Anatomy of a TSCA Problem Formulation Document: The Case of NMP

July 11, 2018

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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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Javaneh Nekoomaram is an associate in the environmental and workplace safety and health (OSHA) practice groups at Keller and Heckman.

Ms. Nekoomaram practices in all areas of environmental law as well as occupational health and safety law, and chemical control law. She routinely advises clients on a broad range of environmental health and safety compliance issues.

Prior to joining Keller and Heckman, Ms. Nekoomaram served for three years as Counsel for the American Coatings Association where she was responsible for the association's Occupational Health and Safety, Product Stewardship, and Environmental Management Committees. She provided regulatory compliance and advocacy on a number of issues on behalf of the coatings industry including TSCA, Prop 65, hazard communication and labeling, state chemical regulation, hazardous waste, air and water quality, occupational health and safety, and chemical safety regulations. She also served as Advocacy Counsel for the Graffiti Resource Council, an organization supported by the aerosol coatings industry that provides anti-graffiti strategies for cities across the country.

While in law school, Ms. Nekoomaram was a member of the Dean's Tutorial Society and the Order of the Barristers, and participated in the National Health Law Moot Court Competition and the Wagner National Labor and Employment Law Moot Court Competition.

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Agenda

- EPA's recent release of problem formulation documents for the first 10 chemicals to undergo risk evaluation
- The problem formulation document for NMP
- What the problem formulation document tells us about EPA's likely focus in the NMP risk evaluation
- Opportunities for industry to influence the outcome

Components of a TSCA Sec. 6 Risk Evaluation

- **Scope of the Risk Evaluation** – includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations EPA expects to consider. The scope will also include:
  - A **Conceptual Model**, which will describe the relationships between the chemical, the conditions of use, and human and environment exposure and risk.
  - An **Analysis Plan**, which will identify the approaches and methods EPA intends to use to assess exposures and hazards.
- **Draft Scope** is published in the Federal Register no later than 3 months from the initiation of the risk evaluation process and a 45-day public comment period is provided.

Components of a TSCA Sec. 6 Risk Evaluation (2)

- **Final Scope** is published no later than 6 months after initiation of the risk evaluation, as required by the law.
- **Hazard assessment; exposure assessment; risk characterization; risk determination**
- Conditions of use determined to present an unreasonable risk will move immediately into risk management.
- **Draft risk evaluation** is peer reviewed and a 60-day public comment period is provided.
- **Final risk evaluation** is published no later than 3 to 3.5 years after identification of the chemical as a high priority for risk evaluation.

Process for First 10 Chemicals

- Because TSCA only allowed EPA 6 months from the time it identified the first 10 chemicals to finalize the scoping documents, EPA did not release draft scopes for public consultation.
- Instead, it issued the scopes in “preliminary” final form in June 2017.
- Although not open to formal notice and comment, EPA did receive comments that:
  - the scopes were not as robust as required under TSCA; and
  - EPA should incorporate systematic review principles in conducting risk evaluation.
- In response, EPA agreed to issue Problem Formulation Documents to refine the Scopes. EPA also decided to release an “Application of Systematic Review in TSCA Risk Evaluations” document for public comment.

Ten Problem Formulation Documents

- Formal notice of the availability of problem formulation documents for the first 10 chemicals and the Systematic Review strategy was published in the Federal Register on June 11, 2018. FR 12520.
- Comments are due by **July 26, 2018**.
- General observations – EPA clarified
  - It does not intend to evaluate exposure routes it considers adequately regulated under other laws. For example, the ozone depletion potential of carbon tetrachloride, methylene chloride and 1-bromopropane (1-BP) will not be evaluated because these risks are "adequately assessed and effectively managed under the Clean Air Act (CAA)".
  - It does not intend to evaluate legacy uses (Asbestos).
  - Certain consumer uses of several chemicals are considered insignificant and will not be evaluated, such as:
    - consumer exposures to 1,4-dioxane;
    - carbon tetrachloride in cleaners and degreasers intended for consumer use; and
    - consumer exposures of 1-BP in degreasers for engine care.

NMP Problem Formulation Document

- Docket: EPA-HQ-OPPT-2016-0743
- Also at https://www.epa.gov/sites/production/files/2018-06/documents/nmp_pf_05-31-18.pdf
- EPA decided that all conditions of use identified in the NMP Scope document will be evaluated.
- Uses assessed in the 2015 NMP risk assessment are to be re-evaluated by applying the standards and guidance provided under amended TSCA, notably the scientific standards in Section 26 of TSCA, the Risk Evaluation Framework Rule (40 CFR Part 702) and EPA's Application of Systematic Review in TSCA Risk Evaluations document.
- This signals that the Obama era Section 6(a) proposed rules for use of NMP in commercial and consumer paint and coating removal (82 FR 7464) will likely not be finalized even though EPA states: "It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed NMP regulation."

NMP Uses

- Based on CDR data NMP is an important chemical with annual production of 160 million plus pounds.
- 3 of the largest uses are paints and coatings; solvents for cleaning and degreasing; and ink, toner and colorant products.
- There are a number of important minor uses.

NMP Uses EPA Plans to Evaluate

- **Paints and coatings**
- **Solvents for cleaning and degreasing**
- **Ink, toner, and colorant products**
- **Processing aids specific to petroleum production** including extraction of aromatic hydrocarbons from lube oils; separation and recovery of aromatic hydrocarbons from mixed hydrocarbon feedstocks; recovery of acetylenes, olefins and diolefins; removal of sulfur compounds from natural gas and refinery gases; and dehydration of natural gas.
- **Adhesives and sealants**
- **Reaction medium for polymerization reactions** including in the synthesis of polyvinyl acetate, polyvinyl fluoride, polystyrene, nylon, polyimides, polyesters, acrylics, polycarbonates and synthetic elastomers. EPA notes that some polymer-based resin and coating formulations, such as polyurethane dispersions, will include NMP in the final formulation.
- **Textiles and clothing**. EPA notes that although NMP has been found in textiles, EPA has not identified information specific to the use of NMP in the textile industry.
- **Lithium ion battery manufacturing**
- Although EPA mentions use as of NMP as a solvent and extraction medium for the manufacture and formulation of pharmaceuticals, this use is outside of TSCA's jurisdiction.

Some Preliminary Human Exposure Observations

- EPA will use occupational exposure data available from OSHA's Chemical Exposure Health Data (CEHD) and the NIOSH Health Hazard Evaluation (HHE) program data.
- EPA expects dermal exposure to be a significant route of exposure for consumers and bystanders.
- EPA believes there is a potential for inhalation exposure to consumers and bystanders during heating or spray application of products that contain NMP.
- Also a potential for oral exposure to consumers from contact with NMP-containing products via hand-to-mouth activity. Incidental ingestion may be important during use of formulations, products or other articles that contain NMP (*e.g.*, children's toys, arts and crafts kits, games, bedding, textiles, and kitchenware).

Some Preliminary Environmental Exposure Assumptions

- Most (> 90%) of the NMP releases to wastewater will be removed by biodegradation.
- Negligible (< 1%) removal of NMP via adsorption to sludge or volatilization to air.
- Volatilization from surface water is unlikely to be a significant removal pathway for NMP.
- Aerobic biodegradation is expected to be the primary removal pathway for NMP in many surface water environments but is not expected to be rapid.
- NMP exhibits low potential for bioaccumulation in the environment and is not expected to bioaccumulate or bioconcentrate in aquatic organisms.
- Focus on environmental exposure is likely to be the surface water pathway.
- Based on 2015 TRI data, 386 facilities reported **a total of 78.8 million pounds of NMP waste managed.** Of this total, only **0.2% (~14,000 pounds) were discharged to water.**
- **The "high-end" surface water concentrations based on modeling ranged from 224 µg/L to 0.00005 µg/L, for the acute and chronic exposure scenario, respectively. The maximum acute scenario concentration was 224 µg/L and the maximum chronic scenario concentration was 11 µg/L.**

Other Exposure Assumptions

- **Potentially Exposed and Susceptible Subpopulations**
  - Workers and occupational non-users.
  - Consumers and bystanders associated with consumer use.
  - Individuals who live or work near manufacturing, processing, use or disposal sites.
- Safe Drinking Water Act (SDWA) and the Resource Conservation and Recovery Act (RCRA) regulation to play an important role in eliminating concern for exposures from drinking water and disposal pathways.
- OSHA or CPSC regulation likely to be downplayed.

Final Thoughts

- Problem formulation document is much more developed than the scoping document
- Hazard information seems robust
- Human exposure likely to drive the risk assessment
- Exposure to consumers and particularly children from some uses will be important
- Key gaps are a good understanding of potential occupational, bystander and consumer exposure from minor but important uses of NMP
- Not much time left to comment but if you care about minor uses, then you should weigh in

Please join us at 1:00 PM Eastern U.S.
Wednesday, July 25, 2018
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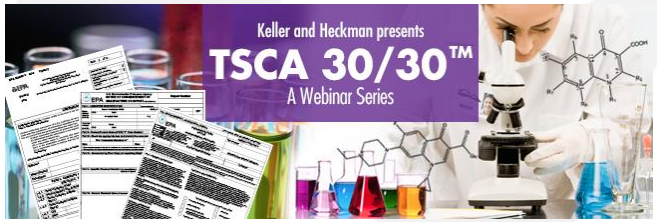

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THANK YOU

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