JTRP *1*, 1–5, 2025

Review

JTRP Journal of Toxicology and Regulatory Policy

Disciplinary differences and institutional factors that bear on the international differences in regulating PFAS

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https://doi.org/10.69982/j.jtrp.2025.24.0007

SUMMARY

Lawyers and scientists are not merely proverbial ships passing in the night; they live on different planets mentally. As a long-time environmental lawyer and law professor who has been happily married to a distinguished toxicologist, Gail Charnley PhD, for over two decades, I have come to see how our professional training influences us to see the world differently. In this essay, I try to explain the difference between how lawyers and scientists view the world and significance of those differences for risk regulation, including the regulation of per- and polyfluoroalkyl substances (PFAS).

KEY WORDS: International differences; 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.

There are over 1.3 million active lawyers in the United States[1] and over 8.8 million scientists worldwide.[2] The premise for this paper is not that all of them think exactly alike. Rather, like those in other disciplines, lawyers and scientists typically share certain assumptions about how the world works, which are commonly encapsulated in the concept of a shared "legal culture"[3] or a shared "scientific culture."[4] It is to these broadly shared—but also sometimes actively debated—professional norms and assumptions that I refer as "the scientific worldview" and "competing legal world views."

1. THE SCIENTIFIC WORLD VIEW

Scientists are used to expecting a high level of empirical proof, typically at the 95% confidence level, before accepting a causal relationship as proven. There are good reasons for this, including that science is a collective activity that takes as a given prior scientific work that meets the prevailing norms for scientific proof unless and until shown otherwise.[5]

ABBREVIATIONS: EPA, United States Environmental Protection Agency; OIRA, Office of Information and Regulatory Affairs.

2. COMPETING LEGAL WORLD VIEWS

The world that lawyers, legislators and regulators inhabit is very different. Unlike the scientific search for provable truths, legal world views accept of the inevitability of errors in all human decisions, and therefore, propose competing ways to weigh the costs and benefits of an error in one direction as opposed to another.

The modern environmental era at the national level began in the late 1960s, but since the early 1980s, an important strand of the world view shared by many lawyers, legislators, and regulators is borrowed from neoclassical economics. This shared perspective, sometimes called the "neoclassical consensus," aims to maximize aggregate social welfare through government regulation to address "market failures" and thereby increase aggregate social welfare.[6] The principal tool in the neo-classical project of reforming regulation is benefit–cost analysis, a technique for analyzing proposed regulatory decisions that traces back to President Reagan's 1981 Executive Order 12291 (https://www.archives.gov/federal-register/codification/executive-order/12291.html), which required benefit–costs analysis in advance for most major rules at the federal level by the White House Office of Information and Regulatory Affairs (OIRA).[7]

However, benefit–cost analysis has been deeply controversial in environmental regulation throughout the formative period for the statutory provisions discussed in this paper. Arrayed against benefit–cost analysis is the "precautionary principle," which is variously defined but comes down to the idea that the "absence of full scientific certainty" should not necessarily preclude regulation.[8] Although never formally adopted in the United States, empirical studies show that many U.S. laws reflect

varying degrees of "precautionary approaches."[9] The environmental laws passed in the United States from 1970 to the present embody a variety of different standards of proof reflecting the on-going debate about the appropriate degree of scientific proof as opposed to precautionary policies in various circumstances.[10]

An example of the way that lawyers and regulators look at the world that may be familiar to most scientists are the different "standards of proof" in court cases. Most of us learn along the way that the standard of proof in a criminal case is "beyond a reasonable doubt," whereas the standard of proof in an ordinary civil lawsuit between two private parties is lower, "a preponderance of the evidence." This difference in legal standards is said to reflect the policy judgment, often attributed to the English jurist William Blackstone, that "[B]etter that ten guilty persons escape, than that one innocent suffer.";[11] on the other hand, in the run of the mill civil case, the law does not take sides and so it aims not to weight the dice either way but to treat both sides equally and rule in favor of whichever has the better case. (To be sure, there are a few civil matters in which particular issues are subject to higher standards of proof, such as "clear and convincing evidence," but even that enhanced standard does not come close to what most scientists would consider "proof.")

Environmental laws also reflect many different standards of proof required for various regulatory actions. At their best, these differing standards for factual support reflect considered policy judgments by the Congress comparing the costs of errors in one direction as opposed to the other. However, in a democratic republic such as ours, legislation specifying a legal standard for regulating may also be tempered by the desire of politicians to send signals to the voting public about how much they care about certain issues.

In recent years, the neoclassical objective of maximizing aggregate social welfare has also come under attack as "distributional factors" (who wins and who loses) have come to play a larger role. This is the basic idea behind the "environmental justice" movement, and it is reflected in many of the policy changes wrought to OIRA review by the Clinton, Obama, and Biden administrations to pay more attention to the "distributional effects" of who is adversely affected by government policies. These reforms reject the idea implicit in the goal maximizing aggregate social welfare that a dollar of cost to a billionaire should be treated equally with a dollar of harm to a poor person who is already overburdened by environmental harms. For example, the Clinton Administration modified the Executive Order creating OIRA review of major rules to require consideration of distributional factors as well as aggregate costs and benefits (Executive Order 12866, https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf). The Biden Administration recently modified the guidance on how to conduct benefit–cost analysis further to encourage agencies to give greater weight to benefits to poor people than to the rich.

> Agencies may choose to conduct a benefit–cost analysis that applies weights to the benefits and costs accruing to different groups to account for the diminishing marginal utility of goods when aggregating those benefits and costs. Diminishing marginal utility means that an additional unit of a good is more valuable to a person (in welfare terms) if they have fewer total goods than if they have more total goods. Weights of this type are most commonly applied in the context of variation in net benefits by income, consumption, or other measures of economic status.

Revisions to Circular A-4 (November 9, 2023) at p.65: https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.

These and other policy considerations play out in a dizzying array of different standards in various environmental laws. A few examples follow:

- *"National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the **judgment of the Administrator**, based on such criteria and allowing an **adequate margin of safety**, are requisite to protect the public health."* Clean Air Act, §109.
- *The Administrator shall promulgate and revise as may be appropriate, regulations designating as hazardous substances, …, such elements, compounds, mixtures, solutions, and substances which, when released into the environment **may present** substantial danger to the public health or welfare or the environment.* CERCLA §102(a).
- *"The Administrator shall periodically review the list established by this subsection … adding pollutants which present, or **may present**, through inhalation or other routes of exposure, a **threat** of adverse human health effects ….* Clean Air Act §112.
- "*The term 'pollutant' means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, **chemical wastes, biological materials**, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water."* Clean Water Act §502.
- "*The Administrator shall, in accordance with the procedures established by this subsection, publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for a contaminant … if the Administrator determines that—*
  - (i) *the contaminant **may have an adverse effect** on the health of persons;*
  - (ii) *the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and*
  - (iii) ***in the sole judgment of the Administrator**, regulation of such contaminant presents a **meaningful opportunity for health risk reduction** for persons served by public water systems."* Safe Drinking Water Act, 42 U.S. Code § 300 g–1(b)(1).

And of course, statutory requirements and procedures for setting environmental standards also vary widely from country to country.[9]

3. EXAMPLES OF THE REGULATORY MELDING LAW AND SCIENCE

Courts and lawyers spend much of their time arguing about what these Delphic words in regulatory statutes mean in practice. However, at the workshop on which this symposium is based, most of the scientists dismissed them as mere "adjectives." Grammatically, some are indeed modifiers, but others establish varying degrees of precaution such that a mere "threat" that a substance "may" have an adverse effect on public health is enough to regulate. The wording of the governing statutes has enormous practical importance, as well as going a long way to explaining why many agency decisions do not reflect the same degree of rigor in assessing the Science that most scientists expect. Few, if any, United States Environmental Protection Agency (EPA) statutes require scientific proof at a 95% confidence level as a precondition for regulation.

One illustration is the precedent-setting cases featured prominently in many environmental law textbooks *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir.)(*en banc*), *cert. denied*, 426 U.S. 941 (1976), Available at https://casetext.com/case/ethyl-corp-v-epa. That case involved an EPA rule requiring the removal of lead as a fuel additive from gasoline. The court specifically held that the evidence of harm from exposure to lead from gasoline did not have to be proven as a scientific fact but that whether to remove it was a "delegated legislative policy decision" that the courts would not review "with the rigor customary for questions of fact." In other words, even lesser evidence of possible harm than the already lenient standards for "substantial evidence" discussed in the next section would be sufficient.

History has shown the wisdom of that reduced burden on proof for regulation of fuel additives. There was very little benefit from lead as a fuel additive, only a small increase in horsepower and fuel economy, plus lead was quickly replaced by other fuel additives; consequently, even a small risk to public health was not worth taking. Plus at the time, EPA believed that the only exposure route from lead in gasoline was that lead dust from vehicle exhaust that could settle curbside, and children would get the dust on their hands while playing in the street and then put them into their mouths, thereby ingesting the lead, the so-called "pica" exposure route. We later learned that there is also an inhalation exposure route for lead particulate, as well as seeing adverse effects of lead at lower and lower levels in the body as more studies were conducted.[12]

I was privileged to work on the *Ethyl* case as a law clerk to then Chief Judge David Bazelon. I was fresh out of a district court clerkship and had seen a lot of civil trials applying the higher standards for proof applicable to trials in court and so I would have come out the other way because I thought EPA had not proved its case, particularly with regard to exposure. Judge Bazelon was older and wiser, and he cast the decisive vote to uphold EPA's actions, in part because the victims were thought to be largely minority children in cities.

The decision to remove lead from gasoline is often cited today as one of the most successful EPA decisions from a public health perspective, and most of the rest of the world eventually followed our lead.[13] However, at the time the evidence was weak and at best only suggestive that lead from gasoline, as opposed to ingestion of lead paint, might be causing health problems.

That experience taught me that the strength of the evidence of harm is not always as important as the nature and extent of the possible harm to public health. A distinguished Assistant Administrator of EPA's Office for Research and Development, Paul Gilman, made that point a few years back in an oral comment at an annual meeting of the Society for Risk Analysis that I attended: he said something like "the purpose of risk assessment EPA is to make sure that we never under-estimate a risk to public health." Note: he did not say always to get the science right but to never underestimate a risk to public health. Like it or not, the job assigned to EPA by Congress is to protect public health, not to minimize the economic costs for pollution controls or environmental clean-ups that turn out in retrospect to have been unnecessary, or to establish scientific truths that can be relied upon by future generations.

4. QUALITY CONTROL OF EPA SCIENCE

Nonetheless, a number of institutional "checks and balances" have been put in place to try to ensure that EPA and other agencies that regulate risk have a reasonable basis in the existing science for their decisions. These include judicial review by the courts, review before promulgation of major rules by the OIRA, advisory boards of outside scientists in the agencies, and review and criticism of selected decisions by the National Academy of Sciences. For a variety of reasons, all of these checks and balances have been weakened in recent years.

The system of judicial review of agency decisions has been ably summarized in the article in this symposium by Eric Gotting, and I will not duplicate his analysis. I will only note that the standards that courts use to review the scientific evidence relied upon by administrative agencies is highly deferential.

Under the main governing statute, usually the Administrative Procedure Act, 5 U.S.C. §§701 *et seq*., the standard for trial type proceedings is "substantial evidence." That sounds good, but the case law defines "substantial evidence" as "such evidence as might appeal to a reasonable mind" but "more than a scintilla" (*Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951), https://supreme.justia.com/cases/federal/us/340/474/). The word "scintilla" is not in common usage, but it means only a "trace" (https://www.merriam-webster.com/dictionary/scintilla). Thus, because an administrative agency is presumed to be more expert in its subject than are generalist judges, it only has to have "more than a trace" of evidence to support its conclusions. I illustrate this principle by telling my administrative law classes that if only 10% of experts believe something, and 90% of experts disbelieve it, the agency is free to go with the 10% minority opinion, and that probably satisfies the (so-called) substantial evidence test.

The standard in rulemaking which most agencies use for risk regulation is not "substantial evidence" but "capricious and arbitrary" [*Citizens to Preserve Overton Park v. Volpe*, 332 U.S. 402 (1971)]. In 1984, Justice Scalia, then on the D.C. Circuit, expressed the view that the capricious and arbitrary standard

boiled down to the same thing as the substantial evidence test, *Assn of Data Processing Service Orgs. V. Bd. of Governors, Federal Reserve Sys.,* [745 F.2d 677 (D.C. Cir. 1984)]. Although some academics and courts think the arbitrary and capricious standard is even weaker than already weak substantial evidence standard (Fox, 2000), I think Scalia was right and both of them merely require some minimally rational basis for its conclusions, even if a proposition has not been proven scientifically and even if the majority of scientists would disagree with it.

These weak standards for judicial review are the ones that apply to all cases challenging actions by administrative agencies, not only the ones involving scientific conclusions. But worse yet, the courts have developed an even more deferential standard of review for issues "on the frontiers of science" based on a casual phrase in a Supreme Court case: *Baltimore Gas and Electric Co. v. NRDC*, 462 U.S. 87, 104 (1983) ("when examining agency determinations at the frontiers of science … a reviewing court must generally be at its most deferential"), https://supreme.justia.com/cases/federal/us/462/87/. Some experts have characterized this as "super-deference," but I have criticized it as "no look judicial review."[14] I share my Earth and Water Law colleague Susan Bodine's hope in her article in this symposium that courts may eventually hold that "substantial likelihood" really means "substantial likelihood," "substantial" really means "substantial," and "danger" really means "danger," placing somewhat stronger constraints on "agency discretion." However, today court decisions invalidating agency decisions for insufficient scientific support in the record are as rare as hens' teeth.

Moreover, even in the rare cases in which an agency decision is set aside for lack of sufficient support in the record, the usual remedy is to send the case back to the agency for a "do over," which is technically called a *remand*. In the only empirical study that I know of that explored what happens on remand after agencies lose in court, a colleague and I discovered that according to the parties, most of the time that agency does the same thing again and merely provides more explanation and evidentiary support or makes only minor changes.[15]

5. OTHER CHECKS AND BALANCES ON AGENCY SCIENCE

The perceived inadequacy of judicial review to ensure that agency decisions are based on "good science" has led to several other devices. In my opinion, they have also failed to assure that agencies have a reliable scientific basis for their decisions.

The first of these to develop was boards of outside scientists to advise the agencies. In some kinds of regulation, review by such outside advisers is required, although in few, if any, is approval by the science advisers required. The agencies have learned how to neuter science advisory boards by firing the hold-overs and appointing scientists more in tune with the current administrations' policy preferences, including many who are recipients of research grants from the agency. The Trump Administration tried to bar scientists who are receiving EPA grants from serving on EPA's science Advisory Board, but its policy was set aside in court in a suit brought by the environmental advocacy group, the Natural Resource Defense Council.[16]

As noted above, since the Reagan Administration, most major rules are reviewed before proposal and again before promulgation by the OIRA. The OIRA staff consists almost entirely of economists and experts in benefit–cost analysis. Briefly during the George W. Bush Administration, OIRA Administrator John Graham hired a toxicologist, Nancy Beck, one of the contributors to this symposium. Unfortunately, subsequent OIRA Administrators have not followed Graham's lead but have focused almost exclusively on estimates of cost and benefits prepared by the agencies.

In addition, OIRA considers not only the direct benefits from reducing exposures to a single chemical but also the "co-benefits" that result indirectly from the controls put in place to control the substance over which the agency has statutory authority.[17] Co-benefits played a major role in EPA's recent exceeding low (4 parts per trillion) maximum contaminant level for certain per- and polyfluoroalkyl substances (PFAS). For years, going back to when I served as its General Counsel (1989–1991), EPA has wanted to control "disinfection by-products" that results from chlorination of water that contains particles of organic material. However, the agency was reluctant to do so because of the large costs that requiring activated carbon treatment of drinking water would have imposed on municipal drinking water systems. However, some hope that now the private companies that manufactured or used PFAS will be held responsible for the costs of removing the PFAS by activated charcoal filtration, which will also have the co-benefit of removing most of the disinfection by-products.

For a while in 1990s and early 2000s, the National Academy of Sciences reviewed and criticized a number of EPA decisions, particularly the risk assessments conducted by its Integrated Risk Assessment System. That practice has atrophied in recent years for reasons that I do not fully understand.

6. CONCLUSION

The disparities in risk-based standards for exposure to PFASs documented in this symposium are not unexpected. In part, they are due to differences in statutory standards within regulatory programs in the United States and between the United States and other countries, but the weakness of checks and balances on agency science may also contribute to them.

DECLARATION OF COMPETING INTERESTS STATEMENT

At the time of the workshop and the drafting of this paper, the author had no competing interests. However, for a brief period between the two, he was retained by a technical expert to advise on certain legal process issues including OIRA review. That technical expert was in turn advising a law firm that was in turn advising a chemical company that had manufactured certain PFAS compounds.

Received: September 30, 2024
Revised: December 13, 2024
Accepted: December 25, 2024
Published: February 7, 2025

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