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Review

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"Best available science" and agency decision-making

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SUMMARY

United States federal agencies charged with protection of human health and the environment, such as the United States Environmental Protection Agency, aspire to use "best available science," "follow the science," and make decisions based on the "weight of the evidence." However, risk-based regulatory decisions often are judgment calls and even policy choices that depend on how the decision-maker looks at and weighs the scientific evidence through the lens of programmatic or even personal preferences. Agencies must take action even in the absence of definitive science and often are given significant discretion when making risk-based decisions. However, courts may pay close attention to statutory language that puts constraints on how agencies are to exercise their discretion. The purpose of this brief essay is to explain to the risk assessment community how risk assessments are used in agency decision-making. I then discuss how courts may review risk-based agency decisions and the potential implications for per- and polyfluoroalkyl substances regulatory actions that are currently being challenged in court.

KEY WORDS: Legal issues; PFOA; Regulatory policy; Risk assessment

HIGHLIGHTS

- This paper is part of a workshop in the Beyond Science and Decisions project of the Alliance for Risk Assessment (*ARA*) that discussed the international differences in the perfluorooctanoate (PFOA) safe dose along with legal issues associated with widely differing values.

ABBREVIATIONS: ARARs, applicable or relevant and appropriate requirements; CDC, Centers for Disease Control and Prevention; CERCLA, Comprehensive Environmental Response, Compensation, and Liability Act; EPA, United States Environmental Protection Agency; IEUBK, Integrated Exposure Uptake Biokinetic Model for Lead in Children; IRIS, ORD's Integrated Risk Information System; MCLs, maximum contaminant levels; NMFS, National Marine Fisheries Service; OEHHA, California's Office of Environmental Health Hazard Assessment; ORD, EPA's Office of Research and Development; PCE, perchloroethylene; PFAS, per- and polyfluoroalkyl substances; PFOA, perfluorooctanoate; PFOS, perfluorooctanesulfonic acid; ROD, record of decision; SDWA, Safe Drinking Water Act.

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1. RISK-BASED DECISIONS

1.1. Identifying best available science

Regulatory agencies like United States Environmental Protection Agency (EPA) generally use best available science when making risk-based decisions. However, what science is "best" can be a judgment call.

A dispute over risk at a Superfund site provides an example of this point. In this example, there was a dispute between scientists at EPA's Office of Research and Development (ORD) and scientists at California's Office of Environmental Health Hazard Assessment (OEHHA) regarding the level of risk posed by inhalation of perchloroethylene (PCE).

Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and its implementing regulations (the National Contingency Plan), EPA sets cleanup levels based on legally applicable or relevant and appropriate regulatory standards or, in the absence of such standards, on other peer reviewed toxicity values.[1,2] The Superfund program has established a hierarchy for consideration of toxicity values, placing values set by ORD's Integrated Risk Information System (IRIS) program at the top of the hierarchy.[3]

In 2007, when the Air Force issued (and EPA concurred with) a cleanup plan addressing human exposure resulting from vapor intrusion for part of Edwards Air Force Base in California there was no IRIS number for PCE. However, that changed in 2012 when ORD established an IRIS reference concentration for inhalation

exposure to PCE.[4] The 2012 IRIS number was *less* stringent than the concentration that had previously been used in the Edwards Air Force Base remedy decision.[5] After EPA issued its 2012 PCE IRIS number, the Air Force sought to change the remedy for Edwards Air Force Base to use the less stringent IRIS number, which would have reduced the number of buildings requiring remediation for vapor intrusion. California objected. They wanted the remedy modified to meet California's PCE inhalation number, which was even more stringent than the number used in the 2007 remedy decision. EPA Region 9 agreed with California. The Air Force elevated the dispute to EPA Headquarters.

ORD staff briefed senior managers at EPA Headquarters on the dispute. They explained why California's PCE inhalation concentration number was different from EPA's even though both ORD scientists and OEHHA scientists reviewed the same studies. In this case, the studies that ORD staff thought were "best" supported a less stringent inhalation concentration while the studies that OEHHA staff thought were "best" supported a more stringent number. The choice of studies to consider "best available" was ultimately a judgment call made by the EPA ORD scientists. Two equally valid risk numbers, when applied to a specific Superfund site, resulted in vastly different results. Ultimately, the PCE inhalation number in the record of decision (ROD) for Edwards Air Force Base was not changed upward or downward. However, that decision was based on a legal interpretation of the Superfund regulations, not risk.[b]

1.2. Adopting changing scientific information

A decision whether or when to apply new or revised scientific information also can be a judgment call for regulatory agencies.

In 1994, EPA's Superfund program established 400 ppm as the recommended level for evaluating lead in soil at residential locations.[6] This screening level was based a risk management goal of no more than 5% of exposed children having blood lead levels exceeding 10 μg/dL. That blood lead level was the "level of concern" identified at that time by the Centers for Disease Control and Prevention (CDC) for determining when a public health intervention is appropriate. In 2012, CDC changed its terminology and adopted a blood lead reference value to identify which children have more lead in their blood than most children. The 2012 CDC blood lead reference value was 5 μg/dL. In 2021, CDC lowered its blood lead reference value again, to 3.5 μg/dL.

Despite the fact that its lead in soil screening level was based on an outdated CDC blood lead value, EPA did not change it until very recently. In January 2024, EPA updated its residential soil lead guidance to recommend a screening level of 200 ppm.[7] This screening level is expected to achieve a risk management goal of no more than 5% of exposed children having blood lead levels exceeding 5 μg/dL, which was CDC's 2012 reference value. To achieve a goal of no more than 5% of exposed children having blood lead levels exceeding 3.5 μg/dL, CDC's current reference value, EPA would have had to lower its screening level to 100 ppm.

EPA's updated guidance explains that the agency has not yet evaluated its Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) at blood lead levels below 5 μg/dL. But, even absent this evaluation, EPA recommends 100 ppm instead of 200 ppm as a screening level for lead in soil if there are multiple sources of lead present.

Why did it take so long for EPA to update is lead in soil screening guidance? There are multiple reasons. One was concern over the accuracy of the IEUBK model. In addition, EPA may have been concerned over impacts to the Superfund program. The lower blood lead level screening number means that many completed cleanups may no longer be considered protective and would have to be reopened. EPA also may have been concerned with setting a lead in soil screening level below levels that researchers have found in urban soils, due to the legacy of leaded gasoline and other sources.[8] It appears that these programmatic policy concerns impacted EPA's decision on identifying a risk screening level for lead in soils.

1.3. Identifying a single regulatory number based on multiple scientific studies

Identifying a single regulatory number based on the "weight of the evidence" derived from multiple scientific studies also can be a judgment call.

In 2008, EPA updated its National Ambient Air Quality Standards for lead, lowering the standard 1.5 $\mu g/m^3$ to 0.15 $\mu g/m^3$.[9] The Clean Air Act requires the EPA Administrator to set air quality criteria to protect public health with an adequate margin of safety, based on "the latest scientific knowledge."[10] In the decision meeting, the Air Office staff presented a scatter plot showing results from multiple studies on the impact of lead exposure on the IQs of children. The dots were all over the plot, making it difficult to identify any trend line. Further, the studies from which the data were derived involved different methods and age groups. Nonetheless, the Air Office staff told the EPA Administrator that the weight of the evidence supported a standard of 0.15 $\mu g/m^3$ to keep IQ loss below 2 points and, based on the staff recommendation, that was the number he selected.

Some commenters criticized the decision as not protective enough by failing to consider sensitive subpopulations.[11] However, as noted by Justice Breyer in his concurring opinion in *Whitman v. American Trucking Associations*, the Clean Air Act does not require the elimination of risk and allows the Administrator of the EPA to evaluate various populations and accept some risk.[12,13] The amount of risk to accept is a policy choice. When the 2008 National Ambient Air Quality Standards for lead were established, those policy choices were embedded in the staff recommendation and were not transparent to the public or even to the Administrator.

[b]EPA took the position that under its Superfund regulations, a cleanup standard can be changed after the ROD is signed only if necessary to ensure protectiveness. Under those regulations, applicable or relevant and appropriate requirements (ARARs) that are incorporated into a ROD are "frozen" at the time the ROD is signed, unless a change is needed to maintain the protectiveness of the remedy. Because EPA believed that the PCE inhalation risk level in the Edwards Air Force Base ROD was protective, it decided no change was warranted, even though that risk level was not a promulgated standard and therefore was not an ARAR.

2. JUDICIAL REVIEW OF AGENCY RISK-BASED DECISIONS

2.1. Degree of deference to agency decision-making

In 2024, the Supreme Court held that courts should not defer to agency interpretations of law and should instead form their own conclusions. This case, *Loper Bright Enterprises v. Raimondo*, involved whether an agency can charge a fee to offset the cost of federal oversight of fisheries management in the absence of express statutory authority to do so.[14] The fee was upheld by the lower courts, citing deference to agency decisions under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (establishing the doctrine that courts defer to agency interpretations of ambiguous statutes unless arbitrary and capricious).

The Supreme Court used this case to overturn the *Chevron* Doctrine. However, *Loper Bright* applies only deference to agency interpretations of law. Accordingly, absent a statutory interpretation issue *Loper Bright* is not likely to affect judicial deference to an agency's risk-based decisions. As my Earth and Water Law colleague Don Elliott points out in his article in this symposium, courts generally try to avoid getting in the middle of disputes over science. A dispute over science generally will not be presented to a court as an interpretation of an ambiguous statute, so *Loper Bright* may not be implicated.

However, as discussed above, risk-based decisions often are blend of science and policy. Following *Loper Bright*, courts will continue to defer to an agency's assessment of risk unless it is arbitrary and capricious. But, the policy choices available to an agency once it identifies a risk may depend on an interpretation of the statute.

For example, in 1976 the D.C. Circuit upheld an EPA decision to regulate lead in gasoline under section 211 of the Clean Air Act.[15] The issue presented to the court was not whether lead presented a risk. Rather, the question was whether EPA acted arbitrarily and capriciously by regulating lead in gasoline when its authority to do so was based on a determination that lead in gasoline "will endanger the public health or welfare." EPA interpreted the word "endanger" to authorize EPA to take a precautionary approach and regulate lead in gasoline in face of uncertainty regarding the degree to which that source of lead exposure contributed to the risks of lead exposure. The court agreed with that interpretation.[c]

However, a court also may disagree with an agency's interpretation of the law. In a recent case, *Maine Lobstermen's Ass'n v. National Marine Fisheries Service*, the D.C. Circuit reviewed an agency decision involving the ongoing controversy over whether lobstering in Maine harms the Right Whale, which is listed as an endangered species.[16]

Under the Endangered Species Act, the National Marine Fisheries Service (NMFS) must use "*the best scientific and commercial data available*," to determine whether the federal fishery is "*not likely*" to jeopardize the survival of a protected species.[17] To interpret the meaning of these statutory requirements, the D.C. Circuit reviewed the history of the Endangered Species Act. According to the court, the "not likely" standard was added to the Endangered Species Act in 1979, in response to the controversy over the snail darter, an endangered species. Before 1979, the Endangered Species Act stated that federal agencies must "not jeopardize" a protected species. In 1978, the statute was used to bring a legal challenge that halted construction of a dam by the Tennessee Valley Authority. Upholding the lower court decision, the Supreme Court held that it was necessary to halt the $100 million dam to save "a relatively small number of three-inch fish among all the countless millions of species extant" because the "institutionalized caution" embedded in the Endangered Species Act compelled that result.[18] According to the D.C. Circuit, Congress reacted by amending the statute to "lighten[] the load to avoid paralysis."

The language of the Endangered Species Act requires NMFS to make an empirical judgment about what is "likely." However, when evaluating data to determine whether a protected species is jeopardized by an action, NMFS had a policy of putting a thumb on the scale in favor of the endangered species and always relying on the worst-case scenario when faced with uncertainty. The D.C. Circuit found that NMFS's policy distorted their "scientific judgment by indulging in worst-case scenarios and pessimistic assumptions to benefit a favored side."

> *Statutory text and structure do not authorize the Service to "generally select the value that would lead to conclusions of higher, rather than lower, risk to endangered or threatened species" whenever it faces a plausible range of values or competing analytical approaches. The statute is focused upon "likely" outcomes, not worst-case scenarios. It requires the Service to use the best available scientific data, not the most pessimistic. The word "available" rings hollow if the Service may hold up an action agency by merely presuming that unavailable data, if only they could be produced, would weigh against the agency action.*[d]

Even though the *Maine Lobstermen* case was decided before *Loper Bright* overturned *Chevron*, the D.C. Circuit did not defer to NMFS and determined that its application of the Endangered Species Act was contrary to law.

2.2. Potential outcomes of judicial review of EPA PFAS regulatory actions

EPA recently adopted regulations relating to per- and polyfluoroalkyl substances (PFAS) under both the Safe Drinking Water Act (SDWA) and under CERCLA. Judicial challenges to both of these regulatory actions are pending in the D.C. Circuit.

Under the SDWA, EPA must establish maximum contaminant levels (MCLs) using "*the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices*" and "*data collected by accepted methods or best available methods*."[19] Before regulating, EPA must determine, based on science and data, that a contaminant may have an adverse effect on the health of persons and that "*there is a substantial likelihood* that the contaminant will occur in public water systems with a frequency *and at levels of public health concern*."

[c]The court also noted that EPA's interpretation was entitled to deference. Of course, after *Loper Bright* that is no longer true.

[d]70 F.4th at 599.

In April 2024, EPA promulgated an MCL rule for six PFAS substances.[20] Challenging that rule in the D.C. Circuit, drinking water providers have argued that EPA relied on data that were not available by assuming that new data would show higher PFAS levels in drinking water systems; that EPA relied on health data that were not peer-reviewed; and that EPA admitted some of the data it used were of low confidence. In response, EPA has argued that the use of the word "may" in the statute gives it the authority to regulate based on the mere possibility of risk. The D.C. Circuit will adopt its own interpretation of the statute and may agree with a precautionary approach and adopt EPA's interpretation of the word "may." Alternatively, the court may decide that the statute requires EPA to rely on available data and peer reviewed studies and to give meaning to statutory standard of "substantial likelihood."

In May 2024, EPA promulgated a rule listing perfluorooctanoate (PFOA) and perfluorooctanesulfonic acid (PFOS) as CERCLA hazardous substances.[21] The CERCLA standard for listing a hazardous substance is a determination that a substance "*when released into the environment may present substantial danger to the public health or welfare or the environment.*" In its Final Rule, EPA says the "may present" means a "possibility," "substantial danger" means "hazard," and "hazard" means an association with adverse human health effects. EPA relied on studies showing such associations in combination with consideration of environmental fate and transport and prevalence as the bases for its determination that PFOA and PFOS may present substantial danger when released into the environment. In the CERCLA litigation, challengers have argued, among other things, that EPA did not properly interpret the standard for listing. Responding, EPA again argued that the word "may" authorizes it to take a precautionary approach, citing the CAA leaded gas case from 1976, discussed above. Again, the D.C. Circuit will adopt its own interpretation of the statute. It may agree with EPA's claim that Congress authorized a precautionary approach. Alternatively, the court could decide that the use of the word "may" in the CERCLA standard for listing is a recognition that risk requires both toxicity and exposure and whether exposure will occur is uncertain.

3. CONCLUSION

Agency risk-based decisions can be judgment calls that are influenced by policy considerations. There is nothing inappropriate about this. Risk assessment will not always point to one clear answer, and an agency decision-maker often is give the discretion to make risk-based decisions. However, even though scientific conclusions are generally granted deference, reviewing courts will reach their own conclusions about the meaning of the statutory standards that agencies are directed to apply. The court may agree with EPA's interpretation of the SDWA and CERCLA in its PFAS rulemakings and uphold these regulations. Or, the court may say "substantial likelihood" really means "substantial likelihood," "substantial" really means "substantial," and "danger" really means "danger," placing some constraints on EPA's discretion to make scientific judgments with regulatory implications.

DECLARATION OF COMPETING INTERESTS STATEMENT

At the time of the workshop and the initial drafting of the paper, the author was retained by a trade association to provide legal and policy advice regarding the impacts of PFAS regulations and to evaluate legislative proposals to address those impacts. Subsequently, the author was retained by the same association to represent them in the litigation challenging the CERCLA PFOA and PFOS listing rule.

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