



Section 6(g): Critical-Use Exemptions and More

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Herb Estreicher

- ◆ Herbert (Herb) Estreicher is a prominent environmental lawyer who holds a Ph.D. in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). 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.



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.



TSCA Section 6(g) (1)

- ◆ EPA **may**, as part of a final Section 6(a) rule, **or in a separate rule**, grant an exemption, if EPA finds that—
 - (1) the specific condition of use is a **critical or essential use** for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or
 - (2) compliance with the requirement would **significantly disrupt** the national economy, national security, or critical infrastructure; or
 - (3) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a **substantial benefit to health, the environment, or public safety**

TSCA Section 6(g) (2)

- ◆ **In proposing an exemption**, EPA must analyze the need for the exemption, and publish the analysis along with a statement describing how the analysis was considered
- ◆ Time-limited exemption, but can be renewed
- ◆ The exemption must include conditions necessary to protect health and the environment while achieving the purposes of the exemption

Exemption Conditions

- ◆ What constitutes a critical or essential use? Critical or essential to whom? A company? An industry? To society?
- ◆ What constitutes a “significant” disruption of the national economy, national security, or critical infrastructure?
- ◆ What constitutes a “substantial benefit” to health, the environment, or public safety?
- ◆ Note, EPA has discretion as to whether to issue an exemption
- ◆ If it does, then the grant of the exemption would be subject to judicial review

Ruminations on Critical or Essential Use (1)



- ◆ Term has its origin under the Montreal Protocol on Substances that Deplete the Ozone Layer
- ◆ The EU is struggling with this concept to decide what exemptions to allow in restrictions

<https://op.europa.eu/en/publication-detail/-/publication/69d5ea0d-d359-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-283635189>

Ruminations on Critical or Essential Use (2)



- ◆ The Montreal Protocol Decision IV/25, paragraph 1, states that a use of a controlled substance should qualify as ‘essential’ only if it meets the following criteria
- ◆ The use is:
 - ◇ Necessary for health, safety AND/OR critical for the functioning of society
 - ◇ AND there are no available technically and economically feasible-alternatives or substitutes that are acceptable from the standpoint of environment and health
- ◆ Decision IV/25 specifies that the ‘functioning of society’ encompasses cultural and intellectual aspects

Grounds for Exemptions will be Developed Case-by-Case



- ◆ EPA has issued no guidance on the circumstances where it would grant an exemption
- ◆ Industries' June 2020 APA petition argued that EPA should codify the Critical or Essential Use Exemption and establish procedures for routine consideration of these exemptions and argued that:
 - ◇ EPA should discuss the factors the agency will consider when determining whether to invoke this authority
 - ◇ This explanation will inform affected stakeholders of the type of information that EPA needs when deciding whether to issue an exemption
 - ◇ EPA's procedural rule should provide illustrative examples of when the agency would grant or refuse to issue an exemption under this provision
- ◆ No action by EPA to date

Asbestos Risk Management Proposed Rule



- ◆ EPA did not propose to grant an exemption from the rule requirements
- ◆ EPA was aware that chlor-alkali chemicals are used in sectors important to the national economy and operation of critical infrastructure to protect human health, for uses such as drinking water treatment
- ◆ EPA requested public comment regarding the need and rationale for a Section 6(g) exemption
- ◆ The alternative for use in the chloro-alkali industry is for EPA to set a reasonable transition period (but can be no longer than 5 years)
- ◆ To that end, EPA solicited comments on among other things the specific and detailed timelines to build asbestos-free facilities or to convert existing asbestos-using facilities to asbestos-free technology, and the availability of asbestos-free technology

Methylene Chloride Risk Management Proposed Rule



- ◆ EPA proposes to provide a ten-year time-limited 6(g) exemption from the prohibition of the use of methylene chloride (MC) for paint and coating removal in civilian aviation with conditions for this exemption to include compliance with the ECEL; and
- ◆ Provide a ten-year time-limited 6(g) exemption under TSCA section 6(g) for emergency use of MC by NASA which are critical or essential and, for which no technically and economically feasible safer alternative is available, with conditions for this exemption to include compliance with the ECEL to the extent technically feasible considering the particular emergency

Some Industries Sought Early Consideration of 6(g) Exemptions



- ◆ Lithium-Ion Cell Manufacturers' Coalition requested a 6(g) exemption for the use of NMP in lithium battery production
- ◆ EaglePicher Technologies sought an exemption for the use of NMP to manufacture specialized batteries for military, space and medical applications
- ◆ Entek sought an exemption for use of TCE in the manufacture of lithium-ion battery separators
- ◆ Viant sought an exemption for use of TCE in open top vapor degreasing in the manufacture of medical devices

Is There Another Approach?

- ◆ Enforcement Discretion?
- ◆ On April 20, 2023, OCSPP requested an Enforcement Statement from EPA's Office of Enforcement and Compliance Assurance to allow the continued use of Decabromodiphenyl Ether (DecaBDE) containing wire and cable insulation in Nuclear Power Generation Facilities
- ◆ The compliance date was January 6, 2023
- ◆ EPA recently learned that alternative insulation is several years away from being qualified with the NRC
- ◆ The Enforcement Discretion is sought to allow EPA time to issue a rule to extend the effective date of the rule
- ◆ No discussion of a 6(g) rulemaking so far

What to Consider When Submitting a TSCA 6(g) Exemption Request (1)



- ◆ Meet with EPA to discuss a potential 6(g) exemption and to present your rationale for the request based on any or all 6(g)(1)(A)-(C) criteria
- ◆ Seek EPA concurrence as to the type of information that should accompany your subsequent 6(g) submission
- ◆ The submission should clearly indicate and support the appropriate the 6(g)(1)(A)-(C) criteria

What to Consider When Submitting a TSCA 6(g) Exemption Request (2)



- ◆ Discuss in some detail the specific COU
 - ◇ Is the COU a critical and/or essential use?
 - Is there a technically, economically, and feasibly available safer alternative?
 - ◇ What are the national economic, national security, and/or critical infrastructure attributes?

What to Consider When Submitting a TSCA 6(g) Exemption Request (3)



- ◇ Are there reasonably available alternatives?
 - Any substantial benefits to health, environment, or public safety of the chemical relative to the available alternatives?
 - If no reasonably available alternatives, what are the potential/prospective alternatives?
 - What is your experience if any with any potential alternatives?
 - Pros/cons and timeframe to fully adopt an alternative?
 - Ask for a reasonable time limitation (e.g., 10 years vs. 20 years)
 - You can always seek an extension to the time limitation

OMB Review of 6(g) Exemptions

- ◆ OMB should review the 6(g) exemption request that is part of the EPA's proposed 6(a) risk management rulemaking under EO 12866
 - ◇ This is another reason to submit your exemption request in ample time for EPA to include it in a 6(a) rulemaking
- ◆ But what if EPA proposes a separate 6(g) rule to address exemption requests?
 - ◇ OMB review should occur if the criteria under EO 12866 for “significant regulatory actions” are met
- ◆ Final consideration: if you can address the unreasonable risk, then under what authority can EPA impose a time limitation?



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Thank You



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