvent state-level regulation of the substances.”
- “This is an apparent attempt at an end run around state action on these chemicals, such as a Maine statute, signed into law on June 13, which would protect children and families from these health-harming chemicals. If EPA takes action, it would block health protective policies from being enacted in other states.” https://www.ourhealthyfuture.org/media/states-act-against-toxic-chemicals-products-and-packaging%C2%A0exxonmobil-and-chemical-industry

Prioritization Candidates

High Priority Candidates

- NGO submitted comments on all 20 high priority candidates.
- Industry trades commented
- Only a few companies commented
- One trade argued that EPA should not exclude uses in order not to defeat Federal pre-emption

Low Priority Candidates

Chemical Name	Docket Number/Comments
1-Butanol, 3-methoxy-, 1-acetate	EPA-HQ-OPPT-2019-0106 0
D-gluco-Heptonic acid, sodium salt (1:1), (2.xi.)-	EPA-HQ-OPPT-2019-0107 1 non-sub
D-Gluconic acid	EPA-HQ-OPPT-2019-0108 0
D-Gluconic acid, calcium salt (2:1)	EPA-HQ-OPPT-2019-0109 0
D-Gluconic acid, .delta.-lactone	EPA-HQ-OPPT-2019-0110 0
D-Gluconic acid, potassium salt (1:1)	EPA-HQ-OPPT-2019-0111 0
D-Gluconic acid, sodium salt (1:1)	EPA-HQ-OPPT-2019-0112 0
Decanedioic acid, 1,10-dibutyl ester	EPA-HQ-OPPT-2019-0113 0
1-Docosanol	EPA-HQ-OPPT-2019-0114 0
1-Eicosanol	EPA-HQ-OPPT-2019-0115 0
1,2-Hexanediol	EPA-HQ-OPPT-2019-0116 0
1-Octadecanol	EPA-HQ-OPPT-2019-0117 0
Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-	EPA-HQ-OPPT-2019-0118 1 - CIR
ropanedioic acid, 1,3-diethyl ester	EPA-HQ-OPPT-2019-0119 0
Propanedioic acid, 1,3-dimethyl ester	EPA-HQ-OPPT-2019-0120 0
Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate	EPA-HQ-OPPT-2019-0121 1 - CIR
Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-	EPA-HQ-OPPT-2019-0122 1 - CIR
2-Propanol, 1,1'-oxybis-	EPA-HQ-OPPT-2019-0123 0
Propanol, oxybis-	EPA-HQ-OPPT-2019-0124 8 Pages/w Refer
Tetracosane, 2,6,10,15,19,23-hexamethyl-	EPA-HQ-OPPT-2019-0125 0

CBI Proposals

CBI Notices of Deficiency

- On July 16, 2019 EPA announced in the Federal Register that:
  - Beginning on August 15, 2019, EPA will no longer send notices of deficiency to businesses whose submissions do not meet all the statutory requirements.
  - Instead, the Agency will provide written notice to affected business submitters that because they submitted procedurally flawed CBI claims, including unsubstantiated CBI claims, those CBI claims are invalid, and the underlying information is not protected from disclosure under TSCA Section 14.
  - Comments not accepted on the EPA announcement.

Industry Reaction

- SOCMA – EPA should rethink this proposal.
- According to the trade press ACC stated:

  > While it would be preferable for the EPA to continue to send out these advance notices, "we understand that doing so is not statutorily mandated.“

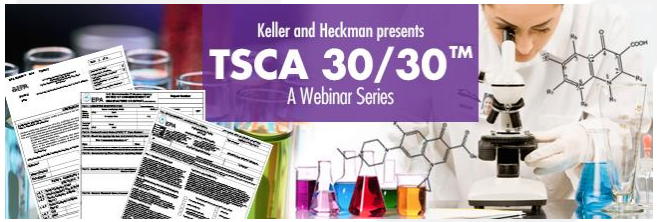
- Comparison to NGO lobbying efforts.

What Next?

- If EPA denies a CBI claim it must
  - Provide written notice
  - Not disclose for 30 days after notice is received.
- Claimant may appeal the denial in the (1) U.S. district court where the claimant resides or has its principal place of business; or (II) the D.C. circuit.
- Disclosure is stayed until appeal is decided.

FINAL THOUGHTS

Please join us at 1:00 PM Eastern U.S.
Wednesday, August 21, 2019
www.khlaw.com/TSCA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, September 11, 2019
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The Next TSCA 30/30:
Wednesday, September 11, 2019

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THANK YOU

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