What the EPA's ban on ongoing uses of asbestos tells us

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n 28 March, the Environmental Protection Agency (EPA) issued its long-awaited first final risk management rule under the Toxic Substances Control Act (TSCA), banning the import and eventual use of chrysotile asbestos. This is the only form of asbestos known to be used in the US.

You may be thinking now that because your company does not import or use asbestos, this does not affect you. You should care about it because the EPA's approach to the risk management of chrysotile asbestos has much broader implications. This article explains why.

Background on review

Chemical stakeholders know that asbestos occupies a unique place in TSCA's history. For decades, exposure to asbestos fibres has been recognised as a source of adverse human health effects and is subject to global restriction. The EPA issued 35 years ago a final TSCA rule in 1989, prohibiting the manufacture, importation, processing and distribution in commerce of most asbestos-containing products based on its legal finding that asbestos constituted an "unreasonable risk" to health and the environment.

Unsurprisingly, the rule was judicially challenged. A federal appellate court vacated it and remanded it to the EPA for further review. The court concluded that agency had failed to consider adequately potential regulatory measures less burdensome than a ban to abate unreasonable risks. It thus effectively gutted the EPA's authority under TSCA Section 6 to ban a



chemical, even one as notoriously hazardous as asbestos.

The EPA's inability to ban asbestos became the rallying cry and poster child for TSCA reform. This came 25 years later in the form of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a law that significantly revises and strengthens the EPA's authority to regulate chemicals, especially existing chemicals like asbestos.

In implementing TSCA, it came as a surprise to no one that among the first ten 'high priority' existing chemicals the EPA selected for risk evaluation immediately after Lautenberg was enacted was asbestos. In 2020, it prepared an elaborate risk evaluation of conditions of use (COUs) of chrysotile asbestos and issued a proposed risk management rule in 2022.

These administrative initiatives, and many more, were themselves cases of first impression for an EPA struggling

to implement a complicated new law with too few resources. This bare-bones overview in no way captures the extensive scientific analyses, administrative process, and challenging legal and science policy issues EPA and others encountered, and to which the regulated community had to respond, during the lengthy rulemaking process.

The ban

Chemical stakeholders of all stripes waited a long, long time for the chemical ban drought to end. Since the chrysotile asbestos rule is the first final risk management rule, its foundational contours and the EPA's legal rationale for banning it are important indicators of risk management decisions yet to come. This is why review of the ban is essential reading for chemical companies in general.

As we predicted, multiple parties in four different federal appellate circuits have judicially challenged

the rule. Some would say that since no one is happy, the EPA must have got it right. These cases will eventually be consolidated, and a long, contentious litigation process will begin to adjudicate the issues, the most significant of which are described below.

Key final prohibitions

Chrysotile asbestos has been imported and used by the chlor-alkali industry for the fabrication of semi-permeable diaphragms used in the production of chlorine and sodium hydroxide. The EPA approached the regulation of chrysotile asbestos used at the handful of sites processing and using asbestos on a site-by-site basis.

As of 28 May 2024, the effective date of the final rule, all persons in the chloralkali industry are prohibited from the manufacture, including import, of chrysotile asbestos, including any products or articles containing it. From five years after the effective date of the final rule, entities are prohibited from processing, distributing in commerce and commercially using it for diaphragms in the chlor-alkali industry, except as provided in the rule.

Entities may process, distribute in commerce and commercially use chrysotile asbestos for diaphragms in the chlor-alkali industry at no more than two facilities until eight years after 28 May 2024, if they meet certain conditions, and at not more than one

facility until 12 years after the effective date of the final rule, if it meets certain conditions specified under the rule.

Interim workplace controls

In addition to the bans noted above, many other prohibitions, restrictions and record-keeping obligations apply, as would be expected under a risk management rule. Central to this discussion is what the EPA decided to require regarding workplace controls during the phase-out period.

For most of the COUs where the prohibition on processing and industrial use will take effect in five or more years, the EPA requires owners or operators to comply with an eighthour existing chemical exposure limit (ECEL), beginning six months after the effective date of the final rule. It identified the specific COUs to which this requirement applies.

The agency's stated goal is to require compliance with these interim workplace controls as set forth in the final rule. Adherence to these adequately addresses, in the EPA's view, the unreasonable risk from chrysotile asbestos to workers directly handling the chemical or in the area where it is used until the relevant ban goes into effect. This is a critically important concept, as the EPA's authority under TSCA Section 6(a) to impose restrictions is explicitly limited "to the extent necessary so that the chemical substance or mixture no longer

presents such risk."

The TSCA risk management requirements may incorporate and reinforce requirements in Occupational Safety and Health Administration (OSHA) standards. For chrysotile asbestos, the EPA's approach for interim controls seeks to align with certain elements of the existing OSHA standard for regulating asbestos under 29 CFR Sections 1910.1001 and 1926.1101.

According to the EPA, the OSHA permissible exposure limit (PEL) and ancillary requirements "have established a long-standing precedent for exposure limit threshold requirements within the regulated community." The agency acknowledges, however, that it is applying a "lower, more protective" ECEL derived from EPA's TSCA risk evaluation.²

Discussion

So why is this important and what are the key takeaway points? First, the rule's scope is significant. It applies to the few, limited ongoing uses of chrysotile asbestos that were not banned in the 1980s. In addition to the chlor-alkali industry uses outlined above, the rule also bans the use of chrysotile asbestos to make industrial gaskets, oilfield brake blocks and aftermarket brakes, and other automotive industry products.

The rule does not apply to the asbestos types that may already be in place, such as in old buildings. These will be addressed in a separate rulemaking including legacy uses and associated issues related to asbestos disposal.

Secondly, the EPA concluded that the use of chrysotile asbestos in chlor-alkali production does not present an unreasonable risk if protective measures are used, such as engineering controls, glove boxes and personal protective equipment (PPE). In the final risk management rule, the agency nevertheless asserts that it must be banned because it "believes than an ECEL cannot ensure that chrysotile asbestos does not present unreasonable risk to workers and, therefore, it is not a substitute for a ban as a long-term risk management solution."3

In other words, the necessary
PPE may not be used correctly, or
monitoring to or below the ECEL "may
at times be problematic," or owners
"may be unable to reliably ensure with
sufficient confidence" that workers
are protected (emphasis added
in each case).²

To some, this reflects a whole lot of unsupported anticipatory speculation that looks more like the precautionary principle than it does a



reasoned cost-benefit risk analysis, as required under TSCA. If this dubious logic prevails, the EPA may be in the awkward position of needing to ban every chemical that it determines as presenting an unreasonable risk when PPE is not used.

Taken to its logical extreme, this means that the agency will be compelled to ban all or nearly every substance it reviews under TSCA Section 6, at least for the foreseeable future, because it is entirely likely that the substances it reviews over the next several decades will be sufficiently hazardous for it to conclude that the chemical substances present an unreasonable risk from routine. unprotected inhalation and/or dermal exposures. This logical inference alone should raise alarm bells for chemical stakeholders.

Finally, the final rule raises novel legal and science policy issues that are equally likely to arise in other risk management rules the EPA is issuing, including the recently promulgated final risk management rule on methylene chloride issued on 8 May.

The EPA's use in the asbestos rule of a rescinded 2018 Application of Systematic Review in TSCA Risk Evaluations (SR Document) invites significant controversy and reflects a serious departure from the agency's commitment to use the best available science as required under TSCA Section 26(h). The crux of this issue is that the US National Academies of Sciences, Engineering, and Medicine reviewed the SR Document and concluded that the EPA's approach to systematic review does "not adequately meet the state-of-practice".3

A related issue is the EPA's derivation of an inhalation unit risk (IUR) for chrysotile asbestos and the use of the IUR for establishing the all-important



ECEL. The EPA derived the IUR on textile worker populations from two facilities, a population many thought to be inadequate and responsible for eliciting an indefensibly strict level because these workers were also exposed to amphibole fibres, a more potent type of asbestos.

The third legal issue relates to the EPA's unreasonable risk determination. The agency referenced its 1994 Guidelines for Statistical Analysis of Occupational Exposure Data (Guidelines) as the justification for evaluating monitoring samples that were below the limit of detection (LOD). It stated that the Guidelines "call for replacing non-detects with the LOD or LOQ [limit of quantification] divided by two or divided by the square root of two, depending on the skewness of the data distributions".4

The approach in the Guidelines conflicts with the EPA's 2008 Framework for Investigating Asbestos-Contaminated Superfund Sites (2008 Framework), which states "[w] hen computing the mean of a set of asbestos measurements, samples that are 'non-detect' should be evaluated using a value of zero, not half the analytical sensitivity". The agency did not state its rationale for not using the 2008 Framework recommendations (i.e. replacing non-detects with zero).

The scientific methods and documents supporting this rule have been publicly challenged by other expert academics in the field. As it is the first final rule under TSCA Section 6, stakeholders should expect no less. This rule is not just about asbestos; it reflects how the EPA will manage unreasonable risks for existing chemical substances it identifies as high-priority substances under Section 6.

Outlook

As explained above, there are plenty of reasons to be alarmed. Details matter and every risk management rule will be different in terms of the data on which the EPA relies to identify unreasonable risk, how it develops a workplace chemical protection programme and how it establishes an ECEL. The court will decide whether it met its legal burden in the chrysotile asbestos rule.

As noted, the agency recently issued a final risk management rule on methylene chloride that reflects many of the same legal and science policy deficiencies. It has already been challenged.⁵ Stakeholders are urged to review carefully all proposed risk management rules, engage actively in the rulemaking process and assert the arguments that align best with their advocacy to ensure the administrative record is complete to optimise the best judicial outcome on appeal.

References:

- 1: See Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Circuit 1991)
- 2: 89 Fed. Reg. 21970 (28 March 2024)
- 3: Application of Systematic Review in TSCA Risk Evaluations, EPA Document EPA-740-P1-8001, Office of Chemical Safety & Pollution Prevention (OCSPP) (May 2018), available at https://www.epa.gov/sites/default/files/201806/documents/final_application_of_sr_in_tsca_05-31-18.pdf
- 4: EPA (2020) Risk Evaluation for Asbestos, Part I: Chrysotile Asbestos, EPA Document EPA-740-R1-8012
- 5: Two small businesses filed a joint petition in the 5th Circuit Court of Appeals. See East Fork Enterprises, Inc. & EPIC Paint Company v. EPA, filed 10 May 2024

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