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ALERT

Companies Must Prepare Now for the Inevitable Litigation Over EPA's Final TSCA Risk Evaluations and Risk Management Rules

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As the U.S. Environmental Protection Agency (EPA or Agency) expects to complete its first ten risk evaluations under the Toxic Substances Control Act (TSCA) by the end of the summer, companies must start taking actions to prepare for the inevitable litigation over the evaluations and their corresponding risk management rules. Specifically, now is the time to be thinking about how to best build the administrative record to challenge or support EPA's final actions. Failure to take these steps may cause your company to waive important arguments in litigation.

This alert highlights the specific areas where companies should be building the administrative record in anticipation of the inevitable litigation. They include:

- Ensuring that EPA's proposed prohibition, restriction, or requirement is necessary to address the identified unreasonable risk of a chemical substance;
- Providing information to EPA on the effect of its proposed rule on the national economy, small businesses, technological innovation, the environment, and public health, in addition to informing EPA's general costs and benefits analysis; and
- Engaging EPA on potential exemptions for replacement parts, articles, and critical or essential uses.

Because these actions take time to develop, we strongly recommend companies start preparing the requisite information as soon as possible. To learn more about how to build a robust record in anticipation of litigation, please contact Erik Baptist.

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Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

The Timing of Litigation

TSCA establishes clear rules for when EPA can be sued over a final risk evaluation. If EPA's final risk evaluation finds that a chemical substance does not present an unreasonable risk, the agency must issue an order, and that order represents the final agency action. Conversely, if EPA's risk evaluation finds an unreasonable risk, the agency must first proceed to a risk management rulemaking, and only after EPA has published the final risk management rule, shall the entire risk evaluation process and rulemaking be considered a final agency action and ripe for legal review. EPA has taken the position that it can issue a final order for the conditions of use that do not present an unreasonable risk while sending the conditions of use that present an unreasonable risk to risk management—essentially bifurcating the timing of litigation for a particular chemical substance.

This article focuses on when EPA has found an unreasonable risk because there is currently much more opportunity to build the administrative record and shape the ultimate outcome during the risk management stage than the risk evaluation process (given EPA's anticipated timing to finish its evaluations in the next few months).

Judicial Review Standard

Section 19 of TSCA sets forth the judicial standard of review for a TSCA section 6 action. Specifically, when reviewing an EPA risk management rule under TSCA section 6(a), including the underlying risk evaluation, a court must hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole.

Simply put, the court will review the risk management rule as well as the associated risk evaluation. Further, EPA's risk management rule needs to be supported by substantial evidence—not just a preponderance of the evidence, a standard found in many other administrative law challenges, including litigation under TSCA section 21, the citizens' petition provision.

The court must also evaluate the evidence in the rulemaking record—taken as a whole. This means that the court will evaluate everything EPA has considered and the public has submitted into the administrative record for both the underlying risk evaluation and the subsequent risk management rulemaking. For these reasons, establishing the risk management rulemaking record is vitally important when anticipating potential litigation.

The Timing of Risk Management Rules

In general, EPA must propose a risk management rule under TSCA section 6(a) for a chemical substance that presents an unreasonable risk no later than one year after publication of that chemical's final risk evaluation. EPA must also generally publish a final rule not later than two years after the agency published the final risk evaluation. Notably, EPA may extend the deadlines of these risk management proposals and final rules for not more than two years, if the aggregate length of extensions (including any needed for the underlying risk evaluation) does not exceed two years. Because EPA has needed at least a six-month extension for the first 10

chemicals, the agency will not be able to extend the deadlines for the risk management actions for the full two years.

Risk Management Options Available to EPA

Under TSCA section 6(a), if EPA finds that a chemical substance or mixture presents an unreasonable risk of injury to human health or the environment, the Agency shall issue a rule that applies one or more of the following requirements to the substance or mixture(s) to the extent necessary so that the chemical substance no longer presents such risk:

- Prohibit or otherwise restrict the chemical or limit the amount of the chemical;
- Prohibit or otherwise restrict the chemical for a particular use or a particular use in a concentration in excess of a specified level;
- Require that a chemical or any article containing that chemical be marked with or accompanied by clear and adequate minimum warnings and instructions;
- Require that manufacturers and processors of a chemical make and maintain records of the processes used to manufacture or process the chemical, or monitor or conduct reasonable and necessary tests to assure compliance;
- Prohibit or otherwise regulate any manner or method of commercial use of such chemical; and
- Prohibit or otherwise regulate any manner or method of disposal of such chemical or any article containing such chemical.

As exemplified above, EPA possesses many options at its disposal to address an unreasonable risk, short of an outright prohibition. Therefore, EPA should work through these options in a stepwise manner to explain whether they would or would not address the identified unreasonable risk. It will assist the Agency in developing a legally and scientifically defensible risk management rule and give stakeholders consistency and transparency into EPA's risk management decisions.

Importantly, since the Lautenberg amendments of 2016, EPA must now regulate only "to the extent necessary" and nothing more. The agency will, therefore, need to show with substantial evidence in the administrative record why a particular prohibition, restriction, or requirement is necessary to address the identified unreasonable risk.

Statement of Effects

Under TSCA section 6(c)(2), EPA must consider and publish a "Statement of Effects" based on reasonably available information with respect to:

- The effects of the chemical substance or mixture on health or the environment and the magnitude of the exposure of human beings and on the environment to the chemical substance or mixture;

- The benefits of the chemical substance or mixture for various uses; and
- The reasonably ascertainable economic consequences of the rule, including consideration of:
  - The likely effect of the rule on the national economy, small businesses, technological innovation, the environment, and public health;
  - The costs and benefits of the proposed regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator; and
  - The cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator.

Moreover, based on the Statement of Effects, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use(s) proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA will publish its Statement of Effects when the agency issues a proposed risk management rule, likely giving stakeholders only 45-60 days to respond to everything in that rulemaking, including the Statement of Effects. Therefore, we strongly encourage stakeholders subject to a risk management rule to engage EPA early and often.

Waiting until EPA issues a proposed rule may be too late for effective advocacy. Through our experience, we know that once EPA has chosen its preferred regulatory option, it is very difficult to convince the Agency to change course. Stakeholders should be generating and developing the data to support such an effects finding—with a goal of submitting it to EPA before it issues its proposal. It can mean the difference between being able to continue using a chemical in safe manner and an outright ban.

Exemptions for Replacement Parts and Articles

TSCA explicitly permits and oftentimes requires exemptions for section 6 risk management rules. Section 6(c)(2), for example, has exemptions for replacement parts and articles. Before EPA can include them in a risk management rule, EPA needs to specifically find that they contribute significantly to the identified risk or are necessary to be regulated:

- For replacement parts, EPA must exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication of the risk management rule, unless EPA finds that such replacement parts contribute significantly to the risk identified in the underlying risk evaluation.
- For articles, when selecting among prohibitions and other restrictions, EPA shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture

only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the chemical does not present the unreasonable risk identified in the risk evaluation.

If EPA has determined that a chemical your company manufactures or uses presents an unreasonable risk, you will want to analyze the final risk evaluation to see if one of these exceptions should or could apply. And if so, you will need to engage EPA in making the case to apply the statutorily required exemption. The Agency may not initially agree with you, so an ongoing dialogue may be necessary to ensure that a proposed rule—and ultimately a final rule—reflects your position.

Exemptions for Critical or Essential Uses

Pursuant to TSCA section 6(g), EPA may grant an exemption from a requirement of a section 6(a) rule for a specific condition of use of a chemical substance or mixture, if EPA finds that:

- 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
- Compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
- 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.

If EPA has determined that your company's condition of use presents an unreasonable risk, then you should consider whether EPA can grant a critical or essential use exemption for your company's specific condition of use. And if it could apply, you should build the administrative record to support such a determination, especially given that, unlike the mandatory exemptions for replacement parts and articles, this exemption is discretionary.

Conclusion

As discussed above, it will be important for you and your company to engage EPA early and often. You should know your audience at the Agency and know what arguments will be most effective. You will also likely need to develop data, collect information, and build the administrative record in anticipation of litigation. The court will not consider new arguments and information during litigation if you have not already laid the foundation for them during the rulemaking and risk evaluation processes. Finally, once EPA proposes a risk management rule, you will need to ensure that the proposed risk management regulations are tailored to the identified risk. EPA may inadvertently draft regulations that negatively impact other uses that the Agency did not determine to present an unreasonable risk.