Supreme Court Update: How Would Changes to Chevron Deference Affect EPA Risk Analyses

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In Brief: Entities subject to EPA regulation are closely watching the U.S. Supreme Court's potential reframing of the *Chevron* deference doctrine. But they should also pay close attention to EPA's extra-regulatory scientific determinations, such as IRIS assessments. These decisions have significant policy implications but will likely not be affected by any changes to *Chevron* deference.

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Advocates for agency accountability eagerly await the U.S. Supreme Court's reconsideration of *Chevron* deference. The pending challenges from financially-overburdened herring fishers provide the Court an opportunity to reassess a key administrative law doctrine from the 1984 case *Chevron v. NRDC*. *Chevron* has required courts to defer to agencies' interpretations of statutes that confer them authority if that statute leaves a gap between its goals and the specifics necessary for implementation.

The current challenge to Chevron comes on the heels of recent Supreme Court decisions establishing the Major Questions doctrine. Should the Court limit the scope of *Chevron* deference, these recent decisions together would send a strong signal that the courts are once again willing – and, indeed, required – to serve as a check on expansive interpretations of agency authority.

Nonetheless, even a complete reversal of the *Chevron* doctrine is unlikely to prevent the U.S. Environmental Protection Agency (EPA) from relying upon controversial science in its rulemaking and enforcement actions, because EPA often makes these key decisions through internal processes that entirely escape judicial review. *Chevron* and the Major Questions doctrine focus on the limits to EPA's statutory authority; they do not address the deference owed to an agency's interpretation of its own regulations. Furthermore, scientific assessments can be highly technical and complex – the type of decision courts have historically hesitated to interfere with.

The Integrated Risk Information System (IRIS) is a key example of the types of decisions that will likely avoid judicial review. The IRIS program was designed to develop objective assessments of the health risks

posed by specific chemicals. EPA's IRIS process has received repeated criticism from the National Academy of Sciences (NAS); nevertheless, the current Administration has moved quickly to complete multiple IRIS assessments and largely deflected objections from states and industry about the integrity of its science. Yet the states and industry cannot challenge these values in court until they are used in a specific rule – and even there, EPA argues the scope of any challenge is limited. As a result, these controversial risk values will likely continue to shape fundamental decisions around EPA policies, regulations, and actions, regardless of any changes to the *Chevron* standard.

IRIS Program Background

EPA uses the IRIS Program to identify and measure health hazards posed by chemicals. It was not designed by Congress or authorized by any statute, but was instead formed as a result of an EPA initiative to consolidate these types of reviews to ensure consistency across all EPA programs. The IRIS Program is part of EPA's Center for Public Health and Environmental Assessment (CPHEA) in the Office of Research and Development (ORD). This distinction from EPA's other offices purportedly ensures that IRIS can develop impartial toxicity information without considering how that information may be applied (such as in setting national air quality or remediation standards).

IRIS was originally conceived as a database of information to help support EPA's regulatory measures. IRIS assessments consider a chemical's (or group of chemicals') toxicity, exposure assessments, and hazards information to describe public health risks at specified exposure levels. The derived IRIS values are supposed to reflect the best current scientific understanding of the risks associated with different chemicals, based on available information.

In practice, however, EPA tailors IRIS values to influence standards and regulations, choosing highly-conservative "risk" values that drive subsequent regulatory decisions. States and other agencies also use this public information to regulate chemicals, and civil litigants base toxic tort claims on these values. Once an IRIS assessment's conclusions are published, EPA argues that the IRIS value is preferred, unless industry can come forward with sufficient evidence to trigger an entirely new IRIS assessment.

Difficulty Challenging IRIS Assessments: The Example of Ethylene Oxide

While EPA espouses IRIS as an impartial scientific method to form the basis of regulations and assessment for chemicals, the lack of transparency and meaningful input can create unreliable and biased outcomes. Because no statute expressly authorized the IRIS program, the process and substance of any such review is entirely within EPA's discretion. Furthermore, because IRIS values may not be challenged until applied in a rule, there is no external oversight of the process itself, and no immediate remedy when that process results in a poorly-supported conclusion. While EPA has issued guidance incorporating peer review and public notice and comment into the IRIS development process (see the new IRIS Handbook), that guidance remains entirely voluntary and thus unenforceable.

The controversial Ethylene Oxide (EO) IRIS value provides a snapshot of EPA's IRIS process – and the myriad obstacles that process creates for states and affected entities. EPA began reevaluating the EO IRIS value in 2006 but did not issue its final assessment until 2016. Throughout that decade, EPA sought public comments, but then brushed off the concerns raised by those comments. EPA also circulated drafts of the IRIS assessment to the Scientific Advisory Board (SAB) for peer review. While the agency made some changes in response to the SAB's comments, the final IRIS assessment – including, critically, the choice of dose-response model, which drives the calculated risk values – was never re-submitted to or approved by the SAB. During this timeframe, the NAS issued two reviews of the IRIS process (in 2011 and 2014). Both

reviews identified significant problems with the IRIS process that were both procedural (*e.g.*, unclear displays of scientific information) and substantive (*e.g.*, relying solely on one study, as EPA did for EO). However, EPA refused to incorporate any of the substantive recommendations into the ongoing EO IRIS assessment.

This decade-long process ended with a surprising finding: EPA concluded that EO was orders of magnitude more hazardous than any prior study had ever suggested, making EO one of the most potent carcinogens EPA had ever assessed. In fact, EPA determined that exposure to a mere 0.1 part per *trillion* EO would create a 1-in-1,000,000 risk of lymphatic cancer (a key threshold for regulatory action). And yet the agency entirely ignored data suggesting that such a dramatic result was entirely inconsistent with real-world evidence – such as the fact that naturally-occurring background levels are typically at least 500 times higher than this figure, or that smokers are exposed to EO on the order of 20,000 ppt, yet, smoking has never been identified as a cause of lymphatic cancer. Numerous commenters raised these issues during the public comment period. EPA ignored all of them.

Instead, EPA moved forward with using the IRIS value as the basis for its rulemaking efforts, most particularly in the "residual risk and technology" (RTR) rule for the Miscellaneous Organic Chemical Manufacturing (MON) source category (MON RTR). Again, commenters raised their many concerns with the science behind the IRIS risk value. This time, EPA dismissed the comments by claiming that they had already been addressed in the IRIS process.

In doing so, EPA developed new criteria that must be satisfied before it would consider any contrary evidence. First, it refused to consider an extensive critique of the IRIS value conducted by the Texas Commission on Environmental Quality (TCEQ), because that study had not yet completed peer review during the public comment period. The agency subsequently granted reconsideration after the TCEQ assessment completed peer review – but in that reconsideration, EPA proclaimed that it would not consider any evidence that disagreed with the IRIS value unless that evidence was strong enough, standing alone, to require a complete reassessment of the IRIS value itself. Not surprisingly, EPA concluded that none of the extensive scientific data and comments submitted met this elevated standard. The MON RTR was finalized after reconsideration in 2021, having never meaningfully addressed the significant concerns commenters raised over the IRIS value.

Since that time, EPA has continued to forge ahead on multiple EO-related agency actions as though the EO risk value were settled science, forcing industry to wrangle with numerous rulemakings, enforcement, and litigation. Environmental groups have demanded that EPA develop new rules citing the EO IRIS to substantiate environmental justice claims. States have issued more restrictive EO standards based on the IRIS value. Toxic tort lawsuits cite the IRIS value as a basis for establishing risk and causation, and some have resulted in millions of dollars of settlement based on the purported risks associated with EO. Meanwhile, the industry challenge to the MON remains with the U.S. Court of Appeals for the D.C. Circuit, where oral argument was heard on February 16, 2024.

Moreover, EPA's commitment to the EO IRIS value has not wavered. In contrast, EPA has undertaken a remarkable public outreach campaign to notify communities that their EO exposures from specific facilities – based on the IRIS risk value – likely contribute to elevated cancer risk in nearby communities. EPA's unfounded reliance on and support of the EO IRIS value continues to significantly impact industry, including through increased litigation risk.

What's Next: New IRIS Values and Recent Developments

It bears emphasis that EO is not a unique example, and its process has been hailed as a "model" for conducting future IRIS assessments. So while changes to *Chevron* may narrow agency reach, tools like

the IRIS Program will continue to form the basis of regulations that lack objective scientific support and legislative authority. EPA's IRIS values will shape administrative decision making for years to come, even for chemicals that have not undergone an IRIS assessment. For example, EPA has leveraged the IRIS value for ethylene oxide as the basis for developing stringent Hazardous Air Pollutant (HAP) rules that will ultimately govern a broad range of HAPs that are "along for the ride."

Last year, EPA announced that it was initiating the internal steps of its IRIS assessment for the following chemicals:

- Ethylbenzene (February 2023)
- Naphthalene (March 2023)
- Nitrate and Nitrite (November 2023)

According to EPA's website, the following chemicals have either completed, or are near completing, their public input steps and should be on your radar for EPA to finalize in the coming year:

- Formaldehyde: External Peer Review completed June 2023
- Arsenic, Inorganic: Public Comment completed December 2023, External Peer Review pending
- Hexavalent-Chromium: External Peer Review completed March 2023
- Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). As EPA continues to target PFAS compounds, it has worked quickly to develop and publish IRIS assessments for the multitude of different compounds. The agency is currently developing assessments for the following PFAS:
  - Perfluorohexanesulfonic Acid (PFHxS): External Peer Review February/March 2024
  - Perfluorodecanoic Acid (PFDA): External Peer Review completed July 2023
  - Perfluorononanoic Acid (PFNA): Internal review ongoing since November 2019

Some recent developments have the potential to increase accountability for EPA's development and use of IRIS values:

1. President Biden has made unbiased science a focus of his reforms to the administrative state, releasing a framework for agencies to develop Scientific Integrity Policies in 2023. EPA internally distributed its draft policy in January 2024, which might drive more reliable methods for EPA to develop IRIS values.
2. Senator John Kennedy (R-LA) recently introduced the No Industrial Restrictions in Secret Act (No IRIS Act), which would prohibit EPA from basing its rulemakings on IRIS unless Congress explicitly authorizes the program. While Senator Kennedy's bill is viewed as being unlikely to pass, at least in its current form, perhaps it will bring much-needed legislative oversight of EPA's IRIS program. Congressman Glenn Grothman (R-WI 6th) introduced a companion bill in the House of Representatives.
3. In October 2023, after EPA refused to consider the Texas Commission on Environmental Quality's EO risk assessment in developing its MON rule, the State requested that the NAS launch a panel to review the State assessment. NAS agreed and is proceeding with that review now.

What Can Industry Do?

- **Industry stakeholders should monitor developments associated with EPA's work on IRIS values.** EPA is currently assessing IRIS values for eighteen constituents. While the majority of these assessments are still being internally scoped and drafted, EPA will issue public notice in the Federal Register when they anticipate releasing the draft assessment for public comment. EPA maintains a database of the compounds currently undergoing an assessment, and interested parties can join a mailing list to receive notices of developments or new assessments.
- **Companies that manufacture or use priority constituents on EPA's IRIS list should seek to participate in assessments, where possible**. Companies should closely monitor developments and utilize the few available public participation opportunities to ensure that the administrative record reflects the full body of scientific literature and data.
- **Manufacturers of consumer products that contain these constituents should assess their regulatory, litigation, and enforcement risk** for impacted products in the US and keep an eye on global trends that can influence the domestic agenda. Connect with experts tracking emerging contaminants that EPA is likely to target next.

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