EXPOSED: Asking the Wrong Question in Risk Regulation

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INTRODUCTION

Back in 1973, the tuna industry wanted to know how much fish Americans were eating. After asking 7,662 households to record their daily fish intake,[1] the answer came back: people ate fish, but not very often—about once a month. While tuna purveyors mulled what to do with this information, the U.S. Environmental Protection Agency (EPA) borrowed their dataset. EPA used these data to derive a key variable in the equation for calculating people's exposure to toxic contaminants in the nation's waters: the fish consumption rate (FCR). This FCR served as the premise for EPA's initial volley of water quality criteria in 1980 and, subsequently, for water quality standards across the nation.[2] Even today, several states' water quality standards are based on this FCR, which assumes that people eat just 6.5 grams

1. HAROLD JAVITZ, SEAFOOD CONSUMPTION DATA ANALYSIS: FINAL REPORT 19 (1980), https://hero.epa.gov/hero/index.cfm/reference/download/reference_id/14202.
2. Water Quality Criteria Documents; Availability, 45 Fed. Reg. 79,318, 79,318 (Nov. 28, 1980).

of fish per day.[3] That Americans' fish consumption habits in the early 1970s continue to undergird environmental standards today is remarkable. Families in Washington, Idaho, and Alaska that put fish on the dinner table more than once a month still do so at their peril. Of greater consequence, however, is that EPA's early attempts to ascertain people's practices became the template for its reigning method of exposure assessment. This method, however, focuses on the wrong question.

Environmental standards determine the future state of our air, waters, and soils. Health-based environmental standards, the concern of this Article, aim to limit contaminants to levels that are safe for or, alternatively, that pose an "acceptable" risk of harm to humans. To establish this level, agency risk assessors consider the toxicity of various chemical substances together with people's circumstances of exposure—their quotidian practices and lifeways that bring them into contact with these toxic substances. This latter inquiry has typically been framed as the question "to what are people exposed?" Agency exposure assessors generally enlist survey, demographic, and other data depicting people's present (or, more accurately, recent past) characteristics and behaviors. This snapshot of contemporary exposure then serves as the premise for health-based standard setting—for requiring environmental conditions that support the behaviors depicted.

However, people's contemporary practices are shaped in part by environmental degradation—by waters that kill off or contaminate our fish; by air that keeps us sedentary or indoors; by soil that makes gardening or mud-pie making perilous. People's behaviors may be constrained; they may or may not reflect practices that are healthful. By setting standards to ensure that people can engage in just these contemporary behaviors, agencies may render "health-based" a misnomer. Moreover, given the operation of negative feedback loops between environmental quality and people's activities and resource uses, exposure assessment's recent-past orientation may undermine progress toward an environment that can in fact support human health.

Fish consumption provides a case in point. Agencies have for years gauged the permissible concentration of mercury, PCBs, and a host of other

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3. On November 15, 2016, EPA announced it was approving in part and disapproving in part updated water quality standards promulgated by the state of Washington; concurrently, EPA issued federal standards for Washington in place of most of the disapproved state-adopted criteria. Once these updates become effective, the current one-meal-per-month (6.5 grams/day) fish consumption rate will remain for only a handful of contaminants in Washington. *See infra* note 150 and accompanying text.

toxic contaminants in our waters and sediments[4] by reference to the 6.5 grams/day FCR.[5] In so doing, they failed to acknowledge that they were writing on a dirty slate. The tuna industry survey that is the source of this figure captured people's practices at a time when the rivers were on fire, our lakes and bays still treated as open sewers, the fish resource had become depleted and contaminated, and tribal harvest was still under open attack. Catching and eating fish during this era was hazardous (if not impossible). A survey of people's fish intake during this period would have reflected these constraints.

While the fish were few and unfit for human consumption four decades ago, things are only somewhat better today. There has been some progress, but our waters nonetheless remain compromised, our fish resource depleted and contaminated. Meanwhile, our awareness of degradation and its consequences for human health has increased. Too, health and environmental agencies have increasingly presided over a shift to quasi-regulatory strategies that rely on "risk avoidance" in lieu of "risk reduction."[6] That is, rather than require polluters to reduce their releases of toxic contaminants, agencies have called upon those exposed to alter their practices in order to avoid contact with these contaminants—for example, issuing fish consumption advisories that urge people to curtail their fish intake.[7] Although people's ability to take "averting" or "compensatory" measures varies greatly,[8] at least some people decrease their fish intake or change their ways to avoid being exposed.[9] Thus,

4. *See* EPA, FACT SHEET: POLYCHLORINATED BIPHENYLS (PCBS) UPDATE: IMPACT ON FISH ADVISORIES 2 (1999) [hereinafter PCB FACT SHEET], https://nepis.epa.gov/Exe/ZyPDF.cgi/901V0A00.PDF?Dockey=901V0A00.PDF; EPA, TECHNICAL FACT SHEET: TRENDS IN BLOOD MERCURY CONCENTRATIONS AMONG WOMEN OF CHILDBEARING AGE 1 (2013) [hereinafter TECHNICAL FACT SHEET], https://nepis.epa.gov/Exe/ZyPDF.cgi/P100LP4L.PDF?Dockey=P100LP4L.PDF. Fish intake is the primary route of human exposure to these contaminants. PCB FACT SHEET, *supra*, at 2.

5. Water Quality Criteria Documents, 45 Fed. Reg. at 79,318.

6. *See* Catherine A. O'Neill, *No Mud Pies: Risk Avoidance as Risk Regulation*, 31 VT. L. REV. 273, 273–76 (2007).

7. *See National Listing of Fish Advisories General Fact Sheet*, EPA, https://www.epa.gov/fish-tech/national-listing-fish-advisories-general-fact-sheet-2011#website (last visited Nov. 8, 2016).

8. *See* O'Neill, *supra* note 6, at 321–26; Catherine A. O'Neill, *Risk Avoidance, Cultural Discrimination, and Environmental Justice for Indigenous Peoples*, 30 ECOLOGY L.Q. 1, 25–26 (2003) [hereinafter O'Neill, *Risk Avoidance*].

9. *See* Elizabeth Hoover, *Cultural and Health Implications of Fish Advisories in a Native American Community*, 2 ECOLOGICAL PROCESSES 1, 7 (2013) (finding that 75% of respondents in Akwesasne community reported decreasing or ceasing entirely their fish intake); Emily Oken et al., *Decline in Fish Consumption Among Pregnant Women After a National Mercury Advisory*, 102 OBSTETRICS & GYNECOLOGY 346, 348 (2003) (finding that pregnant women with access to

it may not advance the aim of environmental health to base water quality standards on newer fish consumption surveys—to replace the dated snapshot with a more recent photograph. Such an approach has led EPA to recommend incremental increases to the national default fish consumption rate for water quality standards—from 6.5 grams/day in 1980,[10] to 17.5 grams/day in 2000,[11] to 22 grams/day in 2015.[12] But these rates reflect an environment in which people's options remain limited, their choices and behaviors constrained.

Nor have agencies considered whether these fish consumption rates are tied in any particular way to practices that would be healthful or support tribal lifeways. The health benefits of frequent fish consumption are widely recognized. Studies show significantly reduced risk of coronary heart disease[13] and colorectal cancer[14] and significantly decreased cognitive decline and risk of brain abnormalities[15] when people consumed ample amounts of fish—ranging from three to seven fish meals per week (roughly 97.2 grams/day to 227 grams/day). Moreover, fishing itself is a healthful activity, and for some people, a culturally important or essential activity. For many American Indian tribes, including the fishing tribes in the Pacific Northwest, every facet of managing, harvesting, distributing, consuming, and honoring

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obstetric care decreased fish consumption in response to publication of federal advisory warning of mercury contamination in certain species of fish); Jay P. Shimshack et al., *Mercury Advisories: Information, Education, and Fish Consumption*, 53 J. ENVTL. ECON. & MGMT. 158, 177 (2007) (finding that among "educated" families with young or nursing children, purchase of canned fish decreased by 50% in response to consumption advisories due to mercury, but finding no change in fish consumption among "less educated" families).

10. Water Quality Criteria Request for Comment, 44 Fed. Reg. 15,926, 79,324.

11. EPA, METHODOLOGY FOR DERIVING AMBIENT WATER QUALITY CRITERIA FOR THE PROTECTION OF HUMAN HEALTH 1-5 (2000), https://nepis.epa.gov/Adobe/PDF/20003D81.pdf.

12. EPA, HUMAN HEALTH AMBIENT WATER QUALITY CRITERIA: 2015 UPDATE 2 (2015).

13. Adam M. Bernstein et al., *Major Dietary Protein Sources and Risk of Coronary Heart Disease in Women*, 122 CIRCULATION 876, 876–77 (2010) (describing results of prospective study following 84,136 women aged thirty to fifty-five for twenty-six years, as part of the Nurses' Health Study, which found a twenty-four percent lower risk of coronary heart disease for those eating one fish serving per day as compared to those eating one red meat serving per day).

14. Megan N. Hall et al., *A 22-year Prospective Study of Fish,* n*-3 Fatty Acid Intake, and Colorectal Cancer Risk in Men*, 17 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1136, 1137–40 (2008) (describing results of prospective study following 22,071 adult men for twenty-two years as part of the Physicians' Health Study, which found thirty-seven percent lower risk of colorectal cancer for those eating five or more fish meals per week as compared to those eating less than one fish meal per week).

15. Z.S. Tan et al., *Red Blood Cell Omega-3 Fatty Acid Levels and Markers of Accelerated Brain Aging*, 78 NEUROLOGY 658, 662–63 (2012).

the fish is woven into the fabric of tribal life.[16] Fish are important for each individual tribal member, and for the tribe as a whole— necessary for health and well-being broadly understood to include not only physiological, but also cultural and spiritual dimensions.[17] For these tribal people, a healthful level of fish intake might be that consonant with "heritage" practices—estimates of historical consumption of fish among fishing peoples in the Pacific Northwest range as high as 1,000 to 1,500 g/day.[18]

This example illustrates why, when agencies use contemporary exposure data to set health-based standards, they potentially set in motion a negative feedback loop. With the waters and sediments required to be clean enough to support only modest levels of fish intake (relative to those that would be healthful or that would be consonant with heritage practices in the fishing tribes), the fish resource would remain depleted and contaminated in some degree. Some individuals might be expected to respond by further decreasing their fish intake or that of their family members. Some individuals might find fewer fish to be caught. The next round of surveys would then reflect even lower fish consumption rates, and agencies would set new standards assuming that little or no human exposure to contaminants occurs via fish consumption. These new standards would therefore permit even greater quantities of contaminants in aquatic ecosystems. And so on.

The fish consumption exposure pathway presents but one example. In areas plagued by air pollution, some people have taken steps to reduce their

16. *See, e.g.*, Catherine A. O'Neill, *Fishable Waters*, 1 AM. INDIAN L.J. 181, 181–83, 187–93 (2013) (gathering evidence of Pacific Northwest tribes' statements to this effect); *see also* discussion *infra* notes 315–25 and accompanying text.

17. *See, e.g.*, Jamie Donatuto et al., *Poisoning the Body to Nourish the Soul: Prioritizing Health Risks and Impacts in a Native American Community*, 13 HEALTH, RISK & SOC'Y 103, 103–04 (2011).

18. *See* Barbara L. Harper et al., *The Spokane Tribe's Multipathway Subsistence Exposure Scenario and Screening Level RME*, 22 RISK ANALYSIS 513, 518 (2002) [hereinafter *Spokane Subsistence Exposure Scenario*] ("Historically, the Spokane Tribe consumed roughly 1000 to 1500 grams of salmon and other fish per day"); *see also* Barbara L. Harper & Deward E. Walker, Jr., *Columbia Basin Heritage Fish Consumption Rates*, 43 HUM. ECOLOGY 237, 242 (2015) [hereinafter *Columbia Basin Consumption Rates*]; Barbara L. Harper & Deward E. Walker, Jr., *Comparison of Contemporary and Heritage Fish Consumption Rates in the Columbia River Basin*, 43 HUM. ECOLOGY 225, 233 (2015) [hereinafter *Comparison of Consumption Rates*].

time outdoors,[19] to curtail their activity level when they do go outside,[20] and to keep their children—particularly those with asthma[21]—inside in response to "ozone alerts" or to their perception that the air quality is poor. In urban neighborhoods saddled with lead and other heavy metal contamination in their soils, some community gardeners have avoided growing vegetables or have refrained from eating the produce they do grow.[22] By premising standards for air, waters and soils on human behaviors in a degraded world, agencies aim for no better—regardless of these behaviors' relationship to health-based standards' promised ends.

How did we come to determine the future state of our waters, air, and soil by reference to exposure assessments conducted in the recent-past tense? This Article examines the history of exposure assessment at EPA in an effort to shed light on this question. Although previous scholarship has considered the

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19. *See* Brian W. Bresnahan et al., *Averting Behavior and Urban Air Pollution*, 73 LAND ECON. 340, 341 (1997) (finding that "persons who experience smog-related symptoms spend significantly less time [about forty minutes per day] outdoors as ozone levels exceed the national standard," and that whereas the majority of respondents who are susceptible to acute symptoms undertake this averting behavior, fewer of those whose adverse health effects were chronic kept themselves indoors); Matthew Neidell & Patrick L. Kinney, *Estimates of the Association Between Ozone and Asthma Hospitalizations that Account for Behavioral Responses to Air Quality Information*, 13 ENVTL. SCI. & POL'Y 97, 97–98 (2010) (finding that individuals take substantial avoidance actions in the face of ozone alerts); Enrico Moretti & Matthew Neidell, *Pollution, Health, and Avoidance Behavior: Evidence from the Ports of Los Angeles* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 14939, 2009) (noting avoidance behavior undertaken in response to personal observation and air quality alerts on high ozone days).

20. *See, e.g.*, Xiao-Jun Wen et al., *Association of Self-Reported Leisure-Time Physical Inactivity with Particulate Matter 2.5 Air Pollution*, 72 J. ENVTL. HEALTH 40, 40 (2009) (finding an association between elevated PM2.5 levels and greater "leisure-time physical inactivity," and positing that people were less active due to either a direct influence, insofar as individuals' ability to be physically active was compromised by elevated levels of PM2.5, or an indirect influence, insofar as individuals reduced their activities in response to media alerts warning of poor air quality episodes). *But cf.* Danielle Bäck et al., *National Evidence on Air Pollution Avoidance Behavior*, 94 LAND ECON. (forthcoming 2016) (manuscript at 3), http://www.public.asu.edu/~nkuminof/BKVV13.pdf (finding that adults generally do not alter their outdoor leisure time or activities as ozone pollution levels rise, presumably given the correlation between increased ozone and improved weather suitable for outdoor activities, i.e., weather conditions such as warmer temperatures and lack of precipitation).

21. *See* Carol Mansfield et al., *The Missing Piece: Valuing Averting Behavior for Children's Ozone Exposures*, 28 RESOURCE & ENERGY ECON. 215, 217 (2006); Xiao-Jun Wen et al., *Association Between Media Alerts of Air Quality Index and Change of Outdoor Activity Among Adult Asthma in Six States, BRFSS, 2005*, 34 J. CMTY. HEALTH 40, 43–44 (2009) (reporting similar findings for adults with asthma).

22. Brent F. Kim et al., *Urban Community Gardeners' Knowledge and Perceptions of Soil Contaminant Risks*, PLOS ONE (Feb. 6, 2014), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0087913#s4.

evolution of risk assessment more generally, this Article is the first to delve into the development of exposure assessment at EPA.

This inquiry reveals that when EPA embarked on health-based standard setting in its early years, little was known about human exposure. There was significant work to be done to stitch together even a basic picture of how people came in contact with the pollutants EPA had been tasked with regulating. Lacking exposure-specific data, EPA drew upon the data then at hand—data that had generally been gathered for other purposes, such as by sociologists seeking to understand the different activity patterns of "operatives" and "housewives," or by industry associations seeking to understand Americans' preferences for tuna noodle casserole. Reflecting the purposes for which they had been gathered, these datasets depicted then-present practice. EPA scientists imported the contemporary orientation of these data into their risk assessment equations—in the process making a normative choice about the human behaviors that the resulting health-based standards would support. Yet, for reasons explained in this Article, EPA appears not to have grappled at any length with the fact that its focus on people's *existing* practices determined the scope of people's *future* practices. Rather, EPA bent its energies toward wrestling with these quirky data and, later, updating and refining them to produce a more finely grained picture of people's contemporary characteristics and behaviors.

Building on these historical insights, this Article critiques current agency practice. It finds that exposure assessment's emphasis on people's actual, contemporary circumstances turns out to be problematic for three reasons. First, exposure assessment is untethered to behaviors that are healthful or vital. As such, the method may undermine the restorative and preventive aims of our foundational environmental laws. The method may also undercut rights-based claims to a healthful environment, including guarantees to robust resources contained in treaties between the United States and American Indian nations. Second, exposure assessment tends to subsume into its depiction of human circumstances any "averting" or "compensatory" actions people have adopted in response to environmental degradation, without questioning whether the relevant baseline should thereby be adjusted. Thus, it effectively replaces statutory approaches premised on risk reduction with an approach that assumes risk avoidance. Third, exposure assessment as practiced also sets up a moving target, as there will always be an argument that newer data would more accurately capture people's current practices. With each of the numerous inputs to an exposure equation subject to constant revision and renewed debate, the occasions for delay are many. These contests in practice have often disserved the aims of environmental health. Upon examination, then, I conclude that exposure assessment's inquiry is misaimed in the standard-setting context; as practiced, it may not serve its purported "health-based" ends.

This Article then considers whether we might ask a better question. I suggest that exposure assessments depict practices and resource uses that are healthful and, in the case of tribal people, consonant with heritage practices. Environmental standards would then reflect—and beget—the environmental conditions necessary to support human health and well-being. Such an approach could be operationalized without radical alterations to the quantitative risk assessment framework, by enlisting exposure scenarios. Recognizing that it is not possible here to elaborate a reoriented exposure assessment method in all its particulars, I nonetheless identify some of the possibilities and venture some responses to the problems that might be anticipated.

This Article proceeds as follows. Part I first provides an overview of exposure assessment, explaining how it typically functions in environmental standard setting. It then identifies three eras in the history of exposure assessment, situating the method's development at EPA in the context of the larger debate about quantitative risk assessment during this time. Having sketched the relevant history in broad strokes, Part II dives more deeply into EPA's early work to consider the forces that shaped the method. It draws upon archival sources documenting EPA's initial efforts to assess people's exposure to contaminants in air and water and to articulate guidance for exposure assessment nationwide. Part III examines exposure assessment as currently practiced and finds it to suffer from several infirmities. This Part concludes that exposure assessment's focus on the recent past disserves the aim of bringing about the environmental conditions necessary for a healthful future. Part IV proposes that exposure assessment be reoriented to align more closely with its purpose when it serves as the premise for health-based standards.

I. BACKGROUND: EXPOSURE ASSESSMENT IN ENVIRONMENTAL REGULATION

Health-based standards constitute an important regulatory approach under the major environmental laws in the United States.[23] Health-based standards

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23. *See, e.g.*, Michael A. Livermore & Richard L. Revesz, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U. L. REV. 1184, 1190 (2014) ("The major U.S. environmental statutes contain three principal approaches for determining the stringency of environmental protection: cost-benefit standards, feasibility standards, and health-based standards.").

determine the amount of contamination that may permissibly be released to or remain in our environment by reference to human health.[24] Standards of this sort seek to eliminate contaminants in excess of levels that are safe for humans or levels that pose an amount of risk deemed acceptable.[25] Human health forms the touchstone for efforts to address harmful substances in our air, water, and soils under numerous federal statutes, including the Clean Water Act (CWA), the Clean Air Act (CAA), and the Comprehensive Environmental Response, Cleanup and Liability Act (CERCLA), as well as under their state and tribal counterparts.[26]

Over the last several decades, quantitative risk assessment (QRA) has come to dominate health-based environmental standard setting.[27] EPA formally embraced QRA beginning in the 1970s.[28] The QRA process is generally described as being comprised of four parts: hazard identification, dose-response extrapolation, exposure assessment, and risk characterization.[29] This Article is concerned primarily with exposure

24. Health-based standards might also be set by reference to ecological health; this topic, however, is beyond the scope of this Article.

25. *See, e.g.*, Livermore & Revesz, *supra* note 23, at 1193–94 (health-based standards "seek either the entire elimination of a public health risk or, failing that, the achievement of what is deemed to be an acceptable level of risk").

26. *See id.* at 1194–96. While this Article focuses on exposure assessment in health-based standing setting, its observations may also be relevant to exposure assessment in other environmental regulatory contexts. For example, the regulation of existing toxic substances under the Toxics Substances Control Act (TSCA) has generally been classified as involving a cost-benefit standard rather than a health-based standard, see *id.* at 1191. While this cost-sensitive frame continues to guide EPA's risk management decisions under TSCA as amended in June of 2016, human health is nonetheless an important touchstone for EPA's assessment of risks. *See The Frank R. Lautenberg Chemical Safety for the 21st Century Act: Frequent Questions*, EPA, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0#effective (last visited Nov. 8, 2016). For example, under the TSCA Work Plan Chemicals Assessment Program, EPA conducts risk assessments in order to identify those chemicals that pose "unacceptable risks" to humans or the environment, and so may warrant regulatory action under TSCA. *TSCA Work Plan Chemicals*, EPA, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals (last updated Aug. 29, 2016).

27. For an excellent discussion of the rise of QRA in health-based regulation, see generally William Boyd, *Genealogies of Risk: Searching for Safety, 1930s-1970s*, 39 ECOLOGY L. Q. 895 (2012). Among other things, Professor Boyd observes that risk-based approaches are likely to continue to hold sway over environmental policy. *See id.* at 980–83. This Article's critique of exposure assessment is based on the assumption that QRA will remain an important tool in environmental decision making; in doing so, however, the Article does not mean to suggest support for risk-based approaches over alternative approaches to environmental problems.

28. *The History of Risk at EPA*, EPA, https://www.epa.gov/risk/about-risk-assessment#tab-2 (last updated May 2, 2016).

29. *See* NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 3 (1983) [hereinafter THE RED BOOK].

assessment. This third component of QRA received comparatively less attention in the early risk literature, and emerged as a coherent field relatively recently. This Part provides an overview of exposure assessment generally and as the method has been used by EPA to set health-based standards. It tracks the history of exposure assessment at EPA, situating the method's development within the larger debate over risk assessment in the environmental regulatory context. This Part concludes with a sketch of exposure science in the new millennium, highlighting the identification of "suppression effects"—a recognition with important implications for exposure assessment that has received relatively little attention.

A. Exposure Assessment

As humans go about their days, they come into contact with any number of toxic contaminants that may adversely affect their health. Exposure assessment considers the nature of this contact—its intensity, frequency, pattern, and duration—and thus forms a part of scientists' understanding of how environmental pollution impacts public health. This section first explains the domain of exposure assessment in general and then describes its role in environmental standard setting.

1. Overview

For scientists concerned with the public health impacts of environmental contaminants, it is necessary to understand the relationship between cause (a toxic agent) and effect (harm to human health).[30] Scientists must study each contaminant from its release at a source; through its movement in one or more media (e.g., air, water, soil); to the point of contact with a human "receptor;" where it will be absorbed or adsorbed and potentially yield a biologically effective dose; and ultimately be expressed in the form of an adverse health effect.[31] Various scientific disciplines are necessary to comprehend this continuum. On one end, environmental science has traditionally concerned itself with the sources that release a toxicant and the processes that transform

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30. *See, e.g.*, Wayne R. Ott, *Exposure Analysis: A Receptor-Oriented Science*, *in* EXPOSURE ANALYSIS 3, 3–6 (Wayne R. Ott et al. eds., 2007).

31. *See, e.g.*, PAUL LIOY & CLIFFORD WEISEL, EXPOSURE SCIENCE: BASIC PRINCIPLES AND APPLICATIONS 5–9, fig.1.1 (2014) (setting forth a descriptive and graphic representation of the role of exposure science in the "continuum from source to effect").

or transport it (i.e., its fate and transport) once in the environment.[32] On the other end, the environmental health sciences have traditionally considered the processes that occur when a biologically effective dose is received by a human body, and include the fields of toxicology and epidemiology.[33] Exposure assessment or "exposure science" serves as the bridge between these two ends of the continuum.[34] Its domain is the question "whether and how a human being actually makes 'contact' with releases into the environment . . . ."[35] Human "exposure" has recently been defined as "[a] person's contact with the concentration of a [chemical, physical, or biological] material before and after it crosses a boundary (nose, skin or mouth) between the human and the environment over an interval of time leading to a potential biologically effective dose."[36] The bridging function of exposure science is underscored by Paul Lioy's amendment to Paracelsus' famed observation; according to Lioy, "'exposure provides the dose that makes the poison.'"[37]

Exposure science's function as bridge is highlighted by the recognition that the continuum from environmental source to adverse health impact is bidirectional. In theory and application, scientists may be called to begin at either end, working in either a "forward" or an "inverse" direction.[38] There are numerous historical and contemporary examples in which scientists began with epidemiological information—whether of a cholera epidemic in 1854 or a Salmonella outbreak in 2008—and then worked in an "inverse" direction to inquire into commonalities in human behaviors that resulted in exposure to a likely source of the harmful agent (e.g., drinking "water from a well at Broad Street, Soho, near Golden Square;"[39] eating peanut butter manufactured by the Peanut Corporation of America[40]). Conversely, there are

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32. *Id.* at 7.

33. *Id.*

34. *Id.* at 5 ("Exposure science's role in advancing public health can be described as the scientific bridge between environmental science and other disciplines within environmental health sciences.").

35. *Id.* at 7.

36. *Id.* at 17 (citing NAT'L RESEARCH COUNCIL, EXPOSURE SCIENCE IN THE 21ST CENTURY: A VISION AND A STRATEGY 31–32 (2012)).

37. *Id.* at 18 (citing Lioy et al., *Exposure Science: A View of the Past and Milestones for the Future*, 118 ENVTL. HEALTH PERSP. 1081, 1084 (2010)).

38. *Id.* at 6 fig.1.1.

39. *Id.* at 1.

40. *See Multistate Outbreak of Salmonella Tryphimurium Infections Linked to Peanut Butter, 2008–2009*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html (last updated May 11, 2009).

many examples in which scientists began with observed data identifying sources of contamination (e.g., smoke-belching stacks on an oil refinery; 55-gallon drums leaking chemicals) and worked "forward" to trace the releases downwind or downgradient until they reach humans whose location and activities may result in contact with potentially harmful concentrations over a relevant time.[41]

Humans may encounter environmental contaminants by various "exposure pathways"—a term that describes the journey of pollutant from a source to a human receptor in an exposed population.[42] People may uptake contaminants via one of three routes: inhalation, dermal absorption, or ingestion.[43] Some chemical contaminants reach humans through a single route of exposure; carbon monoxide (CO), for example, is emitted in gaseous form into the air where it may be inhaled.[44] Other chemical contaminants reach humans through two or more routes of exposure via multiple pathways. Lead, for example, may be present in air, water, food, and soil or dust, where it may be inhaled, ingested, or absorbed dermally.[45]

An exposure assessment measures or models human contact with an environmental contaminant.[46] For some contaminants and routes of exposure, an individual's exposure can be measured directly with high precision, e.g.,

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41. *See* Ott, *supra* note 30, at 3.

42. *See, e.g.*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., PUBLIC HEALTH ASSESSMENT GUIDANCE MANUAL 6–3 (2005), http://www.atsdr.cdc.gov/hac/PHAManual/PDFs/PHAGM_final1-27-05.pdf (explaining that an exposure pathway begins at (1) a contaminant's source or point of release; (2) tracing it as it migrates through environmental media such as air, water, or soil; until (3) a point or location at which people come in contact with a contaminated medium; such that (4) there is physical uptake of the contaminant via one of three routes, namely inhalation, dermal absorption, or ingestion; by (5) a human receptor in a potentially exposed population).

43. *Id.*

44. *See, e.g.*, Ott, *supra* note 30, at 6–7.

45. *Id.*

46. LIOY & WEISEL, *supra* note 31, at 19–20. Note that the matter of human "contact" raises the issue of the point on or in the body at which exposure takes place. Although usage in the field comprehends both the visible, external surface of a person (e.g., the skin or openings into the body such as the mouth or nostrils) and the "exchange boundaries" where absorption takes place (e.g., the lungs or gastrointestinal tract), EPA has clarified that, for its purposes, exposure will be defined "as taking place at the visible external boundary" of the human body, such that exposure assessments provide a quantitative and qualitative evaluation of the breach of that boundary. EPA, GUIDELINES FOR EXPOSURE ASSESSMENT 4–5 (1992), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=429103 [hereinafter 1992 GUIDELINES]; *accord* EPA, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT: PEER REVIEW DRAFT 8 (2016), https://www.regulations.gov/document?D=EPA-HQ-ORD-2015-0684-0002 [hereinafter 2016 GUIDELINES]. This Article discusses human contact in accordance with this EPA definition.

certain air pollutants can be detected by means of a personal exposure monitor worn constantly by an individual.[47] For other contaminants and routes of exposure, such a direct measure of an individual's exposure is not technologically possible or not thought feasible in practice for every individual in a population.[48] Exposure assessors have thus also developed "indirect" methods that enlist measured and modeled data to estimate people's exposure.[49] For example, an indirect approach to assessing exposure to CO might combine measurements of CO concentrations in various microenvironments (e.g., outdoors at work; inside a motor vehicle; indoors at home) with diary-based information recording human activity patterns to predict population exposure in certain urban areas, by means of an exposure model.[50]

The description so far has been somewhat simplified; it should be noted that things can quickly get complicated. The particular variables that must be considered will differ for different contaminants and exposure pathways. For example, adult human exposure to dioxins via the fish ingestion pathway will depend on the quantity and quality of dioxins present in surface waters; the degree to which these dioxins bioaccumulate in the tissue of fish that inhabit the waters (which in turn depends on fish species, perhaps introducing hundreds of possibilities); the quality and quantity of humans' fish intake (which in turn raises issues of the parts of the fish consumed and the impact of preparation methods on contaminant concentration in the consumed fish tissue); the frequency, pattern, and duration of these fish consumption practices over a human lifetime (which in turn raises questions of seasonality and instances of exceedingly large fish intake, as well as the coincidence of various levels of intake with particular human lifestages); and the sex and bodyweight of the humans in question.[51] Moreover, a person may be exposed to dioxin via other pathways and routes; thus, for each chemical contaminant, multiple exposure pathways may be relevant to an individual's total

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47. Ott, *supra* note 30, at 8–10. *See generally* Lance A. Wallace, *Personal Monitors*, *in* EXPOSURE ANALYSIS 99, 99–112 (Wayne R. Ott et al. eds., 2007) (discussing personal monitors).

48. Ott, *supra* note 30, at 6, 8–10 (discussing studies that attempt to identify exposure rates of larger populations by using smaller, representative samples of those populations).

49. *Id.* at 10–12.

50. *Id.*; *see also* Peter G. Flachsbart, *Exposure to Carbon Monoxide*, *in* EXPOSURE ANALYSIS 113, 113–46 (Wayne R. Ott et al. eds., 2007).

51. *See generally* Daniel J. Stralka & Harold A. Ball, *Exposure to Dioxin and Dioxin-Like Compounds*, *in* EXPOSURE ANALYSIS 379, 379–93 (Wayne R. Ott et al. eds., 2007) (discussing the occurrence and fate of dioxin in the environment, dioxin toxicity, and the processes by which humans are exposed to dioxin through various pathways, including fish ingestion).

exposure.[52] Additionally, cumulative exposures must be accounted for: different chemicals may operate via a common mechanism to produce similar adverse human health "endpoints."[53]

Importantly for my purposes, in order to understand human exposure an exposure assessment must take into account people's characteristics and practices—their daily activities at various lifestages that, in our "chemical world,"[54] bring them into contact with toxic substances. Thus, exposure assessors must consider data about where humans reside, work, or otherwise spend their day (e.g., in close proximity to an industrial emissions source or a transportation corridor); how much time they spend engaged in various activities at differing levels of cardiovascular vigor (e.g., sleeping, sitting, exercising) in various locations (e.g., indoors at work; outdoors in a garden); and the quantities of various food and drink items ingested. Exposure assessors also need to understand human behaviors over their lifetimes. Either or both of short-term and long-term exposures may be of concern depending on the chemical at issue. And the lifestage during which a human is exposed can be important to whether contact with a toxic substance begets an adverse health effect. Thus, it has increasingly been emphasized, certain "windows of exposure" can be critical (e.g., for a neurodevelopmental toxin such as methylmercury, it is exposure *in utero* or during childhood that is of greatest concern).[55] It is with the methods used to characterize what might be called the *human behavioral component* of exposure assessment that this Article is primarily concerned.

Exposure assessors can alter their assumptions about the variables that together characterize an individual's exposure under particular circumstances, allowing them to pose "what if" questions.[56] What if kids are assumed to exercise vigorously outdoors and respire accordingly for an hour each day rather than for ten minutes: how much would current air pollutant levels need to decrease, if risk levels are held constant? How much would

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52. *Id.* at 384–89.

53. LIOY & WEISEL, *supra* note 31, at 31–32.

54. *Id.* at 8 (stating because "we do live in a 'chemical world,' and the toxic agents which we are exposed to can enter our body," exposure science is a key input to public health policy).

55. *See* Philippe Grandjean et al., *The Faroes Statement: Human Health Effects of Developmental Exposure to Chemicals in Our Environment*, 102 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 73, 75 (2007) (announcing conclusion on behalf of two dozen scientists in the field that "[t]he periods of embryonic, fetal and infant development are remarkably susceptible to environmental hazards. Toxic exposures to chemical pollutants during these windows of increased susceptibility can cause disease and disability in infants, children and across the entire span of human life" and recommending that agencies' risk assessments do more to take these windows into account).

56. *See, e.g.*, Ott, *supra* note 30, at 10.

risk increase, if air pollutant levels are held constant? What if pregnant women are assumed to drink three liters of water per day rather than the two liters per day currently assumed: how would this affect estimates of risk from exposure to contaminants in surface or groundwater? What if farmworkers are assumed to eschew protective equipment on days when the temperature exceeds eighty degrees?

Exposure assessments can consider people's exposures in the past, at present, or in the future, depending on the purpose for which the assessment is conducted. Agencies may need to reconstruct people's practices over a relevant period in the past, for example, in order to identify potential dietary sources of a foodborne pathogen. Agencies may need to understand people's existing practices, for example, in order to craft immediate public health interventions (e.g., ascertaining how much tap water people ordinarily drink in order to procure adequate bottled water substitutes when the former is contaminated; evaluating the impact of consumption or use advisories that have been in effect); to facilitate emergency preparedness or other planning; or to validate model predictions (e.g., by comparing modeled dose predictions with dietary surveys and biomarker data). By contrast, agencies may need to envision people's practices under future scenarios, for example, in order to set cleanup standards that reflect uses to which a resource will be put, once it is restored.

Because exposure assessment is relevant to a host of inquiries in public health, this sketch so far has been generic. In application to environmental standard setting, exposure assessment functions within a particular "risk management" context. The following subsection describes this particular regulatory application.

2. Exposure Assessment Applied

While exposure assessment is a bridge that might be traversed in either direction, when it is used as part of health-based standard setting, the pertinent regulatory question is "how much of a contaminant to permit in the environment?" Health-based standards start from a threshold below which harmful effects will not occur (for non-carcinogens) or from a judgment about a level of risk that is "acceptable" (for carcinogens or other non-threshold toxicants).[57] Then, working chemical by chemical, agency risk

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57. It should be noted that some chemicals have both carcinogenic and non-carcinogenic human health effects. Additionally, EPA now acknowledges that there may be thresholds for some carcinogens, although the burden of proof is high on those seeking to depart from the default

assessors consider the toxicity of a contaminant together with the human characteristics and practices that lead to exposure to that contaminant. Equation 1 expresses this basic relationship for carcinogens; "toxicity" here is a chemical-specific value.

Equation 1:

$$Risk = Toxicity \times Exposure$$

Risk assessors set environmental standards by solving this equation for contaminant concentration—that is, they calculate the concentration of each chemical that results in the level of risk deemed acceptable for carcinogens (or that ensures that the safe threshold will not be exceeded for non-carcinogens) given particular assumptions about humans' exposure. Equation 2 provides an example of the "exposure" portion of Equation 1 from the water quality standards context for a carcinogen, such as dioxin, to which humans are exposed through ingestion of contaminated fish (which will have bioaccumulated in the fish tissue).[58]

Equation 2:

$$Exposure = \frac{(Contaminant\ Concentration)(Bioaccumulation\ Factor)(FCR)(Exposure\ Duration)}{(Bodyweight)(Averaging\ Time)}$$

As illustrated here, the exposure portion of this risk assessment equation is itself comprised of several parameters that, together, describe the human characteristics and behaviors that engender contact with the contaminant in question: how much fish will an individual consume per day (the FCR), for how long, at what bodyweight?

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assumption of linearity at low doses. *See* EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 3-21 to 3-24 (2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

58. This is a simplified version of the equation used to calculate risk-based water quality standards for carcinogens. To determine the level of each contaminant that may permissibly be discharged to or remain in the environment, agencies assume a certain level of "risk" (e.g., 1 in 1,000,000) and enlist a contaminant-specific value for "toxicity" (describing how potent a carcinogen each is). This simplified equation omits the conversion factors, which ensure a result in the appropriate units. This equation also uses a bioaccumulation factor rather than a bioconcentration factor. While the former more accurately accounts for the aquatic organisms' total uptake of contaminants present in their environment (rather than uptake only via direct contact with the water), the latter is less technically demanding, and so has until recently been used by agencies as the basis for calculating water quality standards. *See, e.g.*, EPA, *supra* note 12, at 2–3 (explaining that EPA's 2015 criteria employ bioaccumulation factors).

Each of the parameters in this equation influences the stringency—the protectiveness—of the resulting regulatory standard, i.e., whether a greater or lesser concentration of the contaminant may be released to or be allowed to remain in the environment. Thus, in the example of dioxin, if one were to assume a relatively greater fish consumption rate, one would need to ensure a commensurately lower contaminant concentration in the water in order to arrive at the same result in terms of the level of risk. Conversely, if one were to assume a relatively greater human bodyweight, one would be able to permit a higher contaminant concentration in the water (given that the bodyweight parameter is in the denominator of the equation) in order to arrive at the same level of risk. As will be elaborated below, EPA has developed and refined a catalogue of default assumptions for the various parameters in the exposure portion of the equation. With arguments supporting values that can differ by several orders of magnitude, the stakes are high for the protectiveness of the resulting environmental standard—and, so, for human health.[59]

Risk assessors employ equations that are variations on this theme, depending on the environmental media at issue and the exposure pathways in play.[60] Agency risk assessors' equations, assumptions, and methods also vary somewhat across agencies and programs, given their differing statutory instructions and the particular regulatory context in which their approaches developed. For example, cleanup of contaminated soil under CERCLA might entail assessing humans' exposure via dermal contact with the soil during gardening activities.[61] EPA's current method involves providing estimates of

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59. Consider, for example, that EPA in 1991 approved Maryland's and Virginia's use of a bioconcentration factor (BCF) of 5,000 to set water quality standards for 2, 3, 7, 8-TCDD (dioxin), in reliance on EPA's 1984 dioxin criteria document. *See* Nat'l Res. Def. Council v. EPA, 16 F.3d 1395, 1399 (4th Cir. 1993). However, EPA conceded that more recent scientific studies had become available; these studies supported a BCF ranging anywhere from 26,000 to 150,000. EPA's approval was upheld by the Fourth Circuit in *National Resources*. *Id.* at 1403. While, as noted in *National Resources*, the use of a BCF is being replaced by the use of a bioaccumulation factor, this example illustrates the considerable range of values that may be plausible for a given parameter in the risk assessment equation. *Id.*

60. *See generally* EPA, EXAMPLE EXPOSURE SCENARIOS 46, 88, 91 (2004) (providing equations and assumptions for various exposure scenarios, depicting, for example, ingestion of contaminated water by adult males in a "high physical activity" occupation (steel mill workers); inhalation of contaminated indoor air by school-aged children; and dermal contact with contaminated soil by adult residential gardeners).

61. *Id.* at 91–99 (illustrating that exposure via this pathway would entail considering the concentration of contaminants in the soil; the surface area of the skin that contacts the soil; the amount of soil that adheres to the skin per unit surface area; the fraction of contaminant in the soil

exposure under both present and future (i.e., after the application of regulatory controls) land-use assumptions at a site.[62] Despite some differences in approach, however, exposure assessors throughout EPA proceed conceptually in the manner outlined above, enlisting some version of Equation 2 and inputting some roster of values for the variables in this equation.

Notably, for those variables characterizing the human behavioral component of exposure, EPA assessors have consistently used values depicting people's contemporary practices. These values are derived from data about human behaviors and activity patterns (typically gathered via retrospective surveys or activity diaries, e.g., food frequency questionnaires), from demographic and other data, and from inferences and professional judgment. Debate has focused largely on whether EPA's assumptions have accurately portrayed what real people in fact do.

In order to provide context for understanding this debate and why, I will argue in Part III, it is misaimed, the next section considers the history of exposure assessment in environmental standard setting at EPA.

B. History of Exposure Assessment in Environmental Standard Setting at EPA

This section outlines the history of exposure assessment as it has been developed by EPA for purposes of setting health-based standards. It begins by discussing the rise of QRA, observing that debate during this early period centered on the method in general and on issues raised by the "toxicity" portion of the risk assessment equation, as opposed to the "exposure" portion. It then discusses the subsequent era, during which the import of the exposure portion came to be recognized, and exposure assessment came into its own.

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that penetrates the skin; and the frequency and duration of a person's contact); *see* Kim et al., *supra* note 22, at 8.

62. *See* EPA, *supra* note 60, at 91–99; EPA, RISK ASSESSMENT GUIDANCE FOR SUPERFUND VOL. 1: HUMAN HEALTH EVALUATION MANUAL (PART A) 1-6 (1989), http://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdf [hereinafter EPA, 1989 SUPERFUND RAGS] ("In the exposure assessment, reasonable maximum estimates of exposure are developed for both current and future land-use assumptions. Current exposure estimates are used to determine whether a threat exists based on existing exposure conditions at the site. Future exposure estimates are used to provide decision-makers with an understanding of potential future exposures and threats and include a qualitative estimate of the likelihood of such exposures occurring."). Note, however, that EPA's estimate of future exposure at a site is nonetheless based on exposure factors depicting people's *contemporary* practices. *See* discussion *infra* note 415 and accompanying text.

It closes by considering the forces that, in the new millennium, further shaped the field, leading us to exposure assessment as practiced today.

1. Rise of Quantitative Risk Assessment: A Focus on Toxicity

In the early years of QRA's ascendancy, discussion in scientific and policy circles tended to focus on issues other than exposure assessment. Debate initially reflected a preoccupation with establishing the new method's bona fides as a rational, scientific basis for regulating suspected carcinogens—in advance of conclusive proof that these substances indeed caused cancer in humans. This undertaking included articulating QRA's component steps and, among other things, promoting a separation of what were deemed matters of risk assessment, on the one hand, and risk management, on the other.[63]

EPA's efforts during this period were focused on synthesizing the growing body of experimental toxicological and epidemiological data necessary to characterize the toxicity of contaminants in the environment, and on articulating a consistent method to be used for agency risk assessments.[64] In the 1980s, EPA unveiled its Integrated Risk Information System (IRIS), the database that documents the evidence of health effects from a host of chemical substances.[65] In 1986, EPA issued a series of five guidance documents setting forth the analytic methods to be used in conducting risk assessments, only one of which was aimed at exposure assessment.[66]

63. *See, e.g.*, THE RED BOOK, *supra* note 29, at 7 (recommending that all agencies "maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives"); Richard A. Merrill, *The Red Book in Historical Context*, 9 J. HUM. & ECOLOGICAL RISK ASSESSMENT 1119, 1124 (2003) (describing the Committee's embrace of the novel intellectual premise that "the government's identification of a hazard, its examination of exposure(s), its analysis of the relationship between dose and response, and its ultimate assessment of the risk posed should be undertaken and reported separately from its evaluation and choice of the regulatory options. This premise, which permeates the 'Red Book,' has endured as a working principle, generally, if not universally, followed by the risk regulating agencies."); *see also* William D. Ruckelshaus, *Science, Risk, and Public Policy*, 221 SCI. 1026, 1026–27 (1983) (pledging to ensure that risk assessment at EPA would be rigorous, thorough and based on science rather than influenced by "policy considerations").

64. *See, e.g.*, Roy E. Albert, *Carcinogen Risk Assessment in the U.S. Environmental Protection Agency*, 24 CRITICAL REVS. TOXICOLOGY 75 (1994).

65. *See Integrated Risk Information System (IRIS)*, EPA, http://www.epa.gov/iris/ (last updated Sept. 1, 2016); *The History of Risk at EPA*, *supra* note 28.

66. *See* Guidelines for Estimating Exposures, 51 Fed. Reg. 34,042, 34,042 (Sept. 24, 1986); *The History of Risk at EPA, supra* note 28 (these five documents set forth the analytical methods to be used in assessing cancer, mutagenicity, chemical mixtures, developmental toxicology, and exposure assessment).

Throughout this time, debate focused on issues relevant to the toxicity portion of the risk assessment equation, such as theories of carcinogenesis, and bases for inter-species extrapolation.[67]

During these early years, the matter of "data gaps" loomed large, as the scope and complexity of the task of regulating toxics became increasingly clear.[68] Scientific advances enabled identification of a growing roster of carcinogens.[69] Yet understanding of the mechanisms of carcinogenesis was still emerging, and epidemiological data about human exposure to relatively low doses of chemicals in the environment did not exist—nor could it be gathered in the near term. Rather, toxicologists gathered data about animal exposure to relatively high doses of chemicals in the laboratory, and risk assessors devised methods for extrapolating from the results of these experiments to the policy-relevant question of effects on humans. In one of the foundational documents in the field, known colloquially as *The Red Book*, the National Research Council emphasized the challenges posed by the significant gaps in scientific understanding, stating that "[t]he Committee believes that the basic problem in risk assessment is the sparseness and uncertainty of the scientific knowledge of the health hazards addressed."[70] Other commentators' depiction of our ignorance was pithier: a risk

67. *See* JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 153 (1988) (stating that the "lack of information about human dose-response curves at the doses that are important to regulatory policy" is "the essential problem" for quantitative risk assessment, and recounting the debate over the suspected carcinogens formaldehyde and benzene by way of illustration); *see also* John D. Graham, *Historical Perspective on Risk Assessment in the Federal Government*, 102 TOXICOLOGY 29, 33–34, 37–40, 41–42 (1995). *Compare* Richard J. Zeckhauser & W. Kip Viscusi, *Risk Within Reason*, 248 SCI. 559, 562 (1990) (criticizing "misplaced conservatism" in agencies' risk assessment method, including frequent reliance on "results from the most sensitive animal species"), *and* David G. Hoel, *Carcinogenic Risk*, 1 RISK ANALYSIS 63, 64 (1981) (discussing implications of "the conservative 'one-hit' model" of carcinogenesis for estimates of risk), *with* Adam M. Finkel, *Is Risk Assessment Really Too Conservative? Revising the Revisionists*, 14 COLUM. J. ENVTL. L. 427, 439–43 (1989) (arguing that methods for extrapolation from animal data may actually underestimate the magnitude of many risks to humans), *and* John C. Bailar III et al., *One-Hit Models of Carcinogenesis: Conservative or Not?*, 8 RISK ANALYSIS 485, 497 (1988) (arguing that although the one-hit model of carcinogenesis currently used by agency risk assessors is considered to be the most conservative among the available theories, it "may substantially understate true risks at low exposures").

68. *See, e.g.*, John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 297–98 (1991) (discussing considerable information demands of QRA and identifying numerous "data gaps" at each stage in the risk assessment process).

69. *See, e.g.*, Richard Wilson, *Risks Caused by Low Levels of Pollution*, 51 YALE J. BIOLOGY & MED. 37, 47–48 (1978) (explaining that the only known carcinogens in 1958 were soot, radiation, tobacco smoke, and B-naphthylamine).

70. THE RED BOOK, *supra* note 29, at 5–6.

assessment for trichloroethylene under various possible dose-response models was described as "provid[ing] a range of uncertainty equivalent to not knowing whether one has enough money to buy a cup of coffee or pay off the national debt."[71]

EPA responded to these yawning data gaps, seeking both to "fill" and "bridge" them. Thus, while research proceeded to identify hazards and characterize dose and response, EPA developed methods enabling risk assessments to be conducted in the face of uncertainty.[72] These methods employed default assumptions, uncertainty factors, and other devices in order to account for the fact that we knew that we did not know.[73] Debate during this period, in turn, focused on EPA's approaches to uncertainty. Regulated entities and some commentators began in the 1980s to argue that EPA employed default assumptions and other devices that were too "conservative," with the result that environmental standards were unnecessarily stringent.[74] Other commentators questioned this assessment, offering examples of "anticonservative" elements in agencies' use of QRA and instances in which EPA's default assumptions were likely to understate actual exposure.[75]

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71. C. Richard Cothern et al., *Estimating Risk to Human Health*, 20 ENVTL. SCI. & TECH. 111, 115 (1986).

72. *See generally* EPA OFFICE OF THE SCI. ADVISOR, EPA, STAFF PAPER: RISK ASSESSMENT PRINCIPLES & PRACTICES (2004), http://archive.epa.gov/osa/pdfs/web/pdf/ratf-final.pdf; MARK. R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS (1999) (chronicling EPA's acquisition and use of policy-relevant science from the 1970s through the 1990s).

73. *See, e.g.*, EPA, *supra* note 72, at 51–98 (devoting chapter to describing EPA method for addressing "information gaps" in risk assessments by means of "default and extrapolation assumptions"); THE RED BOOK, *supra* note 29, at 63 (explaining a default assumption as "the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary"); *see also* Gregg P. Macey, *The Architecture of Ignorance*, 2013 UTAH L. REV. 1627, 1632–38 (discussing "gaps and silences" in the science necessary to support environmental regulatory decisions, and canvassing the statutory and regulatory responses that have been suggested to address this dearth of knowledge).

74. *See, e.g.*, Sheila Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 OSIRIS 194, 205 (1992) (recounting that the "chemical manufacturers had the most to gain from a relaxation of EPA's default assumptions . . . [and] [t]he American Industrial Health Council, a coalition of chemical companies and trade associations, emerged as a strong and persistent critic of federal cancer policies" during this period); Albert L. Nichols & Robert J. Zeckhauser, *The Perils of Prudence: How Conventional Risk Assessments Distort Regulations*, 8 REG. TOXICOLOGY & PHARMACOLOGY 61, 61 (1988).

75. *See, e.g.*, Cothern et al., *supra* note 71, at 113 (observing that cancer risks projected for TCE are based on assumed drinking water intake of 2 liters/day for a 70-kg adult lifetime but pointing out that "[i]ndividuals may experience many times this intake rate. Formula-fed infants and young children, for example, have average intake rates that are as much as eight times greater than those of average adults. Adults in tropical areas may consume twice as much liquid as the

The publication of *The Red Book* also introduced the matter of distinguishing between "risk assessment" and "risk management."[76] The National Research Council's recommendation to this end is oft-quoted: "regulatory agencies [should] take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives."[77] Less frequently quoted is the balance of this recommendation: "that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies,"[78] or the clarification that this recommendation "does not imply that [these functions] should be isolated from each other; in practice they interact, and communication in both directions is desirable and should not be disrupted."[79] Nonetheless—and to the dismay of some members of the committee that authored *The Red Book*—EPA understood this recommendation to require a formal, institutional separation of risk assessment and risk management within the agency.[80] Then-administrator William Ruckelshaus, for example, held up EPA's construction of a firewall between the two as an example of its commitment to scientific objectivity in regulatory decision making.[81] Thus, despite *The Red Book*'s acknowledgment that risk assessment required both "scientific findings and policy judgments," EPA sought to bolster its credibility by downplaying the latter, portraying its risk assessments as a matter of data-driven, scientific analysis.[82]

Although exposure was implicated in these formative discussions, exposure assessment did not occupy center stage.[83] Indeed, in some contexts,

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average, as may athletically inclined adults when engaged in strenuous physical activity. Persons who are ill also may consume much more water than the average.").

76. THE RED BOOK, *supra* note 29, at 6–7.

77. *Id.* at 7.

78. *Id.*

79. *Id.* at 6.

80. *See* D. Warner North, *Reflections on the Red/Mis-Read Book, 20 Years After*, 9 HUMAN & ECOLOGICAL RISK ASSESSMENT 1145, 1145 (2003).

81. Ruckelshaus, *supra* note 63, at 1026; Warner North, *supra* note 80, at 1150–51.

82. *See, e.g.*, Jasanoff, *supra* note 74, at 207–14 (providing a detailed narrative of EPA's efforts to restore its credibility by maintaining "the boundary between science and policy").

83. *See, e.g.*, Ott, *supra* note 30 (writing in 2006, observing that research was more developed in the other steps involved in risk assessment and that research on exposure assessment had only been undertaken comparatively recently, with progress in the last 20 years); Dennis J. Paustenbach, *The Practice of Exposure Assessment: A State-of-the-Art Review*, 3 J. TOXICOLOGY & ENVTL. HEALTH 179, 233 (2000) (observing, for example, that the method for estimating uptake of toxic chemicals from humans' ingestion of food remained essentially unchanged from the

such as air pollution, health-based standards were initially set without considering exposure as part of the process.[84] Rather, ambient air quality measurements were taken to be a surrogate for human exposure.[85] Here and elsewhere, the data and methods of exposure assessment had yet to be gathered, developed, and formalized. Thus, in the early years of EPA's development of risk assessment method and policy, the exposure portion of the risk assessment equation received comparatively passing attention.

2. Exposure Assessment Comes into Its Own

It is only more recently that consideration turned to exposure assessment, as exposure assessors, regulated industries, and affected groups came to recognize the import of the exposure portion of the risk assessment equation. As late as 1991, the National Research Council, in its review of exposure assessment in the context of air pollution, found it necessary to state that "exposure assessment is the equal partner with toxicology in defining human health risk[s]."[86] In a similar vein, toxicologist Dennis Paustenbach observed in his 2000 "state-of-the-art" review of exposure assessment, "[i]n recent years, an increasing number of environmental scientists have embraced the view that 'toxicology data are important, but they do not mean much without quantitative information about human exposure.'"[87]

EPA, of course, had devoted some attention to exposure assessment, given its role as one of the four steps in the risk assessment process. EPA had necessarily enlisted data and assumptions about exposure in conducting risk assessments prior to this time. And, as noted above, EPA's initial volley of

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1940s to 2000); Peter W. Preuss & Alan M. Erlich, *The Environmental Protection Agency's Risk Assessment Guidelines*, 37 J. AIR & WASTE MGMT. ASS'N 784, 785–87 (1987) (devoting just a few paragraphs to an outline of EPA's exposure assessment method while elaborating the "hazard identification," and "dose-response assessment" steps in substantially greater detail).

84. LIOY & WEISEL, *supra* note 31, at 2–3 ("Initially, the measurement of exposure *was not part* of the process used to establish the link between pollution concentration and health outcomes to achieve a standard.").

85. *Id.* at 7.

86. NAT'L RESEARCH COUNCIL, HUMAN EXPOSURE ASSESSMENT FOR AIR POLLUTANTS 5 (1991). The NRC further observed that while advances in other aspects of risk assessment had been incorporated by EPA, the practice of exposure assessment was still catching up. *Id.* at 17; Dennis J. Paustenbach, *Retrospective on U.S. Health Risk Assessment: How Others Can Benefit*, 6 RISK: HEALTH, SAFETY & ENV'T 283, 284 (1995) ("The difference between [risk] assessments performed in the 1950's and 1960's and those performed in the 1980's and 1990's is the incorporation of a complex and quantitative exposure assessment.").

87. Paustenbach, *supra* note 83, at 180 (noting an increased interest in exposure assessment among toxicologists since about 1990).

guidelines aimed at regularizing risk assessment across the agency in 1986 included guidance for conducting exposure assessments.[88] EPA soon followed up with proposed guidelines addressed to exposure-related measurements in 1988[89] and with more comprehensive guidance for exposure assessment in 1992.[90] Similarly, an early version of EPA's *Exposure Factors Handbook*, the summary of available statistical data on the "factors" needed to calculate human exposure—e.g., water, food, and soil ingestion rates; inhalation rates; skin area and soil adherence factors; and human activity factors—was published in 1989.[91]

During this era, practitioners in the various disciplines involved in exposure assessment sought to define and professionalize the field. Notably, commentators suggest that when the National Research Council had convened the first Committee on Exposure Assessment in 1987 to draw on expertise from various areas of study, it was unclear at that time "what exposure [assessment] meant."[92] After a series of workshops, the group in 1991 issued a report[93] defining basic principles and laying the foundation for the further development of exposure assessment as a coherent field.[94] Practitioners celebrated the "birth of a new science" and debated its method and domain.[95]

Meanwhile the claims of "compounded conservatism" that had started being lodged in the 1980s began to encompass the exposure portion of a risk assessment.[96] Commentators sounding this theme generally took aim at the risk assessment process as a whole, citing a litany of instances in which

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88. Guidelines for Estimating Exposures, 51 Fed. Reg. 34,042, 34,042 (Sept. 24, 1986).

89. Proposed Guidelines for Exposure-Related Measurements, 53 Fed. Reg. 48,830, 48,830 (Dec. 2, 1988).

90. Guidelines for Exposure Assessment, 57 Fed. Reg. 22,888, 22,888 (May 29, 1992); 1992 GUIDELINES, *supra* note 46, at 1. These 1992 guidelines indicate that they replaced both EPA 1986 Exposure Assessment Guidelines and EPA 1988 Exposure-Related Measurement Guidelines. *Id.*

91. *See* OFFICE OF RESEARCH & DEV., EPA, EPA/600/R-090/052F, EXPOSURE FACTORS HANDBOOK: 2011 EDITION (2011).

92. Paul J. Lioy, *Time for a Change: From Exposure Assessment to Exposure Science*, 116 ENVTL. HEALTH PERSP. A282, A282 (2008).

93. NAT'L RESEARCH COUNCIL, *supra* note 86, at 2.

94. Lioy, *supra* note 92 (noting, among the consequences in the immediate aftermath of the NRC report, the formation of the International Society of Exposure Analysis and the establishment of the National Exposure Research Laboratory at EPA).

95. *See, e.g.*, Wayne R. Ott, *Human Exposure Assessment: The Birth of a New Science*, 5 J. EXPOSURE ANALYSIS & ENVTL. EPIDEMIOLOGY 449, 449 (1995).

96. For a summary of the evolution of QRA at EPA and the status of the debate over methods as of the early 1990s, see Alon Rosenthal et al., *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 277–95 (1992).

conservative or protective judgments were being made in the process and arguing that the net effect of these judgments was to produce estimates of risk that were unduly conservative.[97] However, some of these commentators began training their arguments on the methods and assumptions used to characterize exposure. Critics took issue, for example, with exposure assessments' focus on the "maximally exposed individual"[98]—sometimes characterized more potently as a "worst-case" exposure scenario.[99] Whether implicitly or explicitly, these criticisms tended to rest on the assertion that no one's actual circumstances of exposure were described by a composite of high-end or maximum values for the relevant parameters.[100] No one, it was assumed, in fact lived their entire life at the fenceline of a factory that emitted toxic air pollutants.[101] No one's children, it was suggested, actually played in and ingested dirt at a site in their neighborhood that had become contaminated with PCBs, benzene and other chemicals.[102] Indeed, critics sometimes

97. *See* Adam M. Finkel, *Disconnect Brain and Repeat After Me: "Risk Assessment Is Too Conservative,"* 837 ANNALS N.Y. ACAD. OF SCI. 397, 397–98 (1997) (chronicling the spread of the claim that risks are systematically overestimated as a result of overly conservative assumptions).

98. *See, e.g.*, Neil C. Hawkins, *Conservatism in Maximally Exposed Individual (MEI) Predictive Exposure Assessments: A First-Cut Analysis*, 14 REG. TOXICOLOGY & PHARMACOLOGY 107, 107 (1991).

99. *See, e.g.*, Paustenbach, *supra* note 86, at 308–09 (arguing that exposure assessments could be improved if EPA were to move away from "an overemphas[is on] the 'maximally exposed individual' (MEI)" and stating that "a worst-case or MEI analysis" should not be used to characterize "actual or plausible human risks").

100. *See, e.g.*, Graham, *supra* note 67, at 40–41 (decrying the use of exposure scenarios that are "hypothetical and arbitrary" and citing examples, such as a person living 200 meters from a source of toxic air pollution for 70 years—breathing maximum outdoor concentrations of the pollutant for 24 hours/day—or a fisherman consuming 6.5 grams/day of fish caught from a freshwater river near a contaminated source "when fish advisories are in place at these river sites," and lamenting that risk managers "have no clue how many citizens (if any) are actually exposed to the amount of risk indicated in the exposure scenarios"); Paustenbach, *supra* note 86 at 308–09.

101. *See, e.g.*, Graham, *supra* note 67, at 40.

102. *See, e.g.*, STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE 12 (1993) (arguing, famously, that it was folly to set cleanup standards at a site such that future uses would be protective of the "dirt-eating children" who might someday play there and so be exposed to any toxic substances remaining untreated in the soils). *Compare id.* (arguing that further risk reduction was unwarranted at a New Hampshire site, because children were not likely ever to come in contact with the contaminated soils there, for "future building seemed unlikely" given that the area was "a swamp"), *with* Adam M. Finkel, *A Second Opinion on an Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Circle*, 3 N.Y.U. ENVTL. L.J. 295, 314–15 (1995) (noting that "although Breyer concludes . . . that all such [risk] calculations were fanciful because the site was a swamp, it was in fact zoned for residential development" and a marsh occupied only a portion of the site).

caricatured EPA's exposure assumptions as extreme—meant to protect "porch potatoes"[103] and "naked farmers."[104]

These arguments found some traction within the executive branch. For example, EPA's 1989 risk assessment guidance for Superfund sites (RAGs) backed away from exposure assessments that included a focus on an "upper-bound" or maximally exposed individual in favor of focusing on the "reasonably maximally exposed (RME) individual."[105] According to EPA, the RME for various pathways (e.g., dermal contact with contaminants in soil; ingestion of surface water contaminants while swimming) is to be calculated using a mix of upper-bound (e.g., 95th percentile or maximum) and average (e.g., mean or median) values that, in combination, produce an estimate of exposure at a site that is "well above . . . average" but "still within the range of possible exposures."[106] Interestingly, while EPA's 1989 RAGs have since been understood by some to evince a less protective direction for exposure assessments,[107] the Office of the President at the time presented a different characterization. The George H.W. Bush administration's inaugural Regulatory Program of the United States Government portrayed EPA's embrace of the RME concept as an overly conservative departure from an unbiased focus on the "average" or "most likely" level of human exposure.[108] It charged that a focus on the RME would "provide[] a new opportunity for embedding conservative assumptions into exposure assessment and

103. *See* EPA OFFICE OF THE SCI. ADVISOR, *supra* note 72, at 26–29 (explaining how EPA's evaluation of high-end exposures figures in its assessment of a population's exposure to hazardous air pollutants (HAPs) under the Clean Air Act in response to what "has sometimes been referred to as evaluation of 'the porch potato' (i.e., the assumption that someone lives outdoors at the point of maximum concentration at or beyond the fenceline of a facility for 24 hours a day for a lifetime)").

104. *See* Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 857–58 (1996) (stating that "the most remarkable precaution often exists in exposure assessments" which "may presume the existence of 'naked, dirt-eating farmers' near waste sites").

105. EPA, 1989 SUPERFUND RAGS, *supra* note 62, at 6-5.

106. *Id.* at 6-5, 6-34.

107. *See, e.g.*, EPA OFFICE OF THE SCI. ADVISOR, *supra* note 72, at 102. The 1989 RAGs themselves are nuanced. The first definition of the term speaks of RME as depicting *maximum*, *actual* exposures. EPA, 1989 SUPERFUND RAGS, *supra* note 62, at 6-5. EPA then provides an example of a mix of "upper-bound" and "average" values, but the prescription for a "mix" is contextualized, and offered alongside the useful point that the variables are often not independent, for example, the smallest person is unlikely also to have the largest ingestion rate. However, the RAGs came to be viewed as standing for the proposition that "reasonable" or "actual" is not equal to "maximum."

108. OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT: APRIL 1, 1990–MARCH 31, 1991, at 22 & n.65 (1990).

exaggerating estimates of actual human-health risk at Superfund sites."[109] More generally, the Office of the President decried the fact that "[t]he continued reliance on conservative (worst-case) assumptions distorts risk assessments, yielding estimates that may overstate likely risks by several orders of magnitude."[110]

In 1994, the National Research Council issued an important report on risk assessment practice at EPA.[111] Although the 1990 amendments to the Clean Air Act served as the impetus for this review and provided the charge to the Academy, the report addressed risk assessment method generally, that is, beyond its applicability to hazardous air pollutants.[112] The report noted that while progress had been made, gaps in the relevant scientific knowledge remained, and the use of default assumptions could lead to either over- or under-estimates of risk.[113] The report broke ground, however, in teasing out the issues raised by uncertainty, on the one hand, and variability, on the other.[114] While EPA had previously considered and articulated responses to the problem of uncertainty (the lack of knowledge about the true value for a parameter in question), it had not given much express attention to the matter of variability (the fact that the true value for a parameter in question is described by a range). In particular, the report noted, EPA did "not generally consider[]" interindividual variability—differences among people with respect to susceptibility and exposure "related to age, lifestyle, genetic background, sex, ethnicity, and other factors"—in its risk assessments.[115]

Yet, with the coalescence of the environmental justice movement, evidence came to the fore that interindividual variability was often considerable in a world where particular groups, such as tribal members or communities of color, were more susceptible or exposed than the so-called "average American" whose circumstances had tended to inform agencies' risk assessments up to this point.[116] Those on the receiving end of pollution

109. *Id.*

110. *Id.* at 14 (emphasis omitted).

111. NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 4 (1994).

112. Clean Air Act, 42 U.S.C. § 7412(o) (2012); NAT'L RESEARCH COUNCIL, *supra* note 111 at 3.

113. NAT'L RESEARCH COUNCIL, *supra* note 111, at 1–2, 6–7.

114. *Id.* at 6–7. *See generally id.* at 160–87, 188–223 (discussing uncertainty and variability, respectively).

115. *Id.* at 11.

116. *See, e.g.*, Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103, 116, 142, 151 (discussing, among other concerns for environmental justice advocates, the failure of quantitative risk assessments to account for variability in susceptibility); Catherine A. O'Neill, *Variable Justice: Environmental Standards,*

observed that, rather than being overly protective, EPA's default assumptions often understated their actual exposures. They pointed out that real people indeed lived at the fenceline—in fact, at the fenceline for multiple sources.[117] Researchers began to document these observations, among other things gathering quantified data about the practices and lifeways that brought people disproportionately into contact with environmental contaminants. In 1994, for example, the Columbia River Inter-Tribal Fish Commission (CRITFC), published a groundbreaking survey describing the contemporary fish consumption practices of those in its four member tribes.[118] Shortly thereafter, in 1996, the Squaxin Island and Tulalip tribes published a survey of their members' contemporary fish consumption practices.[119] Similarly, fish consumption data were gathered respecting other higher-consuming groups, such as anglers (particularly in coastal locales or in areas with freshwater fisheries), communities of color, or low-income individuals.[120] Criticisms from this quarter thus joined commentators in academia and elsewhere to voice a counter-narrative to the claim that EPA's risk assessments were overly conservative, one that now included attention to exposure assessment.[121] Among other things, some commentators sought to clarify debate, distinguishing responses to uncertainty (which involve a choice among errors, and might be more or less conservative) from responses to variability (which involve a choice among true values, and might be more or

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Contaminated Fish, and "Acceptable" Risk to Native Peoples, 19 STAN. ENVTL. L.J. 3, 36–37 (2000) (discussing the failure of quantitative risk assessments to account for variability in exposure).

117. *See, e.g.*, SHIPRA BANSAL & SAM DAVIS, HOLDING OUR BREATH: ENVIRONMENTAL INJUSTICE EXPOSED IN SOUTHEAST LOS ANGELES: AN ASSESSMENT OF CUMULATIVE HEALTH RISK AND LOCAL AIR POLICY 56–58 (1998).

118. COLUMBIA RIVER INTER-TRIBAL FISH COMM'N, A FISH CONSUMPTION SURVEY OF THE UMATILLA, NEZ PERCE, YAKAMA, AND WARM SPRINGS TRIBES OF THE COLUMBIA RIVER BASIN 12 (1994), http://www.critfc.org/wp-content/uploads/2015/06/94-3report.pdf.

119. KELLY A. TOY ET AL., A FISH CONSUMPTION SURVEY OF THE TULALIP AND SQUAXIN ISLAND TRIBES OF THE PUGET SOUND REGION 1–2 (1996), http://www.deq.state.or.us/wq/standards/docs/toxics/tulalipsquaxin1996.pdf. For similar early efforts to document fish consumption practices and their import for water quality standards among the Great Lakes tribes, see GREAT LAKES INDIAN FISH & WILDLIFE COMM'N, 1993 GLIFWC SURVEY OF TRIBAL SPEARERS: MERCURY CONCERNS; Patrick C. West, *Health Concerns for Fish-Eating Tribes?*, 18 EPA J. 15, 15–17 (1992) (discussing implications of high level of fish consumption among Great Lakes tribes, given contamination).

120. *See* RUTH SECHENA ET AL., ASIAN AND PACIFIC ISLANDER SEAFOOD CONSUMPTION STUDY 1 (1999), https://nepis.epa.gov/Exe/ZyPDF.cgi/9101NYRX.PDF?Dockey=9101NYRX.PDF (documenting fish consumption practices of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese groups in King County, Washington).

121. *See, e.g.*, Finkel, *supra* note 102.

less protective) and observing that, in cases of interindividual variability, it is not a matter of deciding whether to be more or less conservative but of deciding whom to protect.[122]

Meanwhile, EPA continued to gather new data describing people's circumstances of exposure and to incorporate these data into its risk assessments and guidance documents. EPA began an iterative process of updating its Exposure Factors Handbook,[123] as well as a number of documents setting forth risk assessment method for use in specific contexts, such as water quality[124] or cleanup[125] standards. EPA thus chipped away at the uncertainty that had characterized exposure assessment[126]—and, in the process, often revealed more about the nature and extent of the variability relevant to exposure assessment. As data were gathered about children's dietary habits and daily behaviors, for example, it came to be recognized that children's circumstances of exposure warranted separate treatment.[127] As surveys quantified fish intake among sport anglers and then among tribal and other higher-consuming groups, for example, it became apparent that the fish consumption rate parameter is characterized by a much greater degree of

122. *See* O'Neill, *supra* note 116, at 34–37, 64–69; *see also* Finkel, *supra* note 97, at 405–06.

123. *See About the Exposure Factors Program*, EPA, http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20563 (last visited Nov. 9, 2016) (chronicling process for review and updates, which led to the publication of a 1997 version, a "2009 Update," and a "2011 Edition").

124. *See infra* notes 215–19, 241–54 and accompanying text (recounting evolution of exposure assessment method in EPA's Ambient Water Quality Criteria Methodology, first published in 1980, updated in 2000 and again in 2015).

125. *See, e.g.*, EPA OFFICE OF THE SCI. ADVISOR, *supra* note 72, at 104 ("The risk assessment processes used at individual Superfund sites have evolved over time based on new science and EPA's understanding of new potential exposure pathways. For example, in the early days of the program, dermal exposure was not fully evaluated based on a lack of dermal exposure information; this guidance was updated [in a 2001 draft].").

126. *Id.* at 52 ("When chemical- or site-specific information becomes available and is adequate to use, our risk assessments attempt to use those data rather than the default(s) . . . .").

127. This recognition, however, did not result in the publication of child-specific exposure factors until some years later. *See* EPA, CHILD-SPECIFIC EXPOSURE FACTORS HANDBOOK xxxi (2008), http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=199243 (observing that "[children] consume more of certain foods and water and have higher inhalation rates per unit of body weight than adults. Young children play close to the ground and come into contact with contaminated soil outdoors and with contaminated dust on surfaces and carpets indoors. Ingestion of breast milk may be another potential pathway of exposure for infants and young children" and concluding that an understanding of the differences between children's and adults' exposures is "key for evaluating potential for environmental hazards from pollutants").

variability than had been assumed.[128] As data were gathered, new pathways of exposure sometimes emerged as subjects of regulatory concern; others turned out to be less pressing than originally believed. As more data were amassed, agencies' understanding of human exposure increased.

3. Exposure Assessment in the New Millennium

Exposure assessment continued to gain attention in the new millennium, as it became clear that the assumptions made by exposure assessors could greatly impact the outcome of agencies' risk assessments. In addition, the issue of "suppression" was identified—an issue that began to call into question exposure assessment's standard practice of relying on contemporary exposure data for its calculations.

a. Exposure Parameters Become a Site of Contest

With the increased focus on exposure assessment came the realization that the choices among inputs and methods could greatly affect the outcome of a risk assessment—and the stringency of the resulting environmental standards.[129] Because the potential difference to the bottom line was considerable, the stakes were not small. Regulated industries and other commentators continued to echo the theme of "compounded conservatism," with exposure assessment now squarely in the crosshairs.[130] These industries

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128. *See, e.g.*, EXPOSURE ASSESSMENT GRP., EPA, EPA/600/8-89/043, EXPOSURE FACTORS HANDBOOK 2-35 to 2-40 (1990) https://nepis.epa.gov/Exe/ZyPDF.cgi/30001I91.PDF?Dockey=30001I91.PDF (including angler surveys from 1981, by Puffer and Pierce, in Los Angeles and Tacoma, respectively); *see also* EPA, TECHNICAL SUPPORT DOCUMENT FOR EPA'S FEBRUARY 1991 APPROVAL OF VIRGINIA'S WATER QUALITY STANDARDS REVISIONS 15–18 (1991) (on file with author) (observing, in the course of approving Virginia's WQS for dioxin, that these recent studies had documented average consumption among sport fishers at 30 g/day and 90th percentile consumption at 140 g/day).

129. While the recognition that there were frequent opportunities for dueling risk assessments was not new, the focus on opportunities provided by the exposure portion of the equation was more recent. *See generally* Thomas A. Burke, *The Red Book and the Practice of Environmental Public Health: Promise, Pitfalls, and Progress*, 9 J. HUM. & ECOLOGICAL RISK ASSESSMENT 1203, 1206 (2003) ("The inherent uncertainties of the risk paradigm provide the battleground for dueling risk assessments.").

130. *See, e.g.*, Letter from James W. Conrad, Jr., Assistant General Counsel, Am. Chemistry Council, and Richard A. Becker, Senior Toxicologist/Senior Director, Am. Chemistry Council, to Nancy Beck, Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget app. 5 at 2 (June 15, 2006), https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/comments_rab/acc.pdf (prefacing its seventy-three page appendix of "Examples of Risk Assessments that Grossly Overstate Risks" with the statement that "the Council has found that most of EPA's

saw the opportunity to influence individual risk assessments, such as those conducted in the context of CERCLA cleanups, by contesting the particular inputs and assumptions enlisted.[131] These entities and commentators also sought to influence risk assessment method at EPA and elsewhere in the federal agencies.[132]

In the early years of the new millennium, these claims found a sympathetic ear in the George W. Bush administration. Notably, the Bush-era Office of Management and Budget (OMB) proposed guidance to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies."[133] The OMB guidance sought to mandate the presentation of "central" estimates of risk, i.e., the "mean or average of [a] distribution," which it equated with an "expected" estimate—that is, one that "neither understate[s] nor overstate[s] the risk."[134] This mandate was to be applied in blanket fashion, regardless of whether high-end (i.e., 95th percentile) values were chosen for particular reasons, for example, in response to variability or the need to protect sensitive populations. The proposal did not succeed; among other things, the National Research Council found it to be flawed and recommended its withdrawal.[135] However, it carried forward into the new millennium the claim that risk assessment was dogged by "compounded conservatism."

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overconservativeness has been in estimating exposure parameters, including the magnitude, frequency and duration of exposure" and providing eleven "exposure assessment" examples and ten "toxicity assessment" examples). *But cf.* EPA OFFICE OF THE SCI. ADVISOR, EPA, *supra* note 72, at 13 ("Further, when several parameters are assessed, upper-end values and/or central tendency values are generally combined to generate a risk estimate that falls within the higher end of the population risk range. Currently, the use of the upper part of a range pertains more often to the exposure component of the risk assessment than the hazard/dose-response portion. Many comments to EPA suggest that the combining of upper ends leads to unreasonable estimates of risk. We generally believe otherwise . . . .").

131. Letter from James W. Conrad, Jr., *supra* note 130, at 11.

132. *See id.* at 7.

133. OFFICE OF MANAGEMENT AND BUDGET OF THE UNITED STATES OF AMERICA, PROPOSED RISK ASSESSMENT BULLETIN 3 (Jan. 9, 2006), https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf.

134. *See id.* at 16.

135. NAT'L RESEARCH COUNCIL, NAT'L ACADS. OF SCI., SCIENTIFIC REVIEW OF THE PROPOSED RISK ASSESSMENT BULLETIN FROM THE OFFICE OF MANAGEMENT AND BUDGET 6 (2007) (stating that "the committee concludes that the OMB bulletin is fundamentally flawed and recommends that it be withdrawn"). Among other things, the committee took issue with the OMB's focus on the presentation of "central or expected estimates," noting that such a "blanket prescription" might be inappropriate for some contexts, including "in situations when sensitive populations are of primary concern." *Id.* at 4.

In the meantime, tribes and others disproportionately impacted by contamination continued to amass data documenting their different circumstances of exposure and argued that this data could no longer be ignored. For tribes in particular, these efforts made the point that tribal members are subjected to exposures that not only differ in degree from the "average American" assumed by EPA but also differ in kind from the pathways familiar to EPA, given tribal members' unique lifeways.[136] Tribal people not only eat more fish than a member of the general population, but they also consume different species and use different preparation methods.[137] Tribal people may observe cultural practices and undertake resource uses not common to the general population. For example, gathering and using plants for basketry or for medicinal and other purposes may entail dermal contact and ingestion as tribal people tend, harvest, clean, and use plant materials.[138] These aspects of tribal exposures had heretofore simply not been considered by EPA. An important impetus to gathering and quantifying tribal exposure data was the effort to counter the steady and influential drumbeat portraying

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136. EPA, PAPER ON TRIBAL ISSUES RELATED TO TRIBAL TRADITIONAL LIFEWAYS, RISK ASSESSMENT, AND HEALTH & WELL BEING: DOCUMENTING WHAT WE'VE HEARD 4–7 (2006), https://nepis.epa.gov/Exe/ZyPDF.cgi/P1006LIF.PDF?Dockey=P1006LIF.PDF (summarizing issues and perspectives that emerged from series of National EPA-Tribal Science Council workshops).

137. For example, a study of the Suquamish Tribe in 2000 documented considerably greater rates of fish intake than assumed by EPA at every point of comparison. Whereas EPA's then-current national default of 17.5 g/day reflected the 90th percentile of general population consumption, the corresponding 90th percentile value from the Suquamish survey is 489 g/day. This study, moreover, like those of other higher-consuming populations, described a distribution that was significantly skewed right, with some individuals consuming very large quantities of fish. The maximum value from the Suquamish survey, for example, is 1453 g/day. This study also documented tribal members' consumption of fish species and use of preparation methods not shared by the general population. SUQUAMISH TRIBE, FISH CONSUMPTION SURVEY OF THE SUQUAMISH TRIBE OF THE PORT MADISON INDIAN RESERVATIONS, PUGET SOUND REGION 11, 25, 71 (2000), http://www.deq.state.or.us/wq/standards/docs/toxics/suquamish2000report.pdf (my calculations, based on the value for fish intake in g/kg/day, mean bodyweights for men and women, and percentage of male and female respondents).

138. EPA, *supra* note 136, at 18; *see also* Bev Ortiz, *Contemporary Indian Basketweavers and the Environment*, *in* BEFORE THE WILDERNESS: ENVIRONMENTAL MANAGEMENT BY NATIVE CALIFORNIANS 195, 208 (Thomas C. Blackburn & Kat Anderson eds., 1993) (recounting that one Native weaver refers to her "splitting tooth"—the one she uses to split grasses to ready them for weaving); O'Neill, *Risk Avoidance*, *supra* note 8, at 15–17, 31–34 (elaborating that, whereas non-tribal basketweavers might be expected to obtain pre-processed materials from a craft or hobby store, for tribal people, basketweaving may involve tending plants and their habitats (e.g., pruning, thinning, burning, and otherwise managing plant resources); harvesting the roots, shoots, and other portions of the plants to be used (e.g., digging for, picking, and gathering the plants); preparing these materials by hand (e.g., cleaning, pounding, splitting, dyeing, and otherwise processing the materials); and sometimes holding the grasses or plant materials in their mouths).

agencies' exposure assumptions as fanciful and, so, a source of compounded conservatism.

The growing sophistication of exposure assessment also introduced a source of (and, often, lever for) delay. This concern is explored further below, in Part III.C, but it is noted briefly here, given its role in the development of current practice. As exposure assessment became more sophisticated, the value for each input came to provide a potential site for contest.[139] Some lag is to be expected, of course, between advances in the underlying "bench" science and application of the results in the regulatory arena. But as exposure assessment has come to provide fertile ground for debate, the opportunities for delay have mushroomed.[140] Regulated industries have an incentive to bulk up the process where the resulting delay redounds to their benefit, as is the case when more up-to-date exposure assessments are likely to require more stringent standards. Ongoing efforts to update state water quality standards in the Pacific Northwest provide a case in point.[141] By 2000, states in this region had in hand four recent fish consumption surveys documenting markedly higher rates of intake by tribes and other local populations, such as Asian-Americans and Pacific Islanders. However, in Oregon, Washington, and Idaho, industry repeatedly challenged the scientific defensibility of these surveys;[142] urged that agencies' rulemaking efforts be halted until new, general population surveys could be conducted (an undertaking that is both

139. These contests take place each time generally applicable criteria are issued, standards are set, or guidance documents regarding method are updated. These contests also take place when the particulars are determined for site-specific risk assessments, such as those conducted for cleanups under CERCLA. This effect, moreover, is potentially multiplied where health-based standards are set primarily at the level of the states and tribes under the relevant statutory scheme (e.g., the CWA). *See* discussion *infra* Section III.C.

140. *See generally* THOMAS O. MCGARITY ET AL., SOPHISTICATED SABOTAGE: THE INTELLECTUAL GAMES USED TO SUBVERT RESPONSIBLE REGULATION 86–87 (2004) ("The basic strategy is to require mountains of new information before any protective action can proceed. Some of the information may be genuinely valuable, but much of it is not. In any case, the sheer magnitude of the challenge of generating and studying the information, and questioning and litigating the inevitable gaps and omissions in the models, achieve their intended result: delay, delay, and still more delay. . . . Risk assessment provides a tailor-made opportunity for such sabotage.").

141. *See* O'Neill, *supra* note 16, at 232–40; *see also* discussion *infra* Section III.C.

142. *See* O'Neill, *supra* note 16, at 242–49 (discussing industry's and individuals' requests that the tribal survey data be "verified" through "independent review" and additional "peer-reviewed studies generated through traditional means" and even questioning whether tribal respondents in the Suquamish survey had been "truthful," given that the high fish intake rates it documented "press[] the limits of credibility" in that commenter's view).

expensive and time consuming);[143] and argued for alternative, less protective, values for several inputs to the exposure assessment.[144] In Oregon, such tactics contributed to a process that spanned twelve years before its water quality standards were updated to incorporate a FCR of 175 grams/day.[145] This process included an extensive, year-long review of the four surveys by a panel of independent experts, which found them to be scientifically defensible.[146] Nonetheless, in Washington and Idaho, these same surveys' quality was reviewed and re-reviewed: incredibly, Idaho's review of the Squaxin Island and Tulalip survey was the sixth it had undergone as part of federal or state agency processes.[147] Although Idaho, too, found that these surveys warranted high marks,[148] it nonetheless launched a new, statewide fish consumption survey at industry's behest.[149] As of late 2016, Idaho has not yet promulgated approvable water quality standards, and long-awaited updates to Washington's standards have yet to take effect—leaving the status quo, with its 6.5 grams/day FCR, intact for these states' waters.[150]

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143. *See id.* at 232–41, 245 (recounting industry's call for new general population surveys in order to ensure that water quality standards more realistically reflect fish consumption for the overall Washington population).

144. *See infra* notes 343–69 and accompanying text.

145. *Water Quality Standards for Toxic Pollutants*, OR. DEP'T OF ENVTL. QUALITY, http://www.deq.state.or.us/wq/standards/toxics.htm (last visited Nov. 8, 2016).

146. HUMAN HEALTH FOCUS GROUP, OREGON FISH AND SHELLFISH CONSUMPTION RATE PROJECT 3 (Or. Dep't of Envtl. Quality ed., 2008), http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf [hereinafter OREGON HHFG]. The HHFG found each of these studies to be scientifically defensible, deeming them both "reliable" and "relevant." *Id.* at 7, 39–40.

147. The Squaxin Island and Tulalip data had been reviewed and relied upon three times by EPA and once each by Oregon and Washington prior to Idaho's inquiry into its scientific defensibility. *See* O'Neill, *supra* note 16, at 240–45.

148. *Quality of Survey*, IDAHO DEP'T OF ENVTL. QUALITY, http://www.deq.idaho.gov/media/924655-58-0102-1201-quality-of-survey-criteria-rating-matrix.pdf (last visited Nov. 8, 2016) (assessing the quality and scientific defensibility of 19 fish consumption surveys from around the Pacific Northwest and finding that six of these, including the four studies judged scientifically defensible by Oregon's HHFG and the more recent Lummi Nation study, warranted "a score of 10 or better"). Although there is some place in each state/tribal process for assessing *applicability* to local waters, there is arguably no need to determine anew the scientific *defensibility* of the relevant surveys.

149. *See, e.g.*, J.R. SIMPLOT CO., REVIEW OF FISH CONSUMPTION SURVEYS FOR AMBIENT WATER QUALITY CRITERIA RULEMAKING IN IDAHO 7–8 (2012), https://www.deq.idaho.gov/media/918248-58-0102-1201-simplot-comment-1112.pdf (alleging technical deficiencies in each of the six studies found scientifically defensible by IDEQ and recommending that Idaho move forward with a state-specific fish consumption rate study).

150. Idaho has adopted new water quality standards, effective March 25, 2016. IDAHO DEP'T OF ENVTL. QUALITY, WATER QUALITY: DOCKET NO. 58-0102-1201—FINAL RULE (2016), https://adminrules.idaho.gov/rules/current/58/0102.pdf. These standards incorporate an updated

b. Suppression Effects Identified as an Issue

In the process of articulating the call for standards that were more protective of high-end fish intake, the issue of "suppression" emerged and was given a name. Beginning in 2000, the National Environmental Justice Advisory Council (NEJAC) worked to document and recommend ways to address the disproportionate impacts of contaminated and depleted fish, wildlife, and aquatic resources.[151] Tribal representatives in particular emphasized that degraded ecosystems adversely impacted important tribal resources and undermined tribal members' consumption and use of those resources.[152] They pointed out that surveys of tribal members' contemporary fish intake would reflect consumption rates and patterns that had been greatly altered from historical practices—practices to which tribes had rights, secured in many instances by treaties and other legal protections. The NEJAC recognized, too, that surveys of other groups' contemporary fish intake would also to some extent reflect consumption rates that had been diminished in the face of contamination and depletion—particularly given the recent proliferation of fish consumption advisories nationwide.[153] The NEJAC report, issued in 2002, thus brought attention to the issue of "suppression effects"—enlisting a term coined by one of its workgroup members, Patrick

FCR of 0.065 kilograms/day, i.e., 6.65 grams/day. IDAHO ADMIN. CODE r. 58.01.02.210 (2016). However, until these standards are approved by EPA, the current standards premised on the 6.5 grams/day FCR govern for CWA purposes. Washington has also adopted new water quality standards, effective September 1, 2016. WASH. DEP'T OF ECOLOGY, WATER QUALITY STANDARDS FOR PROTECTING HUMAN HEALTH (FISH CONSUMPTION RATES) CHAPTER 173-201A WAC http://www.ecy.wa.gov/programs/wq/ruledev/wac173201A/1203ov.html. These standards incorporate an updated FCR of 175 grams/day, with exceptions for certain notable toxic contaminants. WASH. ADMIN. CODE § 173-201A (2016); *see* discussion *infra* note 399 and accompanying text. On November 15, 2016, EPA announced that it was approving in part and disapproving in part Washington's updated water quality standards; concurrently, EPA issued federal standards for Washington in place of most of the disapproved state-adopted criteria. The federal standards will take effect thirty days after publication in the federal register. Revision of Certain Federal Water Quality Criteria Applicable to Washington (prepublication version Nov. 15, 2016) (to be codified at 40 C.F.R. pt. 131) (on file with author); Letter from Daniel Opalski, Office of Water & Watersheds, EPA, to Maia Bellon, Director, Dep't of Ecology (Nov. 15, 2016) (on file with author).

151. NAT'L ENVTL. JUSTICE ADVISORY COUNCIL, FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE 1 (2002), https://www.epa.gov/sites/production/files/2015-02/documents/fish-consump-report_1102.pdf.

152. *Id.* at 9.

153. *Id.* at 31–33.

West, to describe the impact of fish consumption advisories on rates purporting to reflect fish intake in Michigan.[154]

> A "suppression effect" occurs when a fish consumption rate (FCR) for a given population, group, or tribe reflects a current level of consumption that is artificially diminished from an appropriate baseline level of consumption for that population, group, or tribe. The more robust baseline level of consumption is suppressed, inasmuch as it does not get captured by the FCR.[155]

Importantly, the NEJAC report highlighted the potential feedback loop set in motion when contemporary survey data, biased downward due to suppression, were used to set environmental standards.

> [W]hen environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. That is to say, agencies will set less protective standards. The downward spiral thus begins, as these aquatic environments and the fish they support will be permitted to become increasingly contaminated, and some individuals in turn might be expected to respond by reducing their fish consumption even further. Or some individuals in turn might find that there are fewer fish to be caught (and those that remain to be increasingly contaminated) or there are fewer places open for shellfish harvesting. In either case, studies would reflect even lower FCRs, and agencies would then set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.[156]

Rather, it was urged, environmentally just standards would require the use of an "appropriate baseline" for the relevant affected group.[157] In the case of the Yakama and other fishing tribes in the Pacific Northwest, for example, the NEJAC report quoted workgroup member Moses Squeochs, then-Environmental Program Director for the Yakama Nation, who pointed to the more robust level of fish consumption supported by the environment as of

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154. *Id.* at 43 (observing that "suppression effects" were recognized and named in an early survey of Michigan sport anglers and served as a basis for adjusting the observed FCR upward).

155. *Id.* at 43–45.

156. *Id.* at 49.

157. *Id.* at 44.

1855, the date of the treaty between the bands of the Yakama and the United States.[158]

The NEJAC's observation that surveys depicting contemporary practices will provide a snapshot distorted by suppression was soon echoed in the legal, science, and risk policy literature.[159] Researchers elaborated that suppression in this context may be a consequence of several factors and that the forces of suppression may have affected different groups in different ways. For the fishing tribes in the Pacific Northwest, for example, these pressures had operated since at least the 1800s and include depletion and contamination of the fish or other resources; denied or diminished access to fishing and harvesting places; and harassment and intimidation by private individuals and public officials alike.[160] For other groups, these forces had shaped behavior more recently, as contamination become evident in the late 1960s and fish consumption advisories became more prevalent beginning in the 1970s and 1980s.[161] Although the forces of suppression include those conditions that would lead people to undertake protective or compensatory measures—what economists call "averting" behaviors[162]—the causes comprehended by the term are broader. More recently, federal, tribal, and state environmental agencies have acknowledged the issues posed by suppression, although their responses have varied. The Spokane Tribe has adopted—and EPA has

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158. *Id.* at 44, n.116.

159. *See, e.g.*, Jamie Donatuto & Barbara L. Harper, *Issues in Evaluating Fish Consumption Rates for Native American Tribes*, 28 RISK ANALYSIS 1497, 1501 (2008); O'Neill, *Risk Avoidance*, *supra* note 8, at 50–51. The term continues to gain recognition. *See, e.g.*, FRASER SHILLING ET AL., CALIFORNIA TRIBES FISH-USE: FINAL REPORT 4 (2014) (documenting FCRs at the 95th percentile between 30 grams/day (Chumash) and 240 grams/day (Pit River) but adding the caveat that "[t]he rate of fish use (frequency and consumption rate) was suppressed for many tribes, compared to traditional rates").

160. Tribal leaders have long observed the myriad causes of suppression operating to diminish tribal fishing and fish consumption. For a useful summary of this subject see Donatuto & Harper, *supra* note 159, at 1500–51. *See also* WILLIAM H. RODGERS, JR., ENVIRONMENTAL LAW IN INDIAN COUNTRY 25 (2005) ("In the latter half of the nineteenth century, the fishing grounds were quickly enclosed. . . . In hundreds of confrontations, the Indians met owners who hadn't heard of the fishing 'servitude,' or who didn't believe in it; who knew for sure that access was not here, but over there; who would let the gates down for only a small and reasonable fee; who would insist the fishery was a private one. . . . The Indians would be introduced to fences and road closures and padlocks and abutments and signs and guard dogs and firearms that were among the pleasures of all fee-simple property owners. . . . Litigation would begin in 1884, and in a fundamental sense, it would never end. Treaty fishing lawsuits continue today into the 21st century.").

161. *See, e.g.*, Oken et al., *supra* note 9 (finding that pregnant women with access to obstetric care decreased fish consumption in response to publication of federal advisory warning of mercury contamination in certain species of fish).

162. *See* discussion *infra* Section III.B.

approved—water quality standards founded on unsuppressed, "heritage" rates.[163] EPA has also supported research into methods documenting heritage exposure scenarios for Wabanaki traditional lifeways[164] and has cited suppression among the reasons for disapproving water quality standards adopted by the state of Maine and applicable to "Indian lands."[165] States, on the other hand, have recognized suppression as an issue, but have sought to cabin its scope and so far have declined to account for it in their standards.[166]

This Part has provided an overview of exposure assessment's role in environmental standard setting. It has tracked the birth of exposure assessment as a "scientific discipline" and followed its increase in stature among the four component parts of quantitative risk assessment process.[167] It has situated the method's development at EPA in the context of the larger debate about risk assessment that served as the backdrop to the agency's work. An important insight revealed by this history is that exposure assessment emerged to join a fray in progress. Although the players were still discussing the rules of the game, the atmosphere in the stadium had already

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163. SPOKANE TRIBE OF INDIANS, SURFACE WATER QUALITY STANDARDS: RESOLUTION 2010-173, at 13 (2010) ("The aquatic organism consumption rate utilized in determining the human health criteria shall be 865 g/day.").

164. BARBARA HARPER & DARREN RANCO, WABANAKI TRADITIONAL CULTURAL LIFEWAYS EXPOSURE SCENARIO 7 (2009), https://www.epa.gov/sites/production/files/2015-08/documents/ditca.pdf (prepared for EPA by the authors, in collaboration with the five federally recognized tribal nations in what is now Maine).

165. EPA, ANALYSIS SUPPORTING EPA'S FEBRUARY 2, 2015 DECISION TO APPROVE, DISAPPROVE, AND MAKE NO DECISION ON, VARIOUS MAINE WATER QUALITY STANDARDS, INCLUDING THOSE APPLIED TO WATERS OF INDIAN LANDS IN MAINE 3 https://www.regulations.gov/document?D=EPA-HQ-OW-2015-0804-0123 (last visited Nov. 8, 2016) ("[T]he data used to determine the fish consumption rate for tribal sustenance consumers must reasonably represent tribal consumers taking fish from tribal waters and fishing practices unsuppressed by concerns about the safety of the fish available to them to consume. . . . EPA concludes that the best available data that represent the unsuppressed sustenance fishing practices of tribal members fishing in tribal waters are contained in the Wabanaki Lifeways study, which looked at the historic sustenance practices of the Tribes in Maine."); Letter from H. Curtis Spalding, Regional Administrator, EPA, Region 1, to Patricia W. Aho, Comm'r, Me. Dep't of Envtl. Prot. (Feb. 2, 2015), https://www.epa.gov/sites/production/files/2016-04/documents/me_let_020215.pdf.

166. *See, e.g.*, Cheryl Niemi & Don Essig, *Discussion on EPA's New FAQ: Human Health Ambient Water Quality Criteria and Fish Consumption Rates* (Apr. 17, 2013), http://www.ecy.wa.gov/programs/wq/swqs/DraftCommentsACWAonEPAHHCFAQdae.pdf.

167. *Accord* LIOY & WEISEL, *supra* note 31 ("Implementation of the exposure science principles and applications as a distinct field has not been recognized until recently."); *see, e.g.*, EXPOSURE ANALYSIS (Wayne R. Ott et al. eds., 2007) (describing itself on the back cover as "the first complete resource in the emerging scientific discipline of exposure analysis" and stating in the Foreword that "[t]his book is dedicated to the development of exposure analysis as a scientific field in its own right" rather than "just a collection of related interdisciplinary approaches").

become charged. However exposure assessors articulated their method, it would need to be responsive to the controversy over the relative roles for "science" and "policy" in risk assessment. This controversy, and especially the concern that estimates of risk do not reflect fanciful, "overly conservative" assumptions about people's characteristics and behaviors, likely shaped exposure assessment at EPA in important and enduring ways.

For much of this time, the critics successfully created a binary in the terms of the debate: exposure assessments that enlisted "high-end" inputs would yield conservative, worst-case estimates; those that enlisted "central tendency" inputs would yield reasonable, actual estimates.[168] This either/or characterization proved remarkably stable, surviving efforts, as discussed above, by the National Research Council to clarify discussion about responses to uncertainty (which, recall, involve a choice among errors, so might be more or less conservative) and variability (which, recall, involve a choice among true values, so might be more or less protective). Had this clarification taken hold, an agency's choice of a high-end value for a highly variable exposure parameter would have been understood to reflect a choice to include more, actual people—or a broader swath of human activities and resource uses—within the resulting standard's protective ambit. Instead, the persistence of the "conservative-versus-actual" description may have left EPA to respond within this frame—hastening to ascertain people's actual, contemporary practices and declining to ponder alternatives to this approach. The next Part looks more closely at exposure assessment's formative years at EPA, in order to shed light on the forces that shaped the method.

II. WHY "EXPOSED"—WHY AN INQUIRY TRAINED ON THE RECENT PAST?

Why did environmental agencies phrase the relevant question: "to what are humans exposed?" Why did EPA focus on data reflecting people's current (or, more precisely, recent-past) exposures for use in aspirational, health-based standards? This Part examines exposure assessment at EPA during the early years. As it turns out, the questions framed and the inquiries pursued during this period played a formative role, likely shaping exposure assessment method for years to come.

168. *See, e.g.*, EPA, *supra* note 60, at 4 (noting that exposure assessors "are cautioned about using all high-end inputs except in cases where screening level or acute estimates are desired because setting all exposure factor inputs to upper-percentile values may result in dose estimates that exceed reasonable maximum values for the population of interest").

When EPA set out to craft the initial rounds of health-based standards, little was known about human exposure. There was significant work to be done to stitch together even a basic picture of how people came in contact with the sizeable roster of pollutants EPA had been tasked with regulating in various environmental media. Not only was the task formidable, but the timeframe was tight. The major environmental statutes imposed deadlines that afforded little time for gathering new data or resolving completely the relevant scientific uncertainties.[169] Rather, as Richard Lazarus recounts, "'EPA in those early days was flying blind.'"[170] So, to begin to understand human exposure, EPA canvassed extant data documenting people's characteristics, demographics, and practices. Because EPA needed to set national standards, it sought data that would be representative of the U.S. population. The datasets that were of sufficient scope had generally been gathered for purposes other than exposure assessment. Rather, they had been assembled by an assortment of researchers from academia, the government, and industry that had recently begun studying Americans' habits, movements, and purchases. The temporal frame of these data reflected the purposes for which they had been gathered: they produced a snapshot of then-contemporary behaviors. EPA scientists imported the contemporary orientation of these data into their risk assessment equations—which, when solved for concentration, produced environmental standards in the requisite units. EPA recognized the significant gaps in the available information, and immediately bent its efforts toward gathering more comprehensive, exposure-relevant data.[171]

In the meantime, EPA sought to define and regularize its exposure assessment method and, in 1986, issued its first agency-wide guidance to this end.[172] The 1986 Exposure Assessment Guidelines reflected the exposure assessments that had been conducted by various program offices to date. Having started down a path of depicting people's contemporary exposures, EPA presented this approach as the template for exposure assessment across its programs.[173] This document described a one-size-fits-all method, without engaging the question of the different purposes for which exposure assessments might be conducted. Given that this guidance was issued on the heels of *The Red Book*'s concern that "risk assessment" be segregated from

169. *See, e.g.*, RICHARD J. LAZARUS, THE MAKING OF ENVIRONMENTAL LAW 70–72 (2004).

170. *Id.* at 71 (quoting historical account of EPA's early standard-setting efforts).

171. Guidelines for Estimating Exposures, 51 Fed. Reg. 34,042, 34,043 (Sept. 24, 1986).

172. *See generally EPA Risk Assessment Guidelines*, EPA, https://cfpub.epa.gov/ncea/raf/rafguid.htm (last updated June 30, 2002).

173. Guidelines for Estimating Exposures, 51 Fed. Reg. at 34,043.

"risk management," it is perhaps unsurprising that EPA expressly declined to discuss its view of exposure assessment's role in health-based standard setting.[174] Rather, EPA sought to locate its method firmly within the realm of objective, science-based assessment.[175] It thus focused on the need for hard numbers (preferably measured, not modeled) reflecting people's actual contemporary exposures—with the possibility of enlisting alternative assumptions more appropriate to future-oriented exposure assessments left unexplored.[176]

Finally, it is worth noting that EPA's early exposure assessments were undertaken in an era of optimism. EPA may not have been led to question exposure assessment's focus on people's contemporary practices because it may have expected them quickly to resemble practices unconstrained by environmental degradation. With environmental conditions expected rapidly to improve, EPA may have counted on the snapshots of exposure that were soon to be taken for the next round of standard setting to reflect people's expanded practices. EPA may also have anticipated that newer, more nuanced data would tend to support more protective standards, given some early experience showing this to be the case. More protective standards would, in turn, beget restored air, waters, and soils. As a consequence, EPA may have expected that any gap between people's current practices and healthful practices would dissipate fairly quickly.

A. The Data at Hand: Operatives, Housewives, and Tuna Noodle Casserole

In 1980, EPA announced the availability of its inaugural water quality criteria for sixty-four toxic pollutants.[177] This document was the first place that the agency described its quantitative risk assessment method, applying it to a large body of carcinogens.[178] EPA stated that "[t]he exposure section of the health effects [analysis] reviews known information on current levels of

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174. *Id.* at 34,054.

175. *Id.* at 34,042.

176. *Id.* at 34,043.

177. Water Quality Criteria Request for Comment, 44 Fed. Reg. 15,926 (Mar. 15, 1976. Sixty-two of these are human health, as opposed to aquatic life, criteria. *Id.* at 79,323.

178. *The History of Risk at EPA*, *supra* note 28 (noting that 1980 Guidelines for Water Quality Criteria were "the first application of quantitative procedures developed by EPA to a large number of carcinogens" and the "first EPA document describing quantitative procedures used in risk assessment"); *see also* Water Quality Criteria Request for Comment, 44 Fed. Reg. at 79,347 app. C ("Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents").

human exposure to the individual pollutant from all sources"[179] e.g., ingestion of fish and water. It explained the inputs to an assessment of exposure via each of these routes and described the bases for quantifying these inputs.[180] In the case of fish intake, EPA noted that "the results of a diet survey were analyzed to calculate the average consumption of freshwater and estuarine fish and shellfish."[181] Although EPA set forth in detail the various components of its method,[182] it offered no discussion of its decision to use information on "current levels of human exposure" to set standards determining the future health of the environment.[183]

In fact, EPA may not have had many options. In this and other early efforts to account for the human behavioral component of exposure, EPA was breaking new ground. As EPA sought to consider people's contact with contaminants in the air and water, it realized that it needed to piece together information about people's characteristics, demographics, and practices—and it found that the information available at the time was wanting. This is because the datasets that were of sufficient scope had been gathered for other purposes—for example, by sociologists seeking to understand humans' quotidian activity patterns,[184] by fish and wildlife agencies seeking to document human pressure on natural resource stocks,[185] or by industry associations seeking to gauge consumer food or leisure preferences for

179. Water Quality Criteria Request for Comment, 44 Fed. Reg. at 79,348.

180. *Id.*

181. *Id.*

182. *Id.* at 79,348–49 (outlining, for example, three different ways one might calculate bioconcentration factors to relate the concentration of chemicals present in ambient waters to the residues in the aquatic organisms that will be consumed by humans).

183. *Id.* at 79,342–57. Nor does EPA discuss its rationale for this choice in response to public comments on the draft Guidelines, according to EPA's "Response to Comments" in Appendix D. *Id.* at 79,357–67 (recounting ninety-one comments and EPA's responses to each comment).

184. A seminal work in this category is THE USE OF TIME: DAILY ACTIVITIES OF URBAN AND SUBURBAN POPULATIONS IN TWELVE COUNTRIES (Alexander Szalai ed., 1972), which gathered "time-budget" data to inform sociological inquiries as diverse as the impact of the television of on how people spent time, the role of people's "trip to work" in their daily lives, and what time-budget data can reveal about "marital cohesion." Other important studies from this era include F. STUART CHAPIN, JR., HUMAN ACTIVITY PATTERNS IN THE CITY: THINGS PEOPLE DO IN TIME AND SPACE (1974), and JOHN P. ROBINSON, HOW AMERICANS USE TIME: A SOCIAL-PSYCHOLOGICAL ANALYSIS OF EVERYDAY BEHAVIOR (1977); *accord* NAT'L RESEARCH COUNCIL, *supra* note 86, at 154 ("[M]ost diary studies [of human time-activity patterns] have been for sociological purposes, not for pollution estimation or environmental research.").

185. Water Quality Criteria Request for Comment, 44 Fed. Reg. at 15,930 (citing Frank Cordle et al., *Human Exposure to Polychlorinated Biphenyls and Polybrominated Biphenyls*, 24 ENVTL. HEALTH PERSP. 157 (1978)). Cordle and his colleagues cite a 1969 National Marine Fisheries Survey of fish purchases as among the sources available at the time that would permit one "to discover what is presently known about U.S. fish consumption habits." *Id.* at 161.

marketing purposes.[186] EPA nonetheless made use of the data at hand, employing assumptions and inferences as needed to address exposure-relevant gaps. For example, if a time-activity diary indicated that a person swam for an hour each day, should it be assumed that this activity occurred outdoors (of concern for assessing exposure to ambient air pollutants), or indoors at a pool? If a creel survey showed that an angler caught four fish from a contaminated bay, should it be assumed that these fish would be eaten by his family, including children (of concern for assessing exposure to neurodevelopmental toxins such as methylmercury that bioaccumulate in fish)?

The sketches below of EPA's work in the context of air and water quality provide a flavor for the monumental nature of the task facing EPA scientists during this era. There was much work to do to wrestle the data into useful form, in order to provide a picture of exposure sufficiently defensible to support EPA's issuance of air quality standards and water quality criteria. EPA recognized that its initial forays were somewhat crude and worked steadily to refine its first-generation assessments.[187] In subsequent iterations, EPA made use of more robust data to produce increasingly fine-grained snapshots of human exposure. However, they remained snapshots, i.e., depictions of contemporary practices. By dint of EPA's reliance in the early years on the data that were at hand, exposure assessments used for health-based standard setting took on the temporal focus of these data.

1. Air

With the passage of the Clean Air Act amendments in 1970, EPA embarked on the task of setting national ambient air quality standards (NAAQS) for several ubiquitous air pollutants.[188] NAAQS are health-based

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186. *See* discussion *infra* Section II.A.2; *see also* Frank Cordle et al., *supra* note 185, at 161 (citing an undated survey by the Sport Fishing Institute as among the sources available at the time documenting fish consumption habits among various subpopulations within the United States).

187. Tom McCurdy, *Estimating Human Exposure to Selected Motor Vehicle Pollutants Using the NEM Series of Models: Lessons to Be Learned*, 5 J. EXPOSURE ANALYSIS & ENVTL. EPIDEMIOLOGY 533, 544–45 (1995).

188. Clean Air Act, 42 U.S.C. §§ 7408(a), 7409(a) (2000) (dubbed "criteria" pollutants, these contaminants are those that are believed to "endanger public health or welfare" and result from "numerous or diverse mobile or stationary sources"). The initial roster of criteria pollutants for which NAAQS were promulgated included photochemical oxidants, hydrocarbons, nitrogen dioxide, carbon monoxide, particulate matter and sulfur dioxide. *See, e.g.*, Bruce C. Jordan et al., *The Use of Scientific Information in Setting Ambient Air Standards*, 52 ENVTL. HEALTH PERSP. 233, 233 (1983).

standards.[189] For each criteria pollutant, EPA scientists determine the relevant adverse human health effects, the time period(s) over which exposure may be of concern, and the population exhibiting the "greatest sensitivity,"[190] e.g., "young children" in the case of lead[191] and cardiovascularly compromised adults in the case of carbon monoxide.[192] EPA then conducts a quantitative assessment of the contaminant concentration levels that will result in adverse health effects being experienced by this sensitive population, given group members' exposure circumstances. Specifically, EPA scientists present an "estimate [of] how many sensitive persons are exposed to potentially harmful levels of air pollution when alternative NAAQS standards are just attained."[193] EPA's assessment serves as the basis for deriving an ambient air quality standard that is protective of the identified population "allowing [for] an adequate margin of safety."[194]

As EPA set out to develop the early NAAQS, it found it had "inherited a fixed-site monitoring program" for air pollutants.[195] This network had been designed so that monitors were located in populous areas in an effort to provide data on the levels of airborne toxic agents to which a significant portion of the population was exposed. However, it was quickly recognized that the monitors did not provide information about the intensity, duration, or pattern of human contact with these toxicants—among other things, because air quality varies over space and time, and people themselves move about and do various things during an ordinary day.[196]

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189. This discussion refers to the "primary" NAAQS. 42 U.S.C. §§ 7408(a), 7409(b)(2) ("[N]ational primary ambient air quality standards . . . shall be . . . standards the attainment and maintenance of which . . . allowing for an adequate margin of safety, are requisite to protect the public health."); *accord* Jordan et al., *supra* note 188, at 234 ("Both the Clean Air Act and its legislative history make it clear that an ambient air quality standard is to be solely health based, designed to protect the most sensitive group of individuals—but not necessarily the most sensitive members of that group—against adverse health effects.").

190. *See generally* Jordan et al., *supra* note 188.

191. Lead: Proposed National Ambient Air Quality Standard, 42 Fed. Reg. 63,076, 63,077 (Dec. 14, 1977).

192. Carbon Monoxide; Proposed Revisions to the National Ambient Air Quality Standards, 45 Fed. Reg. 55,066, 55,070 (Aug. 18, 1980).

193. Jordan et al., *supra* note 188, at 239.

194. 42 U.S.C. § 7409(b)(1). This description of the process is obviously greatly simplified. *See* Lead: Proposed National Ambient Air Quality Standard, 42 Fed. Reg. 63,076 (an example of the 1970s-era NAAQS process); *infra* notes 304 and accompanying text (an example of the 2014 NAAQS for ozone). *See generally* Jordan et al., *supra* note 188.

195. Flachsbart, *supra* note 50, at 114, 121.

196. LIOY & WEISEL, *supra* note 31, at 3; Ott, *supra* note 30, at 10, 12 ("Exposure models are not the same as the traditional outdoor pollutant transport models for predicting outdoor ambient concentrations in air, surface water, or groundwater. Rather, they are designed to predict

EPA thus recognized the need to marry the air quality data produced by its monitoring network with data about humans' activity patterns that had recently been gathered for social scientific purposes—the "time budgets" for typical activities undertaken and locations or "microenvironments" visited.[197] In 1979, EPA's consultants canvassed the available time-budget studies, and selected time diary data from American adults collected in 1975 by a social scientist, John Robinson.[198] This dataset was chosen because it was the "most comprehensive," and also because it was "nationally representative" and the most recent among the candidates.[199]

However, EPA recognized that the time-activity data gathered for other purposes often failed to address the questions necessary to characterize exposure to air pollutants. For example, if one were concerned about human exposure to tropospheric (ground-level) ozone, one would need to know not only how many minutes per day people spent outdoors but also when they spent this time outdoors, given that ozone formation is a diurnal phenomenon affected by temperature and sunlight.[200] Similarly, the timing of people's

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human exposure for a rather mobile human being. . . . Thus they require information on typical personal activities, locations visited during the day, and time budgets of people, as well as information on the likely concentration distributions in the places the people spend their time (ordinary microenvironments such as homes, motor vehicles, stores, restaurants, schools, etc.)"); *accord* TED JOHNSON, A GUIDE TO SELECTED ALGORITHMS, DISTRIBUTIONS, AND DATABASES USED IN EXPOSURE MODELS DEVELOPED BY THE OFFICE OF AIR QUALITY PLANNING AND STANDARDS 1–2 (2002), http://www2.epa.gov/sites/production/files/2013-08/documents/report052202.pdf (observing that researchers had "recommended that such [exposure] estimates be obtained by simulating the movements of people through zones of varying air quality so as to approximate the actual exposure patterns of people living within a defined area").

197. Flachsbart, *supra* note 50, at 120–23 (defining "microenvironment" as "a chunk of air space with a homogenous pollutant concentration"); Ott, *supra* note 30, at 10–12 (describing the "indirect approach" of estimating individual exposures).

198. Memorandum from Marc Roddin, SRI International, to Waheed Siddiqee, SRI International (Feb. 8, 1979) (on file with author).

199. *Id.* (noting, as well, that this dataset recorded the activities of 1519 respondents). A companion memorandum elaborates, "the Robinson 1975 data are the most complete. Location, activity, and occupation codes were used to identify outdoor activity," and indicates that the Robinson 1975 data thus identified twenty-seven outdoor activity categories, whereas the other three leading candidates identified seven or fewer categories involving outdoor activities. Memorandum from Hazel Ellis, SRI International, to Waheed Siddiqee, SRI International, (Feb. 8, 1979) (on file with author). I am grateful to Tom McCurdy for sharing these memoranda and helping me to contextualize their import.

200. NAT'L RESEARCH COUNCIL, *supra* note 86, at 156–57. *See generally* David E. Newby et al., *Expert Position Paper on Air Pollution and Cardiovascular Disease*, EUR. HEART J. (Dec. 9, 2014), http://eurheartj.oxfordjournals.org/content/early/2014/12/08/eurheartj.ehu458 ("Ozone concentrations are highest during the warmest, high-intensity sunlight hours of the day, often

presence in transportation corridors is relevant to understanding exposure to traffic-related air pollutants such as particulate matter, which may peak during morning and evening rush hours.[201] So in constructing NAAQS Exposure Models (NEMs), EPA treated human exposure to airborne contaminants as a time series of human activities (and associated respiration rates[202]) occurring in particular microenvironments at a given air quality in those microenvironments.[203]

The exposure assessment for particulate matter permits a glimpse of how EPA used the available data. EPA tapped census data to derive eleven "age-occupation" cohorts, and matched these with information from time-activity pattern surveys to account for the presence of each cohort in five possible microenvironments, exerting themselves at three possible activity levels.[204] For example, an "operative or laborer" might be depicted as spending nine hours "indoors at work" with six of those hours at a "low" activity level and three of those hours at a "medium" activity level on weekdays; but at home for twenty-four hours on Saturdays, dividing his or her time between indoor and outdoor environments and between activities requiring "low," "medium," and—for one hour on Saturday afternoon—"high" levels of exertion.[205]

Taking a similar approach in the NEM assessing exposure to carbon monoxide in 1982, EPA arrived at fifty-six subgroups within eleven age-occupation cohorts.[206]

> Whenever possible, the activity patterns developed for the subgroups were based on actual human activity data. Because such data are limited to a small number of studies initiated for other

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showing a broad peak from noon to about 9 pm when many people are outdoors, resulting in significant human exposure.").

201. *See generally* Newby et al., *supra* note 200 ("Traffic-related pollutants, such as ultrafine particles and soot, often peak during the morning and evening rush hours, resulting in high exposures for people commuting. [In one study] concentrations . . . in transport areas more than doubled between 8 and 10 am.").

202. EPA's earliest iterations of the NEMs, for nitrogen dioxide and particulate matter, did not incorporate estimates of energy expenditure or respiration (i.e., ventilation) rate; later versions of the NEMs, beginning with those applicable to CO and ozone, included a qualitative estimate of exercise intensity level (low, medium, high) for each activity. JOHNSON, *supra* note 196, at 1–3.

203. McCurdy, *supra* note 187, at 534–35 (describing the "Logic of NEM").

204. TED JOHNSON & ROY A. PAUL, THE NAAQS EXPOSURE MODEL (NEM) AND ITS APPLICATION TO PARTICULATE MATTER 2-1, 2-2 (1981).

205. *Id.* at App. B. These figures reflect the Operatives and Laborers subgroup 3. *Id.*

206. TED JOHNSON & ROY A. PAUL, THE NAAQS EXPOSURE MODEL (NEM) APPLIED TO CARBON MONOXIDE 2-1 to 2-3, App. A (1983); *accord* McCurdy, *supra* note 187, at 543–46.

> purposes, many simplifying assumptions were made in constructing the activity patterns. For example . . . [h]ousewives with school-age children at home were assigned to the transportation vehicle microenvironment more often than housewives with no children at home. In each case, an attempt was made to construct an activity pattern which was consistent with intuitive expectations about what members of that group would do on a typical weekday, Saturday, or Sunday."[207]

As long-time EPA scientist Thomas McCurdy explains, EPA was aware that accounting for even fifty-six subgroups was inadequate to capture fully humans' daily activities and the exposures these entailed.

> Obviously, the use of 56 activity patterns to represent all possible human activities is a major compromise. In addition, the one-hour time resolution is crude, and a number of high-breathing-rate activities of shorter duration were overlooked. These are precisely the activities that lead to a high intake dose. Both shortcomings result in "lumpy" exposure estimates because the rich diversity of human activities is not accounted for.[208]

The one-hour time blocks for the activity patterns were soon refined; the next iteration of the NEM for CO enlisted ten-minute time blocks.[209]

EPA's 1982 CO NEM also addressed ventilation rates, assigning humans' activities to one of three exercise intensity-level descriptors: "light" exercise (8 liters/minute); "medium" exercise (20 liters/minute); and "high" exercise (35 liters/minute).[210] Here, too, a considerable number of professional judgments were required. In fact, EPA's consultants observed that the activity categories used by the time-activity studies did not track neatly with exercise or work load intensity levels needed to estimate ventilation, noting that many of the diaried activities "belonged in two or even sometimes all three categories [of physical exertion]."[211] One colorful example: "Activity 813—Boating—can range in physical activity from lifting one's drink onboard a yacht to crewing on a racing shell."[212] And, here too, refinements were soon

207. JOHNSON & PAUL, *supra* note 206, at 3-5.

208. McCurdy, *supra* note 187, at 543–44.

209. *Id.* at 544.

210. *Id.* at 546.

211. Memorandum from Mark Roddin, *supra* note 198.

212. *Id.* Interestingly, the contractor, SRI International, goes on to express ambivalence about its ability reliably to assign exertion levels to the activity categories generated by the Robinson 1975 time-budget surveys. "Thus, since so many activities can involve a significant range of physical effort, we believe that analysis of any existing data base by activity level would be extremely arbitrary and very misleading for purposes of evaluating population exposure to air

incorporated into EPA's models, as the ventilation rates used for the mid-1980s ozone (O3) NEM involved assigning each ten-minute activity block to one of four, rather than just three, exercise intensity-level ranges.[213]

While additional data were gathered and incorporated, permitting an increasingly fine-grained picture of people's exposures to pollutants in the air, these improvements did not alter the basic approach to exposure assessment between 1976 and 1994. According to McCurdy:

> The logic of the model as a whole did not change during this time, thus variations in NEM models reflect the changing state of knowledge regarding important determinants of human exposure. A review of NEM formulations and applications is thus a review of the expanding database on human activities, mass-balance modeling, and, most importantly, breathing rates associated with human activities.[214]

EPA steadily obtained more exposure-relevant data, but it did not depart from an inquiry focused on people's activities in the recent past.

2. Water

The Clean Water Act amendments of 1972 established a federal structure for setting ambient water quality standards (WQS). Water quality standards are comprised of goals, articulated in the form of "uses" envisioned for each water body, and "water quality criteria," i.e., requirements designed to ensure that the uses are attained.[215] The CWA establishes a baseline "use" of fishable/swimmable waters nationwide.[216] While states (and now tribes) are

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pollution." Nonetheless, handwritten notations on the Roddin Memorandum place an "L," "M," or "H" next to each of the activities designated as taking place outdoors more than 50% of the time. *Id.*

213. McCurdy, *supra* note 187, at 546 (The four exercise level ranges and associated ventilation rates were Light exercise (<25 liters/minute), Medium exercise (26-43 liters/minute), High exercise (44-63 liters/minute), and Very High exercise (>64 liters/minute)).

214. *Id.* at 534; *accord* JOHNSON, *supra* note 196, at 1-2 to 1-5 (observing the similarities in overall approach to exposure assessment taken by the NEMs during this time, even as the models shifted to incorporate more probabilistic elements).

215. Federal Water Pollution Control Act (Clean Water Act), 33 U.S.C. § 1313(c)(2)(A) (2000). EPA's water quality standards regulation describes water quality standards as being comprised of four parts: designated uses, water quality criteria, an antidegradation policy, and implementation policies. 40 C.F.R. §§ 131.10–131.13 (2012).

216. The Clean Water Act sets forth a national goal of "water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water." 33 U.S.C. § 1251(a)(2). EPA has interpreted this goal to require a baseline "use" of fishable/swimmable waters nationwide. 40 C.F.R. § 131.2. Authorized states and tribes, however,

meant to determine their respective beneficial uses and adopt criteria to support those uses, EPA is tasked with providing the latest scientific information about the nature and extent of toxic contaminants and their impact on human and aquatic ecosystem health.[217] EPA is also charged with overseeing states' and tribes' promulgation of WQS, with the responsibility to approve or disapprove WQS and to step in and promulgate WQS for a state or tribe that fails to rectify deficiencies identified by EPA.[218] In 1980, as noted above, EPA issued its first round of criteria for sixty-four toxic pollutants, together with guidance that was to inform efforts, whether by states or by EPA itself, to set or approve human health criteria for use in WQS.[219] According to EPA, water quality criteria are to be derived chemical by chemical: a substance's toxicity is multiplied by an individual's exposure to that substance via the aquatic environment.

Because fish intake is the primary means by which humans are exposed to a host of toxic chemicals, an assessment of people's exposure turned importantly on their fish consumption practices.[220] At the time, EPA had to search for a dataset characterizing human fish intake.[221] Because EPA was crafting national criteria and guidance, it sought a dataset that was sufficiently broad in its coverage as to be "statistically projectable to the U.S. population or sizeable segments thereof."[222] The most robust candidate then available was from a survey conducted in 1973–74 by NPD Research, Inc., "a market

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may identify other, more protective, designated uses for the various water segments within their respective jurisdictions. 40 C.F.R. § 131.4.

217. 33 U.S.C. § 1314(a). Such scientific information issued by EPA is, confusingly, also called "criteria."

218. States and tribes are to submit any revised or new water quality standard to EPA, which is given a short timeline for action—EPA must approve it within sixty days or disapprove it within 90 days. 33 U.S.C. §§ 1313(c)(2)–(3). If the latter, EPA must indicate to the state or tribe the changes to be made in order to meet the requirements of the CWA. *Id.* § 1313(c)(3). If the state or tribe does not make these changes within 90 days, EPA must promulgate water quality standards for that state's or tribe's waters. *Id.* § 1313(c)(3)–(4). And EPA always has the authority, under the "hammer" provision of the CWA, *id.* § 303(c)(4), to promulgate water quality standards "in any case" that this turns out to be "necessary to meet the requirements of [the CWA]." *Id.* § 1313(c)(4)(B).

219. Water Quality Criteria Request for Comment, 44 Fed. Reg. 15,926, 15,926 (Mar. 15, 1979).

220. Water Quality Criteria Documents; Availability, 45 Fed. Reg. 79,318, 79,318 (Nov. 28, 1980).

221. JAVITZ, *supra* note 1, at 1.

222. *Id.* at 2 (explaining that EPA's consultants, SRI, had conducted a literature review and identified four datasets for consideration, which were "the only ones that met the minimum requirement of being statistically projectable to the U.S. population or sizeable segments thereof").

research and consulting firm that specializes in the analysis of consumer purchasing behavior as recorded in monthly diaries."[223] This study had been "funded by the Tuna Research Institute (TRI) as part of a study of tuna consumption";[224] it was designed to take a snapshot of then-current fish consumption practices in households across the United States. Although EPA's consultants in 1980 had identified four datasets that were national in scope, it determined that each of the other three was deficient for EPA's purposes.[225] For example, a National Marine Fisheries Service (NMFS) dataset excluded freshwater and recreationally caught fish; a United States Department of Agriculture (USDA) food consumption survey failed to account for fish consumed in "mixtures" (such as chowders, casseroles, or sandwiches).[226]

The tuna industry survey canvassed a demographic that was, in the vernacular of time, described as 94.3% "Caucasian," 4.6% "Black," 0.6% "Oriental," and 0.6% "Other."[227] Although an initial assessment of this dataset had been used to support a FCR of 18.7 g/day in EPA's proposed criteria,[228] internal EPA correspondence from the summer of 1980 reveals this number to have been the subject of some debate, in part because it had become clear that some data had been lost, but eventually retrieved, from the NPD survey dataset. Emphasizing that "[t]he fish consumption issue has prevented the completion of the final criteria documents, due for publication by September, 1980," Joseph Krivak, then Director of EPA's Criteria and Standards Division, stated bluntly that "a choice has been made" with respect

223. *Id.* at 18.

224. *Id.*

225. *Id.* at 35–36.

226. *Id.* Of the four datasets considered, EPA's consultants determined the "most reliable" source to be the NPD Research, Inc. survey. *Id.* at 18. Each of the other sources considered were, according to SRI, marred by significant deficiencies, e.g., a NMFS database excluded freshwater and recreationally caught fish; a USDA consumption survey failed to account for fish consumed in "mixtures" and had a small sample size; a third survey may have excluded "gamefish," and the dataset was no longer available for queries, such that the survey could not be used for consumption rates at particular percentiles of the surveyed population. *Id.*

227. The percentage calculations are mine, based on a table describing the absolute number of respondents in each of these categories alongside the total number of respondents. *Id.* at 42. Note that these calculations have been rounded to the nearest tenth of a percentage, and do not account for 2 out of the total 24,652 respondents for whom this demographic data is recorded as "missing."

228. Water Quality Criteria Request for Comment, 44 Fed. Reg. 15,926, 15,930 (Mar. 15, 1979).

to key decisions affecting the fish consumption rate.[229] Specifically, Krivak directed that "a new fish consumption number" be calculated using the corrected dataset and, notably, that this number (1) reflect "per capita" fish consumption (i.e., intake by fish consumers and non-fish consumers alike), and (2) exclude consumption of marine species.[230] Accordingly, the mean consumption rate for fish eaters from the NPD survey, 14.3 grams/day,[231] was adjusted by multiplying it by 0.94 to re-include the "non-fish eaters" (thereby arriving at a mean per capita rate of 13.4 grams/day) and then subtracting those species determined to be "marine."[232] This latter determination involved judgment calls by EPA (all salmon, for example, were deemed a marine species, despite their anadromous life histories and, for some, their residency in freshwater throughout their lifecycles).[233] Thus, EPA derived the new FCR of 6.5 grams/day, which formed the basis of its water quality criteria and became the national default rate suggested by way of guidance to states for use in their health-based WQS.[234] States—and, in many cases of state recalcitrance, EPA—incorporated this 6.5 grams/day value into the WQS that they issued over the next several years.[235]

Efforts shortly thereafter to assess human exposure to dioxins in Virginia's surface waters similarly show EPA to have been dependent on data that had been gathered for other purposes. A 1991 memorandum to the file documents EPA's telephone research efforts to track down fish intake data that it had reason to believe had been gathered by the Virginia Seafood Council, by the Virginia Marine Research Institute, by NMFS, by the National Fisheries

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229. Memorandum from Joseph Krivak, Director, EPA, Criteria & Standards Div., to Charles E. Stephan, Envtl. Scientist, EPA, Office of Research & Dev. (June 17, 1980) (on file with author).

230. *Id.*

231. JAVITZ, *supra* note 1, at 37.

232. Memorandum from Charles E. Stephan, Envtl. Scientist, EPA, Office of Research & Dev., to Dr. Jerry Starra, Director, EPA, Criteria & Assessment Office (July 3, 1980) (on file with author).

233. *Id.* (describing criterion for "separat[ing] out the 'marine' organisms," developed in consultation with two other EPA scientists, and discussing the basis for allocating the "rather large amount of the consumed fish and shellfish [that] was listed as 'unclassified' or 'species not reported' in the NPD survey" to the "marine" category).

234. Water Quality Criteria Documents; Availability, 45 Fed. Reg. 79,318, 79,318 (Nov. 28, 1980).

235. *See, e.g.*, WASH. ADMIN. CODE § 173-201A-240(5) (2011) (adopting "National Toxics Rule" for Washington's human health-based criteria for surface water quality); Water Quality Standards: Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance, 57 Fed. Reg. 60,848, 60,863 (Dec. 22, 1992) (to be codified at 40 C.F.R. pt. 131) (enlisting 6.5 g/day fish consumption rate for standards applicable to numerous states who had failed timely to promulgate their own water quality standards).

Institute, or by the USDA's Human Nutrition Information Service—all of which turned out to be unavailable or wanting on various grounds.[236] By this time, EPA was aware of surveys of west coast sport anglers documenting fish consumption rates of 30 grams/day at the average and 140 grams/day at the 90th percentile.[237] EPA was also aware that members of the Mattaponi and Pamunkey tribes consumed fish at greater rates than the national default FCR. EPA contacted tribal leaders, one of whom provided an estimate of Pamunkey tribal members' fish intake, at "once a week," except in the spring, when it was "twice a week" (two fish meals per week is roughly 64.8 grams/day).[238] Although EPA noted this evidence, it stated that tribal leaders' "beliefs were not based on fish consumption studies."[239] Ultimately, in the absence of quantitative data characterizing local fish intake, i.e., by people consuming fish that would be affected by Virginia's standards, Virginia adopted, and EPA approved, water quality standards based on the national default FCR of 6.5 grams/day.[240]

As in the context of air quality, EPA increasingly had reason to appreciate the shortcomings of having had to rely on the available data to determine a key exposure parameter for water quality standards. Surveys conducted in the 1980s and 1990s showed considerable variability in people's fish consumption practices, along geographical, cultural, ethnic, economic, and other lines.[241] However, EPA was relatively slow to revise its first-generation exposure assessment in the case of water quality. It was not until the 1990s drew to a close that EPA began the process of updating its 1980 guidance.[242] Its updated Ambient Water Quality Criteria Methodology was finalized in 2000 and included two default FCRs: 17.5 grams/day for the general population and 142.4 grams/day for "subsistence" populations.[243] By this

236. Memorandum from Linda L. Holst, Program Support Branch, EPA, Region III, to VA Water Quality Standards File (Jan. 11, 1991). The USDA data, for example, while based on a national three-day survey of fish intake, neglected to account for fish consumed in "mixtures" such as chowders, casseroles, or sandwiches, and comprised only 2000 respondents nationwide, and thus "only 40 observations per state, on average"—too few, it was determined, to support a Virginia-specific estimate of fish intake.

237. EPA, *supra* note 128, at 15–18 (citing studies by Puffer and Pierce, in, respectively, Los Angeles and Tacoma, as discussed in EPA's then–current Exposure Factors Handbook).

238. Memorandum from Linda L. Holst, Program Support Branch, EPA, Region III, to VA Water Quality Standards File (Jan. 15, 1991) (recording conversations with tribal leaders, including Warren Cook of the Pamunkey Indian Tribe).

239. EPA, *supra* note 128, at 17–18.

240. *Id.*

241. *See supra* notes 115–22 and accompanying text.

242. EPA, *supra* note 11, at 1-4.

243. *Id.* at 1-13.

time, EPA was able to avail itself of comprehensive data on dietary habits gathered by the USDA by means of its Continuing Survey of Food Intake by Individuals (CSFII)[244] in order to set the national default rate for the general population.[245] It was also able to reference several surveys specifically designed to gauge fish intake by various high-consuming groups in order to set the national default for "subsistence" populations.[246]

As these examples in the context of both air and water quality regulation illustrate, the inadequacies of having to rely on data that happened to be at hand were sometimes noted, even early on. The solution to these shortcomings, it was thought, was simply to gather more exposure-relevant data—to take a better picture of present practice. Ideally, this task meant obtaining direct measures of each individual's contact with (a biologically effective dose of) toxic contaminants, e.g., through use of personal air quality monitors, a nascent technology at the time.[247] More realistically, this task meant improving indirect measures of representative individuals' contact with toxic contaminants, and extrapolating to larger populations.[248] Thus, efforts were aimed at gathering more data in more systematic ways about the human behavioral component of exposure.[249] As one exposure scientist

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244. *See Key Concepts About the History of Dietary Data Collection*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/nchs/tutorials/dietary/SurveyOrientation/DietaryDataOverview/Info1.htm (last visited Nov. 13, 2016). Although termed a "continuing survey," the survey was initially conducted periodically—in 1989–91, 1994–96, and 1998. Beginning in 2002, the CSFII was merged with the National Health and Nutrition Examination Survey (NHANES), and data is "collected continuously rather than on a periodic basis." *Id.*

245. EPA's Draft AWQC Revisions, published in 1998, enlisted the CSFII data from 1989–91. Draft Water Quality Criteria Methodology Revisions Human Health, 63 Fed. Reg. 43,756, 43,762 (Aug. 14, 1998); EPA, AMBIENT WATER QUALITY CRITERIA DERIVATION METHODOLOGY HUMAN HEALTH: TECHNICAL SUPPORT DOCUMENT FINAL DRAFT (1998). EPA's final ambient water quality criteria methodology, published in 2000, enlisted the CSFII data from 1994–96. EPA, *supra* note 11, at 4–24.

246. *See* O'Neill, *supra* note 116, at 34 n.195 (explaining the various groups included under EPA's generic use of the term to refer simply to those people who eat large quantities of fish and contrasting this with Native peoples' use of the term).

247. *See, e.g.*, Ott, *supra* note 30, at 10–12 (describing "direct approach" of estimating individual exposures). *See generally* Wallace, *supra* note 47.

248. Ott, *supra* note 30, at 10–12 (describing "indirect approach" of estimating individual exposures).

249. *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 86, at 163 (suggesting ways to improve survey design to elicit better, exposure-relevant data).

observed: at the time, improving exposure assessment was "thought to be a straightforward task not requiring major theoretical advances."[250]

This "straightforward task" was pursued in earnest. Beginning in the 1990s, EPA availed itself of the more expansive national databases compiled by various federal agencies concerned with indicators of human health and welfare. Thus, air quality standards enlisted population-wide databases documenting human activity patterns, such as the National Human Activity Pattern Survey, which collected information from twenty-four-hour diaries of "human activities and their locations from a sample of 9,386 U.S. residents between October 1992 and September 1994."[251] Water quality standards drew upon nationwide data on dietary habits gathered by the USDA in its CSFII.[252] These comprehensive datasets, in turn, supported more refined models.[253] These advances were reflected in the procession of EPA guidance documents for exposure assessment. EPA's Exposure Factors Handbook, for example, continued to be updated and its scope expanded to reflect the most recent exposure-relevant data.[254] But, even as advances of various sorts permitted a more sophisticated picture of contemporary practices, the temporal frame for exposure assessments was not questioned in view of the purpose to which they were to be put, i.e., standard setting.

B. The Call for Objective, Data-Driven Assessments of Risk

EPA issued its first agency-wide guidance for exposure assessment in 1986, as noted above.[255] These 1986 Exposure Assessment Guidelines define

250. Franklin E. Mirer, *Distortions of the "Mis-Read" Book: Adding Procedural Botox to Paralysis by Analysis*, 9 J. HUM. & ECOLOGICAL RISK ASSESSMENT 1129, 1133 (2003) (describing risk assessment in the aftermath of the Red Book).

251. Flachsbart, *supra* note 50, at 132–33.

252. *See supra* notes 244–45.

253. As of 2014, for example, EPA's Consolidated Human Activity Database (CHAD), had compiled over 45,000 person-days of activity data, collected from twenty-one different human activity pattern surveys; this version of CHAD was used to support the most recent version of EPA's Hazardous Air Pollutant Exposure Model. EPA, THE HAPEM USER'S GUIDE: HAZARDOUS AIR POLLUTANT EXPOSURE MODEL, VERSION 7, at 1-3, (2015) (noting, among the updates to the most recent version, "four new commuting-related microenvironments are included in HAPEM7 for a total of 18 microenvironments").

254. *See* PowerPoint Presentation from the EPA Office of Research & Dev., to the Nat'l Tribal Toxics Council (July 21, 2015) (on file with author) (noting that the Exposure Factors Handbook was first published in 1989, updated in 1997, revised and updated in 2009, and issued in final form most recently in 2011; pointing to instances where data gaps still exist, and portraying the Handbook as a "dynamic," "continuously evolving" document).

255. Guidelines for Estimating Exposures, 51 Fed. Reg. 34,042, 34,042 (Sept. 24, 1986).

exposure assessment broadly, theoretically recognizing that it might usefully have past-, present-, or future-oriented applications in environmental and public health contexts.[256] This recognition, however, is prefatory to the document's main business of setting forth a uniform method for conducting exposure assessments based on current levels of human exposures.[257] The method is laid out in connect-the-dot fashion, starting with release at the source and producing an estimate of exposure to human receptors in a form compatible with the dose-response function required by a particular risk assessment.[258]

EPA used the present tense to discuss the human behavioral component of exposure assessment. "In many cases, exposed populations can be described only generally. In some cases, however, more specific information may be available on matters such as . . . [humans'] characteristics (e.g., trends, sex/age distribution) . . . location . . . [and] habits—transportation habits, eating habits, recreational habits, workplace habits, product use habits, etc."[259] EPA noted that exposure assessments may need to rely on "extant" information, and named "census and other survey data" among those that may be enlisted to characterize the exposed population.[260]

Thus, EPA's first formal attempt to delineate the method emphasized exposure assessment's bridging function between environmental science, at the front end, and toxicology, at the back end. But time is suspended—or, rather, a static, present orientation is assumed, no matter the regulatory context. This is so despite the fact that the National Research Council had expressly recognized in *The Red Book*'s definition of the term that exposure assessment might reflect either present or future conditions: exposure assessment is "[t]he determination of the extent of human exposure before or after application of regulatory controls."[261] Importantly, EPA did not treat separately those instances in which an exposure assessment is used to set future-oriented environmental standards. EPA thus did not grapple with the fact that the human "characteristics, location, and habits" assumed will determine the human practices to be supported in the future. Although there are a handful of instances in which the method is recognized to permit profiles

256. *Id.* at 34,043 ("Exposure assessments may consider past, present, and future exposures with varying techniques for each phase, e.g., modeling of future exposures, measurements of existing exposure, and biological accumulation for past exposures.").

257. *Id.*

258. *Id.* at 34,048–49.

259. *Id.* at 34,048.

260. *Id.* at 34,048, 34,050.

261. THE RED BOOK, *supra* note 29.

of future exposures, these mentions are few in number and appear as asides.[262] While the temporal dimensions of exposure assessment were not entirely ignored, the implications were not plumbed.

The 1986 Exposure Assessment Guidelines never explicitly engaged the issue of the purpose for which an exposure assessment is conducted. This silence, in fact, may have been intentional. Although the proposed version of the Guidelines generated only twenty-nine comments from the public (in addition to input from the Science Advisory Board), the comments lodged reflected the concerns of the day.[263] Chief among these was the concern that "risk assessment" and "risk management" be kept apart.[264] Although the National Research Council's recommendation on this point, recall, was more nuanced, it had come to be characterized by many as stark. Moreover, it had come to be cited in order to cloak one's favored inputs and methods in the mantle of (objective) science, while implying that competing inputs and methods belonged to the realm of (subjective) policy. Accordingly, EPA stated in the final version that it would decline to discuss its "philosophy" or view of "the role of exposure assessment in risk assessment."[265] Rather, "[i]n order to remain consistent with the separation of risk assessment and risk management, any directions to consider applicable laws or regulatory decisions have been stricken from the Guidelines."[266]

EPA's 1986 Exposure Assessment Guidelines also held up "measured" rather than "modeled" data as the gold standard for exposure assessments.[267] This ideal was echoed in EPA's 1988 Guidelines on Exposure-Related Measurements.[268] EPA's guidance recommended further research both to calibrate the models in use and to reduce instances in which modeled, as opposed to measured, data were required.[269] For both efforts, more comprehensive measured data were needed. This preference for measured data permeated EPA's guidance and was taken to apply equally to tracking

262. *See, e.g.*, Guidelines for Estimating Exposures, 51 Fed. Reg. at 34,048 ("Future environmental concentrations resulting from current or past releases may also be projected. In some cases, both the temporal and geographic distributions of the concentration may be assessed.").

263. *Id.* at 34,052.

264. *Id.* at 34,054.

265. *Id.*

266. *Id.*

267. *Id.* at 34,043.

268. Proposed Guidelines for Exposure-Related Measurements, 53 Fed. Reg. 48,830, 48,831 (Dec. 2, 1988).

269. Guidelines for Estimating Exposures, 51 Fed. Reg. at 34,043. This research effort is an ongoing one. *See, e.g.*, Devon C. Payne-Sturges et al., *Personal Exposure Meets Risk Assessment: A Comparison of Measured and Modeled Exposures and Risks in an Urban Community*, 112 ENVTL. HEALTH PERSP. 589, 589 (2004).

the fate and transport of a chemical upon release from a source and characterizing the human behaviors that brought an exposed population into contact with these chemicals in the environment. EPA recognized that the duration, timing, and location of people's activities might, for reasons of feasibility, need to be reconstructed indirectly through the use of recall surveys. While EPA concluded that, properly conducted, indirect methods here could serve as a reasonable surrogate for direct measurement, it nonetheless viewed this as a second-best approach. So EPA worked to ensure that the surveys that supported its environmental standards met the requisites for quality and, over time, that they more comprehensively described the practices of (a growing roster of) the populations of concern. It may be, then, that the ideal of measured data contributed to the pursuit of more detailed depictions of people's "actual" contemporary exposures—with the possibility of entertaining alternative assumptions more appropriate to future-oriented exposure assessments left unexplored, relegated to a realm somewhere beyond the second-best.

Exposure scientists' preoccupation with amassing contemporary data may also have been fueled by the need to bolster the case for imposing health-based standards at all. The impetus for *The Red Book*'s effort to place risk assessment on firmer scientific footing stemmed from public criticism that agencies' regulations, particularly for carcinogens, were not consistently being made on the basis of the best available science.[270] As outlined in Part I.B, industry groups such as the American Industrial Health Council had been vocal in advancing this claim, and the National Research Council, in its transmittal letter for *The Red Book*, observed that "[f]ederal agencies that perform risk assessments are often hard pressed to clearly and convincingly present the scientific basis for their regulatory decision."[271] And, closer to home, exposure scientists at EPA report receiving "push-back" early on regarding their assumptions in support of the NAAQS.[272] For example, industries that would be impacted by the standards questioned exposure assessors' estimates of the "number of kids who exercised," arguing that EPA had overestimated.[273] Given the far-reaching impact of the NAAQS across multiple sectors of the U.S. economy, agency scientists quickly perceived the need to justify EPA's standards as being "data-driven," and endeavored to

270. THE RED BOOK, *supra* note 29, at iii.

271. *Id.*

272. Telephone Interview with Tom McCurdy, Research Physical Scientist, EPA (March 31, 2015) (recounting external "push-back," including from the American Petroleum Institute).

273. *Id.* (recounting this example and noting that EPA's response at the time was to request data to support this contention).

make the entire standard-setting process "more rigorous and more transparent."[274] Although EPA's critics in this instance did not have time-activity data for children to counter EPA's estimates, the terms of the debate were starting to crystalize. As the claim that risk assessment was overly conservative gathered momentum, EPA was increasingly at pains to show that its exposure assessments reflected "actual" rather than hypothetical or "worst-case" assumptions. EPA assessors' refuge was in putting forth detailed, hard numbers of people's "actual" exposure circumstances to back their decisions.[275]

C. The Expectation of Improved Environmental Conditions, Expanded Practices, and Better Data

At least early on, EPA may not have been led to question exposure assessment's contemporary orientation because it may have expected any gap between current practices and healthful practices to dissipate fairly quickly. Recognizing that its first-generation exposure assessments would soon be updated, EPA may have thought that the snapshot of exposure that would be taken for the next round of standard setting would reflect people's expanded practices. It may have been optimistic that environmental conditions would rapidly improve as a result of the raft of environmental legislation passed beginning in the late 1960s.[276] As a consequence, the time-activity, consumption, and other studies that provided the foundation for exposure assessments would be expected soon to capture behaviors that reflected people's choices when they had the whole panoply of options. EPA also may have anticipated that better, newer data would tend to support more protective standards, given some initial experience that had suggested as much.

When EPA undertook its early exposure assessments, Americans were generally optimistic about the sweeping environmental laws that had just

274. *Id.*

275. This dynamic continues to hold sway. *See, e.g.*, EPA, GUIDANCE FOR CONDUCTING FISH AND WILDLIFE CONSUMPTION SURVEYS 2-4 (1998) (stating that a less detailed survey might be appropriate for some purposes but "if regulatory or legal challenges to issuance of an advisory, closure, or water quality standards are anticipated, a highly accurate, legally defensible consumption rate might be required, indicating a need to address more objectives or very detailed objectives in the survey").

276. Keep in mind that health-based standards are but one tool employed by environmental law. *See, e.g.*, Livermore & Revesz, *supra* note 23. It may have been that improvements were anticipated to be brought about by a suite of means, including other statutorily directed reductions (e.g., through feasibility-based standards), or other non-regulatory efforts (e.g., voluntary undertakings).

been enacted.[277] They believed that these measures would accomplish their stated goals, returning the waters to a condition that supported fishing and swimming; ensuring that the air was healthful for even children and other sensitive people to breathe; and restoring contaminated sites to places where people could safely live and work. Although the record is spotty, this optimism may have been shared by exposure scientists and others within EPA. For example, there is some evidence that exposure scientists working to develop the NAAQS expected air quality quickly to improve, such that the need for people to take "averting" or "defensive" measures would soon be eliminated.[278] Similarly, there appears to have been an expectation of improving water quality and, consequently, increased human consumption of fish. Although EPA recognized the immediate need to communicate the risks of fish consumption given widespread contamination, it appeared optimistic that advisories were but a temporary response. Once environmental standards were set and contamination of surface waters reduced, it was trusted, avoidance measures of this sort would no longer be required. Thus, an EPA analysis of potential standards for dioxin discharges from pulp and paper mills in the 1990s assumed that some 20% of anglers, who had undertaken avoidance in response to fish consumption advisories, would resume fishing once standards were in place and advisories lifted.[279]

Additionally, EPA may have anticipated that the newer, more refined data that would be used in successive rounds of standard setting would in fact support more protective standards—which would, in turn, lead to improved environmental conditions. Thus, the relatively crude data that were relied upon as a basis for the first generation of exposure assessments could be expected to be replaced with more nuanced data, as exposure assessors enlisted updated information and honed their models. For example, exposure scientists working to develop NAAQS in the early years believed that the standards would "get tighter as more rigorous data were obtained."[280] Early evidence often bore out this sense; for example, updated data supported the use of more robust respiration rates in second-generation NEMs and NAAQS.[281] As a consequence, according to EPA scientist Thomas McCurdy,

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277. *See, e.g.*, LAZARUS, *supra* note 169, at 87 (observing that "[t]he early statutes promised dramatic, immediate change").

278. Telephone Interview with Tom McCurdy, *supra* note 272.

279. *See* POWELL, *supra* note 72, at 356–60, tbl.G-5.

280. Telephone Interview with Tom McCurdy, *supra* note 272.

281. Compare, for example, the ventilation rates used for the 1982 CO NAAQS (assuming three rates, associated with light exercise (8 liters/minute), medium exercise (20 liters/minute), and high exercise (35 liters/minute), with those used for the subsequent O3 NAAQS (assuming

there would be no reason to make the case for setting "normative" ambient air quality standards.[282] Similarly, in the context of water quality, EPA was aware that the newer fish consumption data being gathered through targeted surveys of anglers and other higher-consuming groups in the early 1980s were revealing markedly greater levels of fish intake.[283] And in a 1992 document, EPA cited "the upward trend in per capita consumption" over the previous decade as among the reasons for gathering "more recent and more detailed" fish consumption data for use in agency risk assessments.[284] These data would support higher FCRs—and, presumably, more protective water quality standards.

The optimism of the early days may have seemed warranted, as many of the most visible manifestations of despoliation were addressed. The rivers were no longer on fire; air pollution was perceptibly decreased.[285] The signals, of course, were mixed, and it soon became recognized that the task was a formidable one—perhaps more so than initially appreciated.[286] However, it may have been that evidence in some prominent cases suggested that environmental conditions were improving—or, at least, that they soon would improve—and that more rigorous data would contribute to a virtuous cycle. It may have seemed that contemporary snapshots would soon reflect people's practices unconstrained by contamination and depletion. Exposure assessors, thus, may not have questioned the expectation of an upward trajectory until

four rates, associated with light exercise (<25 liters/minute), medium exercise (26–43 liters/minute), high exercise (44–63 liters/minute), and very high exercise (>64 liters/minute)). The more recent set of assumptions would have supported relatively more protective standards. *See* McCurdy, *supra* note 187, at 546.

282. Telephone Interview with Tom McCurdy, *supra* note 272.

283. *See* EPA, *supra* note 128 and accompanying text.

284. EPA, CONSUMPTION SURVEYS FOR FISH AND SHELLFISH: A REVIEW AND ANALYSIS OF SURVEY METHODS 3 (1992) (citing K.D. Fisher's 1988 review of nine fish consumption studies); KENNETH D. FISHER, APPROACHES TO ESTIMATING FISH CONSUMPTION IN THE UNITED STATES 20–21 (1988), https://www.faseb.org/Portals/2/PDFs/LSRO_Legacy_Reports/1988_Approaches%20to%20Estimating%20Fish%20Consumption%20in%20the%20United%20States.pdf (finding an upward trend in per capita consumption "over the past decade").

285. *Progress Cleaning the Air and Improving People's Health*, EPA, https://www.epa.gov/clean-air-act-overview/progress-cleaning-air-and-improving-peoples-health (last updated Sept. 6, 2016) ("[F]rom 1970 to 2014, aggregate national emissions of the six common pollutants alone dropped an average of 69 percent while gross domestic product grew by 238 percent.").

286. *See, e.g.*, LAZARUS, *supra* note 169, at 87. *But cf.* MARY CHRISTINA WOOD, NATURE'S TRUST: ENVIRONMENTAL LAW FOR A NEW ECOLOGICAL AGE 47–64 (2014) (contrasting the seemingly bold promise of environmental laws ushered in in the wake of Earth Day in 1970 with the "escape hatches," permit systems, and provisions for agency discretion that have produced, instead, an "entitlement system" for polluting sources and extractive industries).

much later, perhaps after the issue of suppression effects was brought to the public's attention at the outset of the 2000s.

To summarize, in considering how EPA came to frame the relevant question "to what are people exposed?," this Part has discussed a number of factors that may help to explain exposure assessment's recent-past orientation. Because so little was known about human exposure at the time EPA began to set health-based standards, it was an enormous task simply to understand the humans—with all manner and combinations of lifestage, characteristics, and practices—that came into contact with contamination. EPA had to wrestle with data that, having been gathered for purposes other than exposure assessment, were quirky and incomplete. In fact, EPA's work during this period deserves to be recognized for significantly advancing exposure assessment in application, for example, by increasing the extent to which it was informed by exposure-relevant data.

However, the context in which these strides were made at EPA may have shaped the method without affording real opportunity to consider fundamental methodological questions. With exposure assessment a relative late bloomer among the components of quantitative risk assessment, as outlined in Part I, its formative steps took place against a backdrop of a debate that was already comparatively developed. Agency exposure assessors may have perceived the need to move quickly to gather more comprehensive and refined data depicting people's "actual" exposures in order to shore up exposure assessment's place as "exposure science" and to deflect criticisms that EPA's standards were not data-driven. Indeed, the emphasis on the need to gather exposure data in order to reduce uncertainty and enhance scientific rigor and defensibility continues today.[287]

Exposure scientists inside and outside of the agency obviously recognized that the form of the risk assessment equation, with a number of variables comprising its inputs, actually permits "what if" questions.[288] What if people are assumed to harvest and consume fish at healthful levels? As EPA itself observed in a 1998 guidance document for conducting fish and wildlife consumption surveys, a question posed in this manner would require different data to have been gathered: "The type of decision to be made based on the consumption data can drive the survey process; for example . . . is potential consumption information (e.g., in the absence of contaminants) desired to

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287. *See, e.g.*, COMM. ON HUMAN & ENVTL. EXPOSURE SCI. IN THE 21ST CENTURY, NAT'L RESEARCH COUNCIL, EXPOSURE ASSESSMENT IN THE 21ST CENTURY: A VISION AND A STRATEGY 4–5 (2012).

288. *See* Ott, *supra* note 30, at 5.

assist in cleaning up a contaminated site so that fishing or hunting activity can be restored?"[289] It was recognized that nothing, in theory, prohibited a future-oriented, health-based inquiry.

However, exposure assessment has not been undertaken in this way for regulatory standard setting at EPA. If one wants to derive a standard for ambient concentration of some chemical, one simply "plugs in" the contemporary exposure data to the risk assessment algorithm and solves for concentration. As suggested above, it may be that EPA's sensitivity to *The Red Book*'s directive to maintain a firewall between risk assessment and risk management prohibited EPA from even discussing how exposure assessment might fit into the bigger picture. During the formative years, EPA seems not to have engaged the issue of the purpose for which exposure assessments are conducted when employed to set health-based standards—at least not publicly. The question whether it is appropriate to rely on contemporary exposure data to set future-oriented environmental standards appears not to have been debated at any length. Rather, these were the data that happened to be at hand to support EPA's initial standard-setting forays, and the methods used there served as the template for exposure assessments agency-wide. Subsequent developments reinforced a focus on amassing actual, contemporary exposure data. Standards governing the future state of the environment thus came to be founded on inquiries into the recent past.

Having considered the development of exposure assessment at EPA, the next Part turns its attention to the method as currently practiced. It engages the question that appears to have been largely unasked to date: should health-based standards be determined by reference to people's recent-past exposures?

III. EXPOSURE ASSESSMENT REEXAMINED: ASKING THE WRONG QUESTION

Health-based standards require a level of environmental quality that supports just those human characteristics, activities, and lifeways assumed in the underlying exposure assessment. These standards effectively instate a ceiling or boundary on the practices in which people may safely engage, the

289. EPA, *supra* note 275 ("The type of decision to be made based on the consumption data can drive the survey process; for example, risk assessment (predictive/protective) versus diet/health relationships (empirical). Will data on actual consumption be used in relation to observed health effects, or is potential consumption information (e.g., in the absence of contaminants) desired to assist in cleaning up a contaminated site so that fishing or hunting activity can be restored? For whom will the advice be constructed—the general public or a specific population?").

profile of human characteristics and behaviors that will be adequately protected. Exposure assessment in this way defines the scope of future human endeavors.

Although perhaps not appreciated in the early years at EPA, evidence has since emerged that people's contemporary practices are likely constrained by environmental degradation. The activities and resource uses people are able to pursue at present—or in the recent past—may or may not be healthful. In fact, some people have altered their practices in order to avoid harmful contaminants or to compensate for depleted resources. Thus, while a snapshot of exposure taken in the early years of environmental agencies' work may have been unlikely to reflect healthful behaviors (or, in the case of tribal people, heritage lifeways), an updated snapshot of contemporary exposures may not be much more likely to produce this picture. To the contrary, agencies' use of contemporary data may set in motion a negative feedback loop, resulting in declining, rather than improving, environmental conditions. And, as it turns out, a focus on updated depictions introduces opportunities for delay into the environmental regulatory process.

Upon reexamination, this Part argues, "to what are people exposed?" is the wrong question, given the purpose intended to be served by exposure assessment in the health-based standard setting. First, exposure assessment as practiced is not explicitly tied to the purposes of environmental law and policy. It considers only humans' apparent practices, without inquiring how these relate to practices that are healthful or vital. As such, the method is at odds with the promise of a healthful environment embodied in our foundational environmental statutes. It is also at odds with the guarantees of robust resources contained in treaties and other legal instruments that secure protection to American Indian tribes' lifeways. Exposure assessment as practiced may undermine, rather than advance, progress toward the environmental conditions that support basic human functions and lifeways. Second, exposure assessment tends to subsume into its depiction of human practices any "averting" or "compensatory" measures people have adopted in response to environmental degradation. By simply incorporating such self-protective actions into their representation of people's "actual" exposures, however, agencies sidestep the question whether the baseline should be adjusted so. Exposure assessment as practiced effectively replaces statutory approaches premised on risk reduction with an approach that relies on risk avoidance. Third, exposure assessment as practiced provides a powerful lever for delaying the imposition of environmental standards. By focusing on people's actual, contemporary practices, exposure assessment sets up a moving target, as there will always be an argument that newer data constitute the best available science. With each of the numerous inputs to an exposure equation subject to constant revision and renewed debate, the occasions for delay are many. These contests in practice have generally disserved the aim of environmental protection.

A. Exposure Assessment Undermines Healthful or Heritage Practices

Exposure assessment as practiced is untethered to the ends of environmental law and policy. It is absorbed in documenting people's present activity patterns, consumption habits, and resource uses. However, it doesn't inquire into how people's contemporary practices relate to practices that are healthful or vital. This section first takes up exposure assessment's relationship to practices that would be healthful for the general population. It finds that a focus on contemporary behaviors often produces standards that fall short of those that would support a range of healthful undertakings. As such, it observes, agencies' method may be at odds with the restorative and preventive aims of our foundational environmental laws. This section then considers exposure assessment's relationship to practices that would be healthful for American Indian tribal populations—what tribes have termed "heritage" practices. It finds that a focus on contemporary (typically, general population) behaviors often produces standards insufficient to support tribal lifeways. As such, it observes, agencies' method may be at odds with the promises of robust resources contained in treaties and other legal instruments that secure protection for these lifeways.

1. Healthful Practices

In fact, there is evidence to suggest that the practices assumed as the basis for health-based standards often fall well short of those that are considered healthful for humans. Fish, if uncontaminated, are an excellent source of dietary protein, omega-3 fatty acids, and other nutrients.[290] Recent studies underscore the health benefits of ample fish intake for those in the general population in the United States. For example, one study found that women who ate one fish serving per day (227 grams/day) had a 24% lower risk of coronary heart disease than those who ate one red meat serving per day;[291]

290. *See, e.g.*, INST. OF MED., SEAFOOD CHOICES: BALANCING BENEFITS AND RISKS 199 (2007).

291. Bernstein et al., *supra* note 13, at 880 (describing results of prospective study following 84,136 women aged 30 to 55 for 26 years as part of the Nurses' Health Study, which found a 24%

another study found that men who ate five or more fish meals per week (162 grams/day) had a 37% lower risk of colorectal cancer compared to those eating less than one fish meal per week.[292] According to a third study, women and men both demonstrated a continuous positive association between higher blood omega-3 fatty acid levels and lower structural and cognitive brain aging;[293] these results "extended" those of an earlier study finding that consumption of at least three fish meals per week (97.2 grams/day) was associated with decreased risk of brain abnormalities. Note that, in each case, the study design did not permit researchers to determine whether even greater fish intake would produce further health benefits. Still, these results emphasize the point that if the fish consumption rate in our water quality standards were set to support healthful levels of fish intake, it would be significantly greater than 6.5 grams/day.

Indeed, EPA itself recognizes the health benefits of eating fish and recently joined the FDA to issue updated advice in order "to encourage women . . . and young children to eat more fish."[294] These agencies recommend that women who are pregnant (or might become pregnant) or who are breastfeeding eat 8 to 12 ounces of fish per week (32.4 to 48.6 grams/day), while attending to advisories for methylmercury.[295] They cite evidence that "most people eat below the recommended amounts" of fish, "both generally and during pregnancy."[296] Yet even EPA's most recent default FCR for use in water quality standards is protective of fish intake up to just 22 grams/day.[297] While the agencies' joint advice can be squared with EPA's FCR if a woman is able to obtain her fish from some source that is more exacting in its water quality standards or if she is able otherwise to ensure her fish is relatively low in methylmercury,[298] the need for people to

lower risk of coronary heart disease for those eating 1 fish serving per day as compared to those eating 1 red meat serving per day).

292. Hall et al., *supra* note 14, at 1138 (describing results of prospective study following 22,071 adult men for 22 years as part of the Physicians' Health Study, which found 37% lower risk of colorectal cancer for those eating 5 or more fish meals/week as compared to those eating <1 fish meal/week).

293. Tan et al., *supra* note 15, at 660.

294. *Fish: What Pregnant Women and Parents Should Know*, FDA (June 2014), http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm ("The nutritional value of fish is especially important during growth and development before birth, in early infancy for breastfed infants, and in childhood.").

295. *Id.* The conversions from ounces to grams are mine.

296. *Id.*

297. EPA, *supra* note 12.

298. *Fish: What Pregnant Women and Parents Should Know*, *supra* note 294 (providing a list of roughly two dozen "common fish varieties" that compares the "Milligrams of Omega-3

do this sort of reconciling highlights the disconnect between fish consumption rates that reflect contemporary behaviors and rates that would support healthful behaviors.

Similarly, regular physical activity has been shown to have a host of physiological and psychological health benefits for children and adolescents. The American Academy of Pediatrics, for example, has noted the importance of physical activity in maintaining a healthy bodyweight and preventing obesity.[299] In a recent Policy Statement, it cited with approval the Centers for Disease Control and Prevention's (CDC) "recommend[ation] that children and youth accumulate at least 60 minutes daily of moderate to vigorous physical activity."[300] It further recommended that "parents become good role models by increasing their own level of physical activity" and that parents "encourage children to play outside as much as possible."[301] According to the CDC, however, in 2013 only 27.1% of youth in grades 9–12 across the U.S. actually achieved sixty minutes or more of moderate to vigorous physical activity daily.[302] Inhalation rates, of course, vary significantly with the intensity of physical exertion. Whereas youth at roughly this age are estimated to have short-term inhalation rates of 4.8 (10^{-3}) m^3/minute if involved in sedentary pursuits, their inhalation rates climb to 4.9 (10^{-2}) m^3/minute if engaged in high intensity activities—a difference of an order of magnitude.[303] If air quality standards are set based on contemporary physical activity levels among youth, they will reflect—and support—only the relatively sedentary habits of the present.[304]

Fatty Acids (Eicosapentaenoic (EPA) and Docosahexaenoic (DHA)" with the "Micrograms of Mercury" per four ounces of cooked fish).

299. AM. ACAD. OF PEDIATRICS, *Policy Statement, Active Healthy Living: Prevention of Childhood Obesity through Increased Physical Activity*, 117 PEDIATRICS 1834, 1836 (2006), http://pediatrics.aappublications.org/content/pediatrics/117/5/1834.full.pdf.

300. *Id.* at 1837.

301. *Id.* at 1840. It also recommended the "reduction of environmental barriers to an active lifestyle through the construction of safe recreational facilities, parks, playgrounds, bicycle paths, sidewalks, and crosswalks." *Id.* at 1839.

302. *Nutrition, Physical Activity and Obesity: Data, Trends, and Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://nccd.cdc.gov/NPAO_DTM/IndicatorSummary.aspx?category=71&indicator=62 (last visited Nov. 13, 2016).

303. OFFICE OF RESEARCH & DEV., *supra* note 91, at 6-2 to 6-5, tbl.6-2 (listing recommended short-term inhalation rates for those ages 11 to 16 years of age; note that inhalation rates for moderate intensity physical activity are somewhat lower than for vigorous physical activity for this age group, at 2.5 m^3/minute).

304. This discussion greatly simplifies the parameters that would need to be considered to assess human exposure to contaminants in the air. For a sense of the complexity of agencies' exposure assessment in this context, see EPA, HEALTH RISK AND EXPOSURE ASSESSMENT FOR

As these examples illustrate, exposure assessment as practiced may undermine the restorative and preventive aims of our environmental laws. The story of the public outcry that ushered in our foundational environmental statutes is by now a familiar one. By the end of the 1960s, people had become concerned about the befouled state of the nation's air, waters, and soils.[305] People had also come to value improved levels of human health and to reject the notion—embodied in a reliance solely on tort law to address the harms of contamination—that people's only succor for compromises to their health was to be found in ex post compensation.[306] Rather, they sought a future in which humans (and the Earth) wouldn't be made to suffer these harms in the first place. Congress responded to this groundswell by passing a phalanx of statutes with restorative aims and forward-looking, preventive orientations.[307]

OZONE, FINAL REPORT (2014) (comprising 502 pages, exclusive of numerous appendices). Note, too, the particular model output considered by EPA in exposure assessments underlying the NAAQS, i.e., "the percent (and number) of people [in at-risk groups, e.g., all school-aged children (ages 5-18), asthmatic school-aged children (ages 5-18)] exposed to one time (or multiple occurrences) at or above [] 8-hour average O3 concentrations of concern," assuming various ambient standards (existing and alternative) are just met. *Id.* at 5-1 to 5-2. It remains the case, however, that EPA's analysis is based on contemporary human activity patterns, drawn now from an extensive database of diaries contained in the Consolidated Human Activity Database (CHAD). "The current CHAD database contains over 53,000 individual daily diaries including time-location-activity patterns for individuals of both sexes across a wide range of ages . . . [and] is geographically diverse." *Id.* at 5-12 to 5-13.

305. *See* DOUGLAS A. KYSAR, REGULATING FROM NOWHERE: ENVIRONMENTAL LAW AND THE SEARCH FOR OBJECTIVITY 3–4 (2010) (describing the "period of unprecedented legislative activism in the environmental, health, and safety arenas" beginning with the passage of "the National Environmental Policy Act (NEPA) in the waning days of 1969" in response to numerous "salient, culture-altering events" including the first images of the Earth from space, the publication of Rachel Carson's *Silent Spring*, the pollution-caused fires on the Cuyahoga River, and the observance of the first Earth Day); Christopher H. Schroeder, *Lost in the Translation: What Environmental Regulation Does that Tort Cannot Duplicate*, 41 WASHBURN L.J. 583, 593 (2002) (describing the "remarkably short period of time, between 1969 to 1976, when a broad environmental movement helped sweep our core environmental statutes onto the pages of the United States Code").

306. Whereas tort functions largely ex post, offering a remedy for harms that have already occurred, environmental regulation operates ex ante, seeking to prevent harmful levels of contamination in the first place. *See, e.g.*, Schroeder, *supra* note 305, at 590. Tort law may work indirectly toward preventive ends. However, Schroeder explains, "[f]or such a system to deter, it must be able to send a signal to parties regarding their future behavior, but to send that signal it must have a case of prior harm to decide." *Id.*

307. *See, e.g.*, LAZARUS, *supra* note 169, at 62–65 (citing the public's increased awareness of the irreversibility of many environmental harms and the long latency period before adverse health impacts became manifest as the source of the period's intense "public demand for laws that purport to reduce or even eliminate the risks in the first instance"); Schroeder, *supra* note 305, at 594 ("There are many reasons why Congress and the President responded in the manner they did . . . . [a]ny such list would be seriously incomplete, however, without adding the

As Christopher Schroeder observes, the very "logic of environmental regulation in these early statutes discloses the desire of citizens to avoid interactions with the environment that expose them to further risks, so as to express a morality of prevention."[308]

Moreover, this morality of prevention has remained remarkably stable over time.[309] This stability may not be surprising when one considers what Douglas Kysar terms the "constitutional vision" captured in these statutes: "Although not formally enacted as constitutional amendments, many landmark environmental statutes can be seen as efforts to exert a foundationalist impact."[310] And while the "wisdoms of our environmental laws," as Kysar puts it, may be "endangered,"[311] these laws continue to embody a belief—and an expectation—on the part of the American public: our waters could again support fish, our air could again be fit to breathe, and our soils could again serve as safe playgrounds for our children.[312]

Even if one were prepared to dismiss environmental statutes' overarching restorative and preventive aspirations as merely symbolic, health-based provisions instruct agencies to set standards that will achieve a healthful level of environmental quality. Thus, for example, the CWA directs EPA (and states and tribes) to set health-based water quality standards that are "such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter"[313] which include ensuring that waters nationwide

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straightforward structural similarity between what the public wanted and what the legislation promised directly to achieve--the prevention of unacceptable environmental risks.").

308. Schroeder, *supra* note 305, at 594. Schroeder elaborates, "[t]he goal of much modern environmental regulation is to prevent harm to the environment before it occurs, with an implementation structure that includes prior approvals, permits that embody standards to be met, and the monitoring of compliance, all with that goal in mind." *Id.* at 589. *But cf.* WOOD, *supra* note 286.

309. *See, e.g.*, Schroeder, *supra* note 305, at 594. ("The demand for public action to prevent exposure has remained remarkably constant over the years . . . . [c]oncomitantly, the structure of environmental regulation has remained consistently preventive and *ex ante*.").

310. KYSAR, *supra* note 305, at 21.

311. *Id.* at 3.

312. The CWA, for example, sets forth as its goal "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a) (2012). Professor Robert Adler argues that "in the opening sentence of the federal Clean Water Act, Congress articulated one of the broadest ecosystem restoration and protection aspirations in all of environmental law." Robert W. Adler, *The Two Lost Books in the Water Quality Trilogy: The Elusive Objectives of Physical and Biological Integrity*, 33 ENVTL. L. 29, 30 (2003) (emphasis omitted).

313. 33 U.S.C. § 1313(c)(2)(A) (describing the touchstone for water quality standards: "[s]uch standards shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter").

are once again fishable and swimmable.[314] Exposure assessment as practiced in effect modifies this statutory instruction. In a world where fish are contaminated and depleted, exposure assessment's contemporary orientation substitutes "is" for "ought," and "constrained" for "healthful." As practiced, exposure assessment may render "health-based" a misnomer.

2. Heritage Practices

There is also evidence to suggest that the practices assumed as a basis for health-based standards often fall short—and wide—of the mark of heritage practices for indigenous peoples. For the fishing tribes in the Pacific Northwest, for example, fish of all sorts are relied upon today as in the past.[315] Fish are vital to tribal people for the nutrients they provide, to be sure, but fish consumption is imbued with social meaning. As noted above, every facet of managing, harvesting, distributing, consuming, and honoring the fish is woven into the fabric of tribal life. These practices and the knowledge they beget form a central part of the inheritance of each succeeding generation.[316] They are important for the health and well-being of the individual and the collective—with "health and well-being" understood to include not only physiological, but also cultural and spiritual dimensions.[317] For these tribes, a healthful level of fish intake would likely be an amount consonant with heritage practices—that is, the traditional lifeways engaged in by tribal people prior to contact with European settlers. Historical resource uses and practices thus provide the touchstone for heritage rates. However, heritage rates remain relevant for the future, not least because the tribes' right to take fish exists in perpetuity.[318] While estimates of heritage rates will vary from

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314. Under the CWA, water quality standards "express the desired condition or use of a particular waterway." Albuquerque v. Browner, 97 F.3d 415, 419 n.4 (10th Cir. 1996); *see* discussion *supra* note 213–16 and accompanying text (citing CWA's baseline "use" of "fishable/swimmable" waters nationwide).

315. *See, e.g.*, O'Neill, *supra* note 16, at 183–84 (gathering evidence of tribes' statements to this effect).

316. *See generally* Allison M. Dussias, *Spirit Food and Sovereignty: Pathways for Protecting Indigenous Peoples' Subsistence Rights*, 58 CLEV. ST. L. REV. 273, 333–41 (2010) (discussing fishing and other subsistence activities as "bridges" between tribal members and across generations and time).

317. *See, e.g.*, Donatuto et al., *supra* note 17, at 120.

318. *See* O'Neill, *supra* note 14, at 194–202; *accord* Donatuto & Harper, *supra* note 159, at 1500 (describing the relevance of heritage consumption practices for tribes' future health and well-being).

tribe to tribe,[319] the evidence makes clear that these rates will dwarf EPA's default FCRs based on contemporary consumption by the general population (22 grams/day) or even by higher-consuming groups (142.4 grams/day). Recent evidence of historical consumption among the fishing peoples in the Columbia River Basin, for example, documents rates ranging from 1,000 to 1,500 grams/day.[320]

Moreover, as noted by the National Tribal Toxics Council (NTTC), some tribal people in recent or current generations still harvest and consume fish at heritage levels and, importantly, more would do so if there were no restrictions on use due to depletion, contamination, or loss of access.[321] Recent surveys of Swinomish tribal members, for example, showed that they sought to reinvigorate more robust fish consumption practices and to increase their fish intake.[322] In fact, the NTTC noted, "many tribal health programs are recommending healthier (i.e., more traditional) diets that often include or are based on heritage resource consumption."[323] In a similar vein, the Umatilla tribe has looked to "original [fish] consumption rates along the Columbia River and its major tributaries" to set tribal environmental standards in part because this rate "reflects tribal fish restoration goals and healthy lifestyle goals."[324] The disconnect experienced by non-tribal public health and environmental agencies about having to warn people against consuming what would otherwise be a nutritious source of food may also take on additional dimensions for tribes. As Barbara Harper and Stuart Harris explain, "[r]eally there is just a single cultural community that is comprised of human and fish peoples and their rules for behaving and mutually surviving . . . .Writing a

319. *See generally* O'Neill, *supra* note 16, at 212–22.

320. *See, e.g.*, *Spokane Subsistence Exposure Scenario*, *supra* note 18 ("Historically, the Spokane Tribe consumed roughly 1,000 to 1,500 grams of salmon and other fish per day"); *see also Columbia Basin Consumption Rates*, *supra* note 18, at 240–41.

321. NAT'L TRIBAL TOXICS COUNCIL, UNDERSTANDING TRIBAL EXPOSURES TO TOXICS 11–13 (2015).

322. Jamie Donatuto, When Seafood Feeds the Spirit yet Poisons the Body: Developing Health Indicators for Risk Assessment in a Native American Fishing Community 85–89 (2008) (unpublished Ph.D. dissertation, University of British Columbia) (summarizing survey of Swinomish Indian Tribal Community members, finding multiple causes of suppressed consumption, and finding that 73% of respondents stated that they would like to eat more fish than they do now).

323. NAT'L TRIBAL TOXICS COUNCIL, *supra* note 321, at 12.

324. STUART G. HARRIS & BARBARA L. HARPER, CONFEDERATED TRIBES OF THE UMATILLA INDIAN RESERVATION, EXPOSURE SCENARIO FOR CTUIR TRADITIONAL SUBSISTENCE LIFEWAYS app. 44 (2004).

fish advisory to protect some community members from other members is very disquieting."[325]

To take another example, environmental standards for volatile organic compounds, such as trichloroethylene (TCE) in water are typically set on the assumption that humans drink 2 liters/day and are exposed when they bathe or shower for 17 minutes/day, in accordance with contemporary practices in the general population.[326] However, these exposure assumptions are not protective of tribal members of the Elem Band of Pomo Indians, whose lifeways include relatively greater hydration requirements as well as regularly participating in sweat lodges.[327] Rather, an appropriate exposure factor for drinking water intake for the Elem Band of Pomo would be four liters/day.[328] Moreover, as tribal researchers have explained, other facets of tribal members' exposure during preparation for and participation in sweat lodges are simply unaccounted for by agencies' conventional exposure assessments.[329]

Exposure assessment as practiced thus may undercut rights-based claims to healthful environmental conditions. Indian tribes, for example, can assert rights-based claims to the environmental conditions necessary to support particular lifeways or health and well-being more generally. Many tribes have legally protected rights to fish, hunt, and gather, secured by treaties and other means. For example, when the Indian peoples of the Pacific Northwest entered into treaties and agreements ceding lands to the United States, they nonetheless reserved a suite of important rights, including their aboriginal "right of taking fish at usual and accustomed grounds and stations."[330] These treaties have been interpreted by U.S. courts to encompass not only the right to harvest but also the subsidiary rights necessary to render the fishing right

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325. Barbara Harper & Stuart Harris, *Tribal Technical Issues in Risk Reduction Through Fish Advisories*, *in* PROCEEDINGS OF THE AMERICAN FISHERIES SOCIETY: CONTAMINANTS IN FISH 17, 17 (1999). Harper at this time worked for the Fourteen Confederated Tribes and Bands of the Yakama Nation and Harris is a tribal citizen of and worked for the Confederated Tribes of the Umatilla Indian Reservation. *Id.*

326. Cothern, et al., *supra* note 71, at 113 (stating that cancer risks for TCE are generally calculated assuming drinking water intake of 2 liters/day); OFFICE OF RESEARCH & DEV., *supra* note 91, at xx (listing the mean value for bathing/showering at 17 minutes/day (mean is only value given) for adults ages 18 to 64 years).

327. BARBARA L. HARPER ET AL., TRADITIONAL TRIBAL SUBSISTENCE EXPOSURE SCENARIO AND RISK ASSESSMENT GUIDANCE MANUAL 99–101 (2007).

328. *Id.*

329. *Id.*

330. *See, e.g.*, Treaty of Point Elliott, Dwamish-Suquamish-U.S., art. 5, Jan. 22, 1855, 12 Stat. 927 (providing that "[t]he right of taking fish at usual and accustomed grounds and stations is further secured to said Indians in common with all citizens of the Territory.").

of continued relevance for tribal people.[331] Among the facets of the treaty guarantees affirmed by the courts are the following points. The treaties secured to the tribes the right to take fish as a source of subsistence and means of earning a living in perpetuity.[332] The existence of physical or chemical impediments to tribal citizens' harvest or use does not diminish the right itself—"[t]he passage of time and the changed conditions affecting the water courses and the fishery resources in the case area have not eroded and cannot erode the right secured by the treaties."[333] The right to take fish is a reservation of tribes' pre-existing, aboriginal rights; as such, the right is "without any species limitation"[334] and its geographical scope cannot be qualified or limited by the United States and its successors.[335] Finally, neither

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331. For a more extensive discussion of these points, see O'Neill, *supra* note 16, at 193–202, 263–79. Most recently, U.S. courts have affirmed that tribes' treaty-protected "right of taking fish" imposes a duty on the State of Washington "to refrain from impeding fish runs" by improperly building or maintaining stream-blocking culverts, "thereby diminish[ing] fish runs that would otherwise be available for Tribal harvest." United States v. Washington (*Washington I*), No. CV 9213RSM, 2007 WL 2437166, at *10 (W.D. Wash. Aug. 22, 2007); *see also* United States v. Washington (*Washington II*), No. C70-9213, 2013 WL 1334391, at *1 (W.D. Wash. Mar. 29, 2013). In framing his holding, Judge Martinez emphasized the reliability, abundance, and practical function of the fish resource, citing the "significance" of "the right to *take* fish, not just the right to fish," to the tribes, the "[t]ribes' reliance on the unchanging nature of that right," and the assumption by all parties that the Indians' "cherished fisheries would remain robust forever" as a source of food and commerce. *Washington I*, 2007 WL 2437166, at *7–9 (citation omitted). The Ninth Circuit has affirmed. United States v. Washington (*Washington III*), 827 F.3d 836 (9th Cir. 2016). Note that on August 11, 2016, the State of Washington petitioned for a rehearing/rehearing *en banc*. As this article goes to press, the Ninth Circuit has not yet responded to Washington's petition.

332. United States v. Washington (Boldt Decision), 384 F. Supp. 312, 401 (W.D. Wash. 1974) ("The treaty clauses regarding off-reservation fishing . . . secured to the Indians' rights, privileges and immunities distinct from those of other citizens.").

333. *Id.*

334. United States v. Washington, 873 F. Supp. 1422, 1430 (W.D. Wash. 1994). (holding that the treaty fishing rights encompass all available species of fish found in the treating tribes' fishing areas, "[b]ecause the 'right of taking fish' must be read as a reservation of the Indians' pre-existing rights, and because the right to take *any* species, without limit, pre-existed the Stevens Treaties"); *see generally* United States v. Winans, 198 U.S. 371 (1905).

335. The treaty's fishing rights encompass the right to fish in all areas traditionally available to the tribes, and "[agencies] . . . do not have the ability to qualify or limit the Tribes' geographical treaty fishing right (or to allow this to occur . . .) by eliminating a portion of an Indian fishing ground," except as necessary to conserve a species. Muckleshoot Indian Tribe v. Hall, 698 F. Supp. 1504, 1514 (W.D. Wash. 1988) (enjoining construction of a marina in Elliott Bay that would have eliminated a portion of the tribes' usual and accustomed fishing areas); *see also* United States v. Oregon, 718 F.2d 299, 305 (9th Cir. 1983) (holding that "the court must accord primacy to the geographical aspect of the treaty rights").

party to the treaty "may permit the subject matter of these treaties [i.e., the fisheries] to be destroyed."[336]

Human rights instruments recognize basic rights, held by indigenous peoples or by others, to breathe clean air, drink potable water, and eat nourishing and healthful food. The United Nations Declaration on the Rights of Indigenous Peoples, for example, recognizes in Article 20(1) that "Indigenous peoples have the right . . . to be secure in the enjoyment of their own means of subsistence and development, and to engage freely in all their traditional and other economic activities."[337] The Seattle Human Rights Commission recently issued a resolution observing that "health is an internationally recognized human right" and urging the state of Washington, accordingly, to set water quality standards that would protect tribes and other higher-consuming populations' ability to rely on fish for subsistence.[338] And while the United States has eschewed formal recognition of a constitutional or civil right to a healthful environment, various legal theories might be invoked to support a claim that the basic human functions of breathing, drinking, and eating are enjoyed as a matter of right.[339] Exposure assessment, as currently practiced, makes no account for any rights-based benchmark. By looking only to contemporary data, exposure assessment may reflect practices that have fallen below this benchmark—and so enshrine the loss,[340]

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336. United States v. Washington, 520 F.2d 676, 685 (9th Cir. 1975).

337. G.A. Res. 61/295, United Nations Declaration on the Rights of Indigenous Peoples (Sept. 13, 2007).

338. RESOLUTION 14-01: CALLING ON WASHINGTON STATE DEPARTMENT OF ECOLOGY TO RAISE THE STATEWIDE FISH CONSUMPTION RATE, SEATTLE HUMAN RIGHTS COMM'N 1–2 (2014), http://www.seattle.gov/Documents/Departments/SeattleHumanRightsCommission/reports_Resolution_14-01_FishConsumptionRate.pdf (citing numerous human rights instruments).

339. An exploration of such a claim is beyond the scope of this article. Note, however, that the NAAQS, for example, have been characterized as embodying a "rights-based" approach, insofar as they must ensure sensitive populations' ability to breathe and function in ordinary ways, unimpaired by air pollution. *See generally* POWELL, *supra* note 72.

340. *See* IDAHO DEP'T OF ENVTL. QUALITY, IDAHO FISH CONSUMPTION RATE AND HUMAN HEALTH WATER QUALITY CRITERIA—DISCUSSION PAPER #7: RISK MANAGEMENT AND PROTECTION OF HUMAN HEALTH 7 (2014), http://www.deq.idaho.gov/media/1118404/58-0102-1201-discussion-paper7.pdf [hereinafter IDEQ, RISK DISCUSSION PAPER]; IDAHO DEP'T OF ENVTL. QUALITY, PROPOSED WATER QUALITY STANDARDS (2015) (acknowledging the "cultural issues" for tribes when fish are depleted and contaminated but declining to account for suppression in its exposure assessment, instead pointing tribal people to other available options for putting food on the table).

dislocation,[341] and compromised health[342] of the present in environmental standards that govern the future.

In sum, exposure assessment as practiced may undermine the promises of our environmental and other laws and commitments because exposure assessment at bottom is not designed to bring about the environmental conditions necessary to permit healthful practices or heritage lifeways.

B. Exposure Assessment Subsumes People's Protective Actions into a New Baseline

Exposure assessment as practiced effectively subsumes into its depiction of human practices any "averting" or "compensatory" behaviors people have adopted in response to their degraded environment. By enlisting a snapshot of contemporary practices without considering whether these practices have been altered or constrained in the face of contamination and depletion, exposure assessment simply folds people's attempts to protect themselves into the "new normal." But it is not self-evident that people's avoidance efforts ought to be incorporated—without remark or regret—into exposure assessments used to set regulatory standards. If agency risk assessors present as neutral a description of "actual," contemporary human exposure, a normative call gets made in the guise of a technocratic one.

As it has become clear that reducing risk at the source is often difficult or expensive, agencies have increasingly relied on risk avoidance—measures that ask those exposed to alter their ways so that they don't come in contact with contaminants permitted to remain in the environment.[343] Fish consumption advisories have expanded in number and scope and now blanket the nation's waters; air quality alerts are widely publicized via a variety of media. And smart devices and applications now enable people to obtain real-

341. *See, e.g.*, Boeing Corp., Comment Letter on Wash. Dep't of Ecology's Fish Consumption Rate Technical Support Document 13-15 (Oct. 26, 2012) (urging Ecology to provide more "population data" indicating not only the total number of American Indians and Alaska Natives in Washington, but also "the number who live on or near reservations" versus farther from home, and suggesting that it is not appropriate to assume that those in the latter category consume fish at rates documented by the tribal surveys because "[i]t seems likely that American Indians and Alaskan natives who live away from reservations may eat a larger proportion of fish that is not locally raised or harvested, particularly if they live in urban areas").

342. While, to my knowledge, no commentator has publicly suggested using a lower figure for the exposure duration parameter based on an argument that the particular groups exposed have a shorter average lifespan, there is nothing in the method of an exposure assessment founded on actual contemporary data that would prevent such a tack.

343. *See* O'Neill, *supra* note 6.

time readings on the quality of their immediate environs.[344] With this information in hand, at least some people undertake protective or compensatory behaviors in the face of environmental degradation. Whether in response to their own perception of depletion and contamination or in response to risk avoidance measures such as fish consumption advisories and ozone alerts, there is evidence that some people alter their practices as a result of environmental degradation. Some people undertake defensive measures in response to "ozone alerts" or in reaction to "smoggy" conditions or other indications of elevated ozone, particulate matter, or other air pollutants. Studies have shown, for example, that some people reduce their time out of doors,[345] or curtail their activities when they do go outdoors.[346] Some people also keep their children, particularly those with asthma,[347] inside when air quality is poor. Similarly, some people limit their intake of certain species of fish in an effort to protect themselves from perceived contamination or in "compliance" with fish consumption advisories.[348] And some people have had to reduce their fish intake where fewer fish are available for harvest, given depleted stocks due to poor environmental conditions.[349]

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344. *See, e.g.*, Maria Gallucci, *Wearable Technology Takes on Air Pollution and Smog with Personal Air-Quality Monitors*, INT'L BUS. TIMES (July 21, 2015, 2:28 PM), http://www.ibtimes.com/wearable-technology-takes-air-pollution-smog-personal-air-quality-monitors-2018324.

345. *See* Bresnahan et al., *supra* note 19, (finding that "persons who experience smog-related symptoms spend significantly less time [about 40 minutes per day] outdoors as ozone levels exceed the national standard;" but whereas the majority of respondents who are susceptible to acute symptoms undertake this averting behavior, fewer of those whose adverse health effects were chronic kept themselves indoors); Neidell & Kinney, *supra* note 19, at 97 (finding that individuals take substantial avoidance actions in the face of ozone alerts); Moretti & Neidell, *supra* note 19 (noting avoidance behavior undertaken in response to personal observation and air quality alerts on high ozone days).

346. *See* Wen et al., *supra* note 20 (finding an association between elevated PM2.5 levels and greater "leisure-time physical inactivity," and positing that people were less active due to either a direct influence, insofar as individuals' ability to be physically active was compromised by elevated levels of PM2.5, or an indirect influence, insofar as individuals reduced their activities in response to media alerts warning of poor air quality episodes). *But cf.* Bäck et al., *supra* note 20 (finding that adults generally didn't alter their outdoor leisure time or activities as ozone pollution levels rise, presumably given the correlation between increased ozone and improved weather suitable for outdoor activities (i.e., warmer temperatures, lack of precipitation)).

347. *See, e.g.*, Mansfield, et al., *supra* note 21, at 222; *accord* Wen et al., *supra* note 21, at 43 (reporting similar findings for adults with asthma).

348. *See, e.g.*, Oken et al., *supra* note 9, at 346.

349. *See, e.g.*, Letter from Babtist Paul Lumley, Exec. Director, Columbia River Inter-Tribal Fish Comm'n, to Ted Sturdevant, Director, Wash. State Dep't of Ecology 3 (Mar. 19, 2012) (pointing to "the fact that more than 61% of the survey respondents reported that their fish consumption was suppressed by poor fish harvests during the early 1990's" and observing that

But risk avoidance is a controversial and imperfect substitute for risk reduction as a matter of environmental policy, for a number of reasons.[350] Risk avoidance approaches, recall, rely upon the people exposed to alter their practices in order to reduce or eliminate contact with contaminants permitted to be present in the environment. In theory, they break a crucial link in the causal chain between source and adverse health impact—to paraphrase Paul Lioy, without exposure, one receives no dose to make a poison. However, risk avoidance fails to deliver on its promise of "the same amount" of protection as risk reduction. In practice, risk avoidance turns out to be both underinclusive and overinclusive.[351] Risk avoidance is seldom perfectly undertaken: fish consumption advisories may not reach their "target" audience; ozone alerts may advise remaining indoors at times impossible for those whose jobs are out of doors; deed restrictions may include prohibitions on soil disturbances or other activities that are misunderstood.[352] Some people can and do "comply" with risk avoidance warnings; some people cannot or will not.[353] Additionally, risk avoidance measures have been shown to have "spillover" effects. That is, in some cases, averting or compensatory behaviors will be undertaken not only by those most susceptible to a particular contaminant, but also by a broader swath of the population. For example, fish consumption advisories for methylmercury are aimed at children and women of childbearing age, given methylmercury's impact on neurodevelopment; however, studies have found that men and older women have reduced their fish intake in response to these advisories as well.[354]

Chinook salmon availability during the time of the survey was between 80% and 94% lower than in 2002).

350. *See*, *e.g.*, O'Neill, *supra* note 6, at 306–26 (arguing that the perils of relying on risk avoidance as a quasi-regulatory strategy are several and serious); O'Neill, *Risk Avoidance*, *supra* note 8, at 25–40 (discussing risk avoidance measures' particular harms for Native peoples). *But cf.* Cass R. Sunstein, *The Laws of Fear*, 115 HARV. L. REV. 1119, 1154 (2002) (book review) (suggesting that people can avoid pesticides by selecting pesticide-free food, and avoid air pollution by moving to places with cleaner air).

351. *See* O'Neill, *supra* note 6, at 312.

352. *See id.* at 312–16 (recounting evidence to this effect).

353. *See also Fish Taken from Delta Have Most Mercury in California*, MERCURY NEWS (June 3, 2013, 2:23 AM), http://www.mercurynews.com/2013/06/03/fish-taken-from-delta-have-most-mercury-in-california (reporting that, despite signs warning of contamination from mercury, PCBs, dieldrin and DDT, many people still catch and consume fish for both cultural and economic reasons, and quoting University of California Davis researcher Fraser Shilling, who observed "[o]nce you buy your license, the fish becomes a free source of food. And in the lower elevations—closer to the urban areas—immigrants and ethnic minorities tend to be the main people catching fish").

354. Hoover, *supra* note 9 (finding that men were among those in Akwesasne community that limited their intake, despite the fact that the advisories were aimed at women); Shimshack et

Similarly, family members and others beyond the target populations for ozone or particulate matter alerts have curtailed their own activities out of doors in response to information of poor air quality.[355]

Moreover, there is evidence that those who have altered their lifeways or undertaken defensive behavioral adjustments in response to degradation have in many cases done so under duress or with great regret. The loss that is experienced, however, may not register with or be understood by agency decision makers. For example, in discussing the implications of issuing less protective water quality standards, such that tribal members and others who rely on fish would either be placed at greater risk or left to reduce their fish intake, the Idaho Department of Environmental Quality (IDEQ) opined that "given the availability of other healthy food choices, consuming large amounts of fish must be considered a voluntary risk."[356] Whereas "we do not have a choice about breathing air and drinking water," IDEQ maintained, "[i]f a risk is voluntary, the question of individual responsibility arises. . . . [I]ndividual responsibility still plays a role in managing risk associated with fish consumption."[357] The Upper Snake River Tribes responded in the strongest of terms, observing that IDEQ's position was "culturally insensitive and exhibits a startlingly deficient understanding of the relationship between tribal members and fish."[358]

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al., *supra* note 9 (finding that, among "educated" families with young or nursing children, purchase of canned fish decreased by 50% in response to consumption advisories due to mercury, presumably leading to reduced fish intake by family members who were themselves not the target of advisories).

355. *See, e.g.*, Wen et al., *supra* note 20, at 43 (finding that although EPA Air Quality Index guidelines are aimed at sensitive members of the population, many in the general population curtail their activity levels too); Bäck et al., *supra* note 20 (finding absence of avoidance behavior among adults generally, with the exception that, once ozone pollution reaches "very unhealthy" levels, adults who care for those in sensitive groups, i.e., children or older parents "significantly reduce the amount of time they spend outdoors" with family members in these groups, i.e., by 8–10%).

356. IDEQ, RISK DISCUSSION PAPER, *supra* note 340.

357. *Id.* at 7–8. For a response to this position, see Catherine A. O'Neill, Comments to Idaho Dep't of Envtl. Quality: Risk, Human Health, and Water Quality Standards (Jan. 20, 2015) (on file with author).

358. The Upper Snake River Tribes Foundation, Comments to The Idaho Dep't of Envtl. Quality, at 3 (Jan. 20, 2015) (on file with author) (noting that IDEQ persisted in its position, despite presentations by members of the Nez Perce and Shoshone-Bannock tribes and comments by other tribal members who have "repeatedly and resoundingly described the importance of fish to their people, not only for sustenance, but for their cultural identity and well-being").

In fact, there is disagreement among commentators about how to consider people's averting or defensive behaviors.[359] Whether viewed as part of the baseline or as introduced bias may be in the eye of the beholder. Some commentators have simply assumed that any avoidance undertaken by those exposed would be incorporated into an "accurate" depiction of exposure. Former OIRA Director John Graham, for example, called for assessments using "actual" rather than "hypothetical" descriptions of exposure and questioned "how many citizens (if any) are actually exposed to the amount of risk" suggested by the assumption that "for 70 years a sport fisherman is assumed to eat 6.5 grams per day of contaminated fish caught from specific freshwater river sites near an industrial source of water pollution when fish advisories are in place at these river sites."[360] The implication is that, on Graham's view, exposure assessment would be improved if it incorporated the avoidance behaviors he presumes in response to these advisories, which would mean that people's actual fish intake is less than 6.5 grams per day. In a similar vein, other commentators have called for using measurements of people's "actual behavior," including any behavioral "adjustments" undertaken in the face of air pollution, to assess exposure and inform policy. Having found that the majority of those people susceptible to acute symptoms changed their behavior by staying indoors during "smoggy conditions," Brian Bresnahan, et al. argue that estimates of health effects that "ignore averting behavior may be seriously biased" and so overestimate the gains from policies that would reduce risk.[361] Rather, they argue, humans' "behavioral adjustments" should be incorporated into regulatory assessments and, additionally, might be encouraged as a matter of "socially efficient externality policy" for addressing human health risks.[362]

On the other hand, some commentators have criticized agencies' failure to account for avoidance behaviors (such as staying indoors) in technical assessments of the health impacts of air pollution. Having found that people take substantial avoidance actions in response to personal observation and air quality alerts, Matthew Neidell and various colleagues argue that estimates of ozone's adverse health effects that don't account for these actions will be

359. Note that the debate to date has largely taken place in the economics literature, such that the positions espoused pro and con apply most directly to efforts to assess regulatory impacts—i.e., costs and benefits of regulation—rather than assessments of exposure. However, these commentators sometimes venture recommendations that pertain more specifically to risk assessment and risk management.

360. Graham, *supra* note 67, at 40–41.

361. Bresnahan et al., *supra* note 19, at 340, 355–56.

362. *Id.* at 340.

significantly biased downward, and the costs to society of ozone pollution understated.[363] Similarly, Xiao-Jun Wen et al. have observed that the adverse health effects of PM2.5 should be viewed as including not only any increased incidence of respiratory and cardiovascular diseases, but also the increased "leisure time physical inactivity" induced by PM2.5 pollution and the attendant air quality alerts.[364]

These differing views of averting behaviors seem to be present among environmental agencies as well. EPA scientists working to develop the early NAAQS recount that "evidence of averting behavior was cited by those advocating that assumptions about people's exposures be reduced," such that less stringent standards could be assumed to be adequately protective.[365] More recently, EPA's 2014 exposure assessment for the O3 NAAQS declines to make the call as between baseline or bias; rather, it handles averting behaviors by varying the relevant assumptions to ask what the impact would be if it were to decide one way or the other. Thus, it estimates that 30.3% of asthmatic school-age children take averting actions, reducing their time outdoors by 44 minutes, and calculates the impact this would have on its assessments of the portion of the population exposed to ozone above healthy levels.[366] On the other hand, sometimes agencies appear to be folding people's averting behaviors into their baseline without comment. For example, West Virginia recently justified its decision to set its water quality standards for mercury at levels less stringent than the national default recommended by EPA on the basis of a 2008 fish consumption survey showing that people in West Virginia ate less fish than the "average American."[367] This survey was conducted, notably, after fish consumption advisories warning of mercury contamination had been in place for several years on West Virginia waters.[368] Neither the state nor the EPA, in approving the state's standards, considered

363. Neidell & Kinney, *supra* note 19, at 97 (finding that individuals take substantial avoidance actions in the face of ozone alerts and arguing that "estimates of the [health effect of ambient ozone] that ignore these actions are biased [downward] and may significantly understate the costs to society from ozone concentrations"); Moretti & Neidell, *supra* note 19, at 16 (calculating impact of avoidance behavior undertaken in response to personal observation and air quality alerts on high ozone days and arguing that a failure to account for individuals' compensatory actions "significantly understates the effect of ozone on health").

364. Wen et al., *supra* note 20.

365. Telephone Interview with Tom McCurdy, *supra* note 272 (noting that these advocates came from both inside and outside the agency).

366. EPA, *supra* note 304, at 5-53 to 5-54.

367. Catherine A. O'Neill, *Fish Tales from West Virginia*, CTR. FOR PROGRESSIVE REFORM BLOG (May 26, 2009), http://www.progressivereform.org/printBlog.cfm?idBlog=666E5F8E-1E0B-E803-CA8FB8D956561BA5.

368. *Id.*

the influence of people's averting behaviors on West Virginians' contemporary fish intake rates. These agencies simply took people's present practices as a given, and set the less protective standards accordingly.

Baseline or bias? To the extent that people's defensive behaviors are subsumed into a snapshot of contemporary exposure, agencies make the call in favor of the former. But exposure assessment conducted in this manner effectively replaces statutory approaches premised on risk reduction with an approach that relies on risk avoidance. In so doing, agencies arguably modify these statutes' health-based instructions without acknowledging that they are doing so.[369] Moreover, given the highly technical nature of quantitative risk assessment, the modification is perhaps unlikely to be discerned by the non-expert public—a point that raises transparency and legitimacy concerns.

C. Exposure Assessment Provides a Lever for Delaying Environmental Protection

Exposure assessment, if framed to train its inquiry on contemporary practices, sets up a moving target because there will always be an argument that newer data constitute the best available science. Given the numerous inputs into any assessment of exposure, there are numerous potential sites for contest. With each component of these inputs subject to constant revision, the occasions for delay, in the service of "sound science," are many. While these contests could in theory go either way, favoring inputs that result in more or less protective standards, in practice, they have served the interests of regulated industry. Industry is able to make use of the opportunities afforded to call for—and supply—ever more recent and more finely grained snapshots of people's "actual" practices. Even if agencies' updated assessments turn out to support standards that are somewhat more protective of human health, industry will have bought itself time—often years of time—during which the older, less protective standards remain in effect. Exposure assessment as practiced turns out to provide a powerful lever for delay.

The ongoing saga of Washington's efforts to revise its water quality standards illustrates how exposure assessment can be used to add years to the process. Washington had conceded the need to update its FCR in the mid-1990s—shortly after the CRITFC and Squaxin Island/Tulalip surveys

369. Livermore & Revesz, *supra* note 23, at 1233 (highlighting the negative consequences of agency decision making that includes "the unacknowledged consideration" of a factor such as cost). *See generally* Glen Staszewski, *Reason-Giving and Accountability*, 93 MINN. L. REV. 1253, 1279–84 (2009) (providing a summary of arguments in favor of reason-giving).

became available and underscored the gulf between Washington's assumptions about fish intake and tribal peoples' fish consumption practices.[370] Washington's Department of Ecology issued a draft technical support document in 1999 in light of these and other local data, anticipated for use in revising its sediment cleanup standards and WQS.[371] Although the Clean Water Act intends frequent updates to states' WQS, requiring states to evaluate whether revisions are necessary every three years, Washington did not formally embark upon its effort to revise its WQS until its triennial review of 2010.[372] Throughout the ensuing rulemaking processes, industry made use of the opportunities afforded by exposure assessment to contest inputs and, ultimately, delay issuance of the standards.

Regarding a key input to these exposure assessments, the FCR, EPA guidance puts a premium on quantified, local data of people's fish consumption practices, and directs that higher-consuming populations be considered and protected.[373] By the time Washington embarked on its rulemaking process in earnest, it possessed a library of local fish consumption surveys, all of which had recently been reviewed by an independent technical advisory body as part of a neighboring state's (Oregon's) WQS revisions.[374] Nonetheless, Washington undertook its own extensive technical review, after which it, too, found the surveys to be scientifically defensible, and as a result of which it recommended a default FCR in the range of 157 to 267 grams/day.[375] Industry invoked the need for "sound science" both to dispute Ecology's assumptions and to prolong the rulemaking process.[376] First, industry questioned the validity of existing studies and used this as a basis to request additional rounds of pubic process to debate the FCR.[377] Second, industry called for more studies, urging that rulemaking be halted until a

370. LESLIE KEILL & LON KISSINGER, ANALYSIS AND SELECTION OF FISH CONSUMPTION RATES FOR WASHINGTON STATE RISK ASSESSMENTS AND RISK-BASED STANDARDS, at i–ii (drft. 1999), https://fortress.wa.gov/ecy/publications/documents/99200.pdf.

371. *Id.* This document was never issued in final form.

372. *Triennial Review Process for Surface Water Quality Standards*, WASH. DEP'T ECOLOGY, http://www.ecy.wa.gov/programs/wq/swqs/triennial_review.html (last updated Aug. 2011).

373. EPA, *supra* note 11, at 1-12 to 1-13.

374. *Id.*

375. WASH. DEP'T OF ECOLOGY, FISH CONSUMPTION RATES TECHNICAL SUPPORT DOCUMENT 7 (2011), https://fortress.wa.gov/ecy/publications/summarypages/1109050.html; *see* O'Neill, *supra* note 16, at 240–45.

376. Boeing Corp., Comment Letter on Wash. Dep't of Ecology's Fish Consumption Rate Technical Support Document 3 (Oct. 26, 2012) (calling for the use of "sound science" in determining a FCR and setting standards).

377. *See* O'Neill, *supra* note 16, at 242–49.

statewide fish consumption survey could be undertaken.[378] Failing this,[379] they sought an analysis and ultimately reanalysis of existing national fish intake data.[380] Industry successfully bulked up the process, adding multiple (largely redundant) technical reviews of the fish consumption surveys—and thus years—to Washington's rulemaking timelines.[381] Nonetheless, and without a hint of irony, one industry commentator buttressed its call for further study with the argument that the CRITFC survey data were now outdated.[382]

Industry also took the opportunity to challenge other aspects of the exposure assessment, questioning inputs that would support more protective standards—portraying their call to be one for enlisting better, newer "actual" data. For example, an industry association took issue with the exposure duration parameter, arguing that the standard assumption that an individual is exposed to contaminants throughout a 70-year lifetime is unrealistic, given people's actual practices.[383] Rather, it argued, "individuals are likely to move many times during their lifetimes and, as a result of those moves, may change their fishing locations and the sources of the fish they consume."[384] Citing the median general population residence time of eight years, it observed "the

378. *See id.* at 232–41.

379. Ecology declined to launch a new study, citing the commonsense point that a survey of the general population was not likely to produce useful data, given the need for WQS to protect the higher consumers affected by Washington's standards—whose fish intake rates were amply documented. TVW House Env't Comm., *Ted Sturdevant, Testimony Before the Washington House Environment Committee, Work Session: Update on Fish Consumption Rates and Water Quality Standards*, TVW (Nov. 30, 2012), http://tvw.org/index.php?option=com_tvwplayer&eventID=2012111039.

380. Ecology capitulated to these requests, adding an analysis of national data to its second Technical Support Document and commissioning an independent reanalysis of national and state data. Nw. Indian Fisheries Comm'n, Comment Letter on State's Proposed Rule for Human Health Criteria and Implementation Tools in WA State Water Quality Standards, at 35 (Mar. 23, 2015), http://www.ecy.wa.gov/programs/wq/ruledev/wac173201A/comments/0056c.pdf.

381. *See, e.g.*, Robert McClure, *Business Interests Trump Health Concerns in Fish Consumption Fight*, INVESTIGATE WEST (Mar. 30, 2013), http://invw.org/2013/03/30/politics-trumps-health-in-1344 (documenting, through e-mails obtained under the Washington Public Records Law, industry's "intense lobbying campaign" to delay and dilute Washington's standards).

382. J.R. Simplot Co., Comment Letter on Washington's Fish Consumption Rates Technical Support Document (Version 2.0), at 6 (Oct. 26, 2012) (stating that the CRITFC "survey was conducted in 1991/1992 and as such, may not reflect current conditions").

383. NAT'L COUNCIL FOR AIR AND STREAM IMPROVEMENT, INC., A REVIEW OF METHODS FOR DERIVING HUMAN HEALTH-BASED WATER QUALITY CRITERIA WITH CONSIDERATION OF PROTECTIVENESS 3–4 (2012) [hereinafter NCASI, REVIEW].

384. *Id.* at 23.

assumption that a person lives in the same place and is exposed to the same level of contamination for a 70 year lifetime results in criteria that are up to 8 times more stringent than if a median exposure period were assumed."[385] In a similar vein, an industry consultant suggested to Ecology that the bodyweight parameter be increased, arguing that tribal and other newer data supported replacing the current assumption of 70 kg with an 80 kg figure.[386] This change, it was pointed out, would result in water quality standards that were 10–15% more lenient.[387] Additionally, intoning the specter of "compounded conservatism," industry questioned the use of a deterministic method at all, calling instead for probabilistic techniques.[388] One industry association even supplied a probabilistic analysis—this 66-page prêt-à-porter analysis, notably, generated an exposure assessment that would yield more lenient standards.[389]

Perhaps unsurprisingly, industry was selective in its pursuit of better, newer exposure data. While it argued for an updated value for the bodyweight parameter, it did not advocate for updating other parameters such as lifespan or surface water intake. This is so despite the fact that EPA had revised the recommended default values for both of these parameters, as it had for bodyweight, in the most recent version of its Exposure Factors Handbook and

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385. *Id.* at 3. NCASI's comparison is to a median residence time of 8 years for the general U.S. population. *Id.* at 24–25.

386. Catherine A. O'Neill, *Washington State's Weakened Water Quality Standards Will Keep Fish Off the Table, Undermine Tribal Health*, CTR. FOR PROGRESSIVE REFORM BLOG (March 4, 2014), http://www.progressivereform.org/CPRBlog.cfm?idBlog=8D9DD724-B323-B46A-857B382825C93F62 (documenting an e-mail from a consultant for the Association of Washington Business to the Washington State Department of Ecology water quality staff suggesting this change and recounting the Washington State Department of Ecology e-mail attributing its decision to move to 80 kg figure to this suggestion).

387. *See id.*

388. Boeing Corp., Comment Letter on Wash. Dep't of Ecology's Fish Consumption Rate Technical Support Document 16–17 (Oct. 26, 2012) (decrying the "compounding levels of conservatism inherent in the deterministic approach" and arguing that probabilistic techniques result in more realistic estimates of risk); *see also* NCASI, REVIEW, *supra* note 383, at 1, 27 (stating that "[i]t is well-known, and mathematically intuitive, that the practice of selecting 'upper end of range' values for multiple parameters in a risk equation will lead to over-conservative estimates of risk or, in the case of [human health ambient water quality criteria], overly restrictive criteria" and arguing that the impact of such "compounded conservatism" is a "highly unlikely and highly protective scenario").

389. Letter from Christian M. McCabe, Exec. Director, Nw. Pulp & Paper Ass'n, to Kelly Susewind, Special Assistant for Water Quality, Wash. Dep't of Ecology at 25, 1 (Feb. 4, 2014) (transmitting attached 66-page document, prepared by Arcadis consulting, that presents the results of a probabilistic analysis that it recommends for use in Washington, arguing that it is "based on the best available science").

other guidance.[390] The 2011 Exposure Factors Handbook updates the average life expectancy nationwide from 70 to 78 years, based on the most recent data.[391] And, local data published by the Washington Department of Health in 2013 document life expectancy for Washingtonians at 80.3 years, with recent trends "show[ing] that Washingtonians are living longer" than in previous times.[392] Similarly, more recent general population data for surface water intake would support increasing this parameter from 2 liters/day to as high as 3 liters/day.[393]

Each of the industry arguments canvassed above—whether for new studies, or alternative inputs, or probabilistic methods—would have supported less protective standards, were they to carry the day. Each was disputed, with evidence to the contrary offered in support, by those seeking more protective standards. For example, tribes and others urged Washington to assume no less than a 70-year exposure duration, given that tribal people in fact live in the same place, and harvest fish from the same locations for their entire lives—indeed, many have treaty-secured rights to do so, and these legal protections are tied to particular places.[394] Yet, industry is generally better positioned to make use of the opportunities afforded by exposure assessment—bringing to bear its financial resources and the knowledge it has gained as a repeat player in environmental rulemaking processes.[395] Even so,

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390. *See* OFFICE OF RESEARCH & DEV., *supra* note 91, at 18-1.

391. *Id.*

392. WASH. DEP'T OF HEALTH, MORTALITY AND LIFE EXPECTANCY 1, 5 (2013), http://www.doh.wa.gov/Portals/1/Documents/5500/GHS-MLE2013.pdf (reporting the 80.3 years figure and adding that "[t]rends in life expectancy show that Washingtonians are living longer: the average life expectancy for those born in 2011 is 80 years, about five years longer than for those born in 1980").

393. OFFICE OF RESEARCH & DEV., *supra* note 91, at xi (drinking water intake for consumers only, mean value = 1.227 liters/day whereas 95th percentile value is 3.092 liters/day, both for adults >21 years of age). EPA's recent proposed national recommendation for water quality criteria, published in draft in May, 2014, embraced a 3 liters/day figure; however, EPA revised this figure downward to 2.4 liters/day in the final criteria in response to public comments. EPA, EPA RESPONSE TO SCIENTIFIC VIEWS FROM THE PUBLIC ON DRAFT UPDATED NATIONAL RECOMMENDED WATER QUALITY CRITERIA FOR THE PROTECTION OF HUMAN HEALTH 11–14 (2015).

394. *See, e.g.*, Catherine A. O'Neill, Comments to Washington Department of Ecology: Proposed Revisions to Water Quality Standards for the State of Washington, Chapter 173-201A WAC 1–10, 34 (Mar. 23, 2015), http://www.ecy.wa.gov/programs/wq/ruledev/wac173201A/comments/0036b.pdf.

395. *See, e.g.*, Boeing Corp., Comment Letter on Wash. Dep't of Ecology's Fish Consumption Rate Technical Support Document 16–17 (Oct. 26, 2012) (commending Florida's probabilistic approach, based on Boeing's experience in the WQS rulemaking process there).

in Washington, industry sometimes won and sometimes lost these contests.[396] For example, Ecology was persuaded to use the 80 kg value in its proposed standards, citing the availability of "new science and local data."[397] And Ecology retained its exposure duration assumption (at 70 years), despite the more protective value supported by new science and local data.[398] On the other hand, Ecology proposed to increase the FCR to 175 grams/day (although this apparent increase does not apply to the four contaminants—methylmercury, PCBs, dioxins, and arsenic—that are arguably of greatest concern).[399] Nonetheless, even where updated exposure data turn out to support standards that are somewhat more protective of human health, industry will have bought itself time during which the older, less protective standards remain in effect.[400] So, from industry's perspective, there is value

396. The "scorecard" must now be traced through two formal rule proposals. Ecology officially proposed updated water quality standards in early 2015, only to withdraw them at the direction of the Governor later that year. Press Release, Office of the Governor of the State of Wash., Inslee Directs Ecology to Evaluate Options on Pending Clean Water Rules (July 31, 2015) (announcing that Governor Jay Inslee has directed the Department of Ecology to "reconsider its draft clean water rules," which had been scheduled to be finalized on Aug. 3, 2015). Ecology then proposed a second set of updated standards in early 2016; these were adopted on August 1, 2016. *Rulemaking: Water Quality Standards for Protecting Human Health*, WASH. DEP'T OF ECOLOGY, http://www.ecy.wa.gov/programs/wq/ruledev/wac173201A/1203docs.html (last visited Nov. 13, 2016); *see* discussion *supra* note 150.

397. WASH. DEP'T OF ECOLOGY, WASHINGTON STATE WATER QUALITY STANDARDS: HUMAN HEALTH CRITERIA AND IMPLEMENTATION TOOLS: OVERVIEW OF KEY DECISIONS IN RULE AMENDMENT 27 (2016), https://fortress.wa.gov/ecy/publications/documents/1610006.pdf. Ecology cites EPA's 2011 Exposure Factors Handbook, which provides an updated average adult bodyweight of 80 kg (176 pounds) in place of the bodyweight of 70 kg (154 pounds) previously used by Ecology. Ecology also suggests that its decision to adopt an updated bodyweight "closely aligns" with the average adult bodyweights documented in studies of the Tulalip and Suquamish tribes. *Id.* However, this post hoc rationalization rings somewhat hollow in light of Ecology's admission that the "update" was made at the behest of industry. *See* discussion *supra* note 386.

398. *See* WASH. DEP'T OF ECOLOGY, *supra* note 397, at 44–46.

399. These contaminants are of utmost concern given their toxicity and the fact that they are collectively responsible for nearly all of the fish consumption advisories for Washington waters; however, Ecology treats these contaminants separately, employing various devices that effectively leave people to consume fish at the current 6.5 grams/day rate—or worse. *See id.* at 17–20; 29–32; 51–66. *See generally* Catherine A. O'Neill, Comments to Washington Department of Ecology, Proposed Revisions to Water Quality Standards for the State of Washington: Chapter 173-201A WAC (April 22, 2016) http://data.wa.gov/views/7rpc-etc2/files/e1f4d18c-44cd-435c-8877-ca77d0e9f9b4; Catherine A. O'Neill, *Cleaner Waters for Washington at Long Last?*, CTR. FOR PROGRESSIVE REFORM BLOG (Aug. 8, 2016), http://www.progressivereform.org/cprblog.cfm?fkScholar=38. On November 15, 2016, EPA rejected Ecology's less protective approach to these contaminants and, importantly, issued federal water quality standards for Washington governing PCBs and methylmercury. *See* discussion *supra* note 150.

400. *See generally* CATHERINE A. O'NEILL ET AL., THE HUMAN AND ENVIRONMENTAL COSTS OF REGULATORY DELAY (2009), http://www.progressivereform.org/articles/costofdelay_907.pdf.

in having contested the exposure parameters at all: at the very least, it requires time to address each claim. In Washington, the clock is still ticking as of late 2016.

Because any assessment of human exposure is complex and comprises numerous variables, exposure assessments in the regulatory context will likely always provide occasion for disputes and, so, some amount of delay. However, exposure assessment as practiced sets up a moving target. By training its inquiry on contemporary practices, there will always be an argument that newer data constitute the best available science. As a result, agency risk assessors are put on a treadmill, constantly seeking to update the snapshot to reflect what is now contemporary human behavior.

To summarize this Part, there are significant concerns with exposure assessment as currently practiced. Whatever the hope of exposure assessors in the early days at EPA, the method that has evolved is ill-suited for the purpose of actually bringing about improved environmental conditions. It often serves to undermine, rather than support, practices that are basic to human health and flourishing and, in some cases, to which people are entitled as a matter of right. If, as suggested in Part II, EPA's embrace of a contemporary orientation for exposure assessment was somewhat happenstance—an artifact of the data available in the early days of standard setting—it may be that the implications were never considered. Experience in the intervening years, however, has provided reason to question this orientation. We have evidence that people's current behaviors often do not reflect practices consonant with human health or, for the tribes, heritage practices—that current intake and use may be biased downward by suppression, as discussed in Part I. We know that people have taken averting or compensatory actions in the face of environmental degradation; yet when exposure assessments are based on a snapshot of contemporary consumption, people's "adjustments" to their practices and lifeways simply get folded into the new baseline. We have also seen that exposure assessment as practiced increases opportunities to swell the standard-setting process and, ultimately, delay the issuance of more protective environmental standards.

At the very least, the serious deficiencies catalogued in this Part should invert the burden of proof. That is, a focus on people's circumstances in the recent past is not self-evidently appropriate for determining their opportunities for the future. It is also not purely a matter of doing "science" insulated from judgments of "policy." Rather, such an orientation requires an argument that addresses the normative implications of this choice—one that accounts for the serious shortcomings raised here.

But might we, instead, ask a better question? The next Part takes up this challenge, with a view toward the purpose for which exposure assessment is conducted in setting health-based standards.

IV. EXPOSURE ASSESSMENT FOR A PURPOSE

Exposure assessments should reflect the purpose for which they are conducted. Given the forward-looking environmental regulatory context, it makes no sense to home in on the practices of the recent past, particularly where these practices have likely been constrained by degradation. Rather, exposure assessments should depict behaviors that are healthful and resource uses that are consonant with heritage practices. Environmental standards would then reflect—and beget—a world in which the fish resource is robust, the air is clean, and the soils support work and play. They would bring about, rather than undermine, the environmental conditions necessary to support human health and flourishing.

While it is not possible here to envision a reoriented exposure assessment in all its particulars, this Part attempts to make some headway. It begins by considering how exposure assessment might be framed to ask a better question—one that addresses the pathologies identified in the preceding Part. It then identifies some of the problems and possibilities that might be anticipated, venturing some preliminary responses.

A. Asking a Better Question

Exposure assessment in the standard-setting context should be tied to its purpose, namely, bringing about a healthful environment. In order to produce these improvements, exposure assessors need to portray humans' circumstances and behaviors in this future—once environmental resources are restored and people's practices unconstrained. Exposure assessors would need to identify healthful and heritage practices, and enter these inputs into the risk assessment equation. When they solved these equations to derive the relevant health-based environmental standard, the contaminant concentrations permitted would be at levels low enough to allow people safely to engage in the healthful or heritage practices assumed.

Such an approach could be operationalized, moreover, without radical alterations to risk assessment as practiced, by means of enlisting exposure scenarios. This method has, in fact, been described by EPA and elaborated by researchers for use in the tribal context. As EPA explains in its 1992 Exposure Assessment Guidelines, "exposure scenarios can often help risk managers make estimates of the potential impact of possible control actions. This is usually done by changing the assumptions in the exposure scenario to the conditions as they would exist after the contemplated action is implemented, and reassessing the exposure and risk."[401] EPA points out that "if the [exposure] scenario being evaluated is a possible future use or post-control scenario, an assessor must make assumptions in order to estimate what the [exposure] distribution would look like . . . if the possible future use becomes a reality."[402]

Tribal researchers and their colleagues in academia have developed a scenario-based approach for conducting risk assessments that affect tribal resources and practices. As Barbara Harper et al., explain:

> Even though tribal lands have been lost and resources degraded, the objective of many tribes is to regain land, restore resources, and encourage more members to practice healthier (i.e., more traditional) lifestyles and eat healthier (i.e., more native and local whole) food. Therefore, the objective of subsistence exposure scenarios is to describe *original* lifestyles and resource uses . . . because the intent is to restore the ecology so that the original pattern of resource use is both possible (after resources are restored) and safe (after contamination is removed).[403]

As these researchers observe, "'[s]ubsistence' refers to the hunting, fishing, and gathering activities that are fundamental to the way of life of many indigenous peoples. Subsistence utilizes traditional and modern technologies for harvesting and preserving foods as well as for distributing the produce through communal networks of sharing and bartering."[404] In order to construct exposure scenarios of this sort, exposure assessors would need to consider lifeways that are unique to each tribe, including particular resource uses and exposure pathways.[405] Thus an exposure assessment would

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401. 1992 GUIDELINES, *supra* note 46, at 72.

402. *Id.* at 74–75. EPA's proposed 2016 update to its Exposure Assessment Guidelines similarly recognizes the use of exposure scenarios as part of one of three approaches to exposure assessment. 2016 GUIDELINES, *supra* note 46, at 13–14 (explaining that "[t]he indirect approach develops specific exposure scenarios and then uses data (e.g., pollutant concentrations), a series of exposure factors (e.g., contact duration, contact frequency, breathing rate) and models to estimate exposure within the scenario").

403. HARPER ET AL., *supra* note 327, at 26–27 (contrasting the objective of subsistence exposure scenarios, which take as their touchstone "*original*" lifeways and resource uses, with conventional exposure scenarios that take as their touchstone "a snapshot of *contemporary restricted* or *suppressed* uses").

404. *Id.* at 27.

405. *See, e.g.*, NAT'L TRIBAL TOXICS COUNCIL, *supra* note 321, at 7.

need to begin with an understanding of each tribe and its lifeways.[406] An exposure assessment of this sort would also need to draw upon an enlarged roster of disciplinary resources, including data and methods from the fields of archaeology, history, ethnobiology, and nutritional anthropology.[407] Researchers have applied such scenario-based methods to describe a diverse array of tribal lifeways, including those of the Elem (Pomo), Washoe, Umatilla, Spokane, and Wabanaki peoples.[408]

Although scenario-based methods for exposure assessment have been developed most extensively for use in the tribal context—a prominent example of a context in which a reframed approach is appropriate—such methods are potentially applicable elsewhere. Exposure assessors outside of EPA have recognized that there is no theoretical obstacle to varying the inputs to an exposure equation to consider the implications of different assumptions, including "to predict how exposures might change in response to different policies and regulatory (and non-regulatory) actions."[409] Indeed, EPA partially adopts such a forward-looking posture in conducting assessments for CERCLA cleanups. It instructs risk assessors to imagine the future uses at a restored site—including those uses that are not supportable under its current, contaminated conditions, but will become so only after the site is cleaned up to the requisite levels.[410] However, exposure assessors then tend to populate their equations with assumptions drawn from contemporary uses and data—such that a harbor that is cleaned up to support a fishing use in the future will only become clean enough to meet today's constrained levels of fish intake. This need not be the case, however: the assumptions used could instead reflect what people would be able to eat, were the fishery robust and uncontaminated. In fact, EPA's proposed 2016 Human Exposure Assessment Guidelines recognize the various regulatory objectives that exposure

406. *Accord* NAT'L TRIBAL TOXICS COUNCIL, *supra* note 321. *See generally* HARPER ET AL., *supra* note 327.

407. *See, e.g.*, NAT'L TRIBAL TOXICS COUNCIL, *supra* note 321, at 27; *Columbia Basin Consumption Rates*, *supra* note 18 (recounting "two approaches to accurately defining heritage fish consumption rates in the Columbia Basin. One approach is dietary reconstruction based on several lines of evidence (ethnographic, archaeological, historical ecology, nutritional) to estimate overall dietary composition and the caloric contribution of fish, especially salmon. The second approach is review of abundance, harvest, and consumption rates augmented with ethnographic and archaeological evidence over the same geographical area").

408. HARPER ET AL., *supra* note 327 (presenting exposure scenarios for the first four of these tribes); Harper & Ranco, *supra* note 164, at 2.

409. Ott, *supra* note 30, at 10 (discussing the malleability of exposure models, which permit exposure assessors to ask "what if?" questions).

410. *See* EPA, 1989 SUPERFUND RAGS, *supra* note 62.

assessments might serve and specifically embrace the "fit for purpose" concept, such that an exposure assessment is designed to answer the "question at hand."[411] Additionally, the proposed guidelines include an entire chapter that counsels "consideration of lifestages, vulnerable groups, and populations of concern in exposure assessments."[412] This chapter reminds exposure assessors of the need to account, among other things, for "unique exposure issues and scenarios in tribal populations."[413]

What is "healthful," of course, might be a subject of some debate, particularly in a multicultural society. I would suggest that, given the standard-setting context, the scenarios enlisted would be those that support (1) practices to which particular groups are entitled as a matter of right; and (2) characteristics and behaviors of sensitive or "vulnerable" people.[414] Indian tribes are illustrative of the first inquiry, but there may be others. The second inquiry would include those whose vulnerability is a matter of lifestage, e.g., children, or women of childbearing age.

Notably, a reframed exposure assessment would no longer simply subsume any restricted resource uses or averting behaviors into its baseline. People's efforts to compensate in the face of scarcity or to protect themselves and their families in the face of contamination—by finding alternatives to eating fish, by keeping children indoors, or by avoiding a bike commute—would not be taken as a "given." Additionally, transparency and legitimacy would be enhanced, as a shift to reliance on risk avoidance as a matter of policy would not be assumed and supported, even hastened. Those who believe that people's behavioral "adjustments" to degradation ought to be encouraged as a matter of "socially efficient externality policy" will have to persuade the public (and other custodians of Congress' statutory instructions). Such views will not have carried the day without debate, merely

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411. 2016 GUIDELINES, *supra* note 46, at 24, 27. The proposed guidelines address this topic at some length, discussing the importance of planning, scoping, and problem formulation in light of the particular regulatory driver for an exposure assessment (e.g., the relevant statutory provisions, which may require consideration of aggregate or cumulative risks), and the "receptor of interest" (i.e., the individuals, lifestage, groups, or populations of concern), among other considerations. *Id.* at 24–38. While the proposed guidelines do not include specific mention of a reframed exposure assessment such as I propose in this Article, neither would they preclude it.

412. *Id.* at 39–60.

413. *Id.* at 48.

414. I intend this term broadly, as understood by the National Environmental Justice Advisory Council. *See generally* NAT'L ENVTL. JUSTICE ADVISORY COUNCIL, ENSURING RISK REDUCTION IN COMMUNITIES WITH MULTIPLE STRESSORS: ENVIRONMENTAL JUSTICE AND CUMULATIVE RISKS/IMPACTS (2004), https://www.epa.gov/sites/production/files/2015-04/documents/ensuringriskreducationnejac.pdf.

by "doing the math" in an exposure assessment that reflects contemporary practices.[415]

Finally, there would be fewer opportunities for unnecessary delay with an exposure assessment that inquires into human practices that are healthful, rather than those that are merely current. A reframed exposure assessment would no longer be hostage to the claim that the best available science is a more recent snapshot of contemporary human behavior—such that further study is needed before standards can be issued and progress toward environmental health made. Of course, one would expect developments in scientific understanding of human health and well-being, such that new scientific data would need to be incorporated into agencies' assessments. However, it would seem that a depiction of healthful or heritage practices would be somewhat stable—at least compared to the moving target of current, actual behaviors. With the question reframed as "what is healthful?" exposure assessors will at least avoid having to chase more volatile near-term behavioral trends.

The inputs to a reframed exposure assessment would likely still be contested, particularly upon an initial re-tooling of the method. Thus, one would expect debate over precisely which practices, and whose circumstances, ought to be assumed. But, a reframed method shouldn't provide endless opportunities for delay in the name of ascertaining and re-ascertaining "how much fish do people eat now?"; rather, the inquiry should go exactly one round to ascertain "how much fish should people be able to eat?"

B. Problems and Possibilities

A reframed exposure assessment, whatever its merits, would introduce some issues.

1. Determining What Constitutes "Healthful"

It would be necessary to identify the circumstances and behaviors that are to be assumed and, so, supported by the resulting environmental standards. This task is potentially less than straightforward in a multicultural society, given that what is "healthful" for some individuals and groups may not be healthful for others. Which characteristics are mutable, and which immutable; which behaviors are vital, and which dispensable—these are

415. *See, e.g.*, discussion *supra* Section III.B.

questions that may be subject to debate. While humans can be said to have basic physiological requirements in common (e.g., everyone needs to breathe to stay alive), questions remain even here, as the discussion above suggests (e.g., at what rates of respiration, assuming what level of physical activity). These concerns, then, are potentially significant. However, some things might be said in response.

While a reframed exposure assessment would provide occasion for debate over what is healthful, this debate would not be unbounded. Rather, given the limits of human physiology, there is only so much water that can be ingested, only so much air that can be inhaled; there are, in the end, only twenty-four hours in a day. Former Director of Health Standards Programs at the Occupational Safety & Health Administration Adam Finkel offers the example of a risk assessment conducted for the purpose of setting safety standards for wooden ladders that are to support people as they work.[416] The standard could be set to require ladders to hold 130 pounds, because that is the average human bodyweight of the entire population, including newborns and toddlers (a standard, he observes, that "would be fine for 50% of the people" but would mean that "the other 50% of us could not use the ladders without breaking through them at our peril"); or it could be set at the 95th percentile, requiring ladders to hold 200 pounds.[417] But it is unlikely to need to hold 1500 pounds, given what we know about the physiological mechanisms of human weight gain and retention.[418] Thus, while we could debate whether to gauge our ladder safety standards by reference to an average or "central estimate" of bodyweight that includes babies who cannot even walk, the scope of our debate is at least bounded—and ladders will not be required to be infinitely strong.

That said, it may be that even an inquiry thus bounded provides ample fodder for disagreement, and it may be, moreover, that the determination of "what is healthful?" is substituted as the site of contest in a reframed exposure assessment. This raises a potential concern for instances in which such determinations may be misunderstood or misused, particularly if they become politicized. For example, might tepid or minimum recommendations for healthful behaviors be offered as evidence of the assumptions to be

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416. Finkel, *supra* note 97, at 407–08.

417. *Id.*

418. *Id.*; *see also* NAT'L RESEARCH COUNCIL, *supra* note 111, at 191–94 (explaining that physiologists understand the mechanisms by which humans grow and therefore can say that virtually no adults have a bodyweight above or below 70 kg by more than a factor of three).

incorporated in a reframed exposure assessment?[419] And might such assumptions result in environmental standards that would actually be less protective than standards based on contemporary behaviors?

There is potentially a source of purchase in even these debates. If, as I have suggested, a reframed inquiry were to focus on the two scenarios mentioned above—supporting the lifeways to which particular groups are entitled as a matter of right and supporting the characteristics and behaviors of "vulnerable" people—the practices assumed may be sufficiently capacious to support healthful options for all. For example, several fishing tribes have made progress in undertaking this inquiry, and have developed exposure scenarios that depict unsuppressed, heritage-based fish consumption practices.[420] If water quality and cleanup standards were set to support tribes' heritage rates—rates, as noted above, that may be as great as 1,500 grams/day—they likely would also protect non-tribal fish intake at healthful rates. Similarly, if air quality standards were set to ensure air that is clean enough to permit asthmatic children (or whichever group is most vulnerable) to go outside and play, they likely would also support working adult men and bike commuting adult women.

Interestingly, this potential objection—that an inquiry into what is healthful in a multicultural society introduces opportunities for debate—might not have enormous implications in practice. For many exposure pathways, the relevant resources will likely have been accessed and used to an equal or greater degree by Indian people engaging in traditional lifeways than by any immigrant group. This point stems in important part from the fact that Native peoples' practices have been forged on this continent, whereas other groups' practices have been developed elsewhere. As the NTTC explains, Native peoples' ties to their respective environments are "complex and intense"—their uses of the relevant resources for food, medicine, material, and ceremonial purposes may result in exposures via conventional pathways but to higher doses, at greater frequency, and for longer duration than the general population; or in exposures via pathways not shared by the

419. For example, the American Heart Association recommends that adults eat two fish meals per week. *Eating Fish for Heart Health*, AM. HEART ASS'N (May 15, 2015), http://www.heart.org/HEARTORG/Conditions/More/MyHeartandStrokeNews/Eating-Fish-for-Heart-Health_UCM_440433_Article.jsp#.VrAhbdIrJdh. Compare the FCR that would support this recommendation (64.8 grams/day) with the FCR (227 grams/day) that would support the findings of the Nurses' Health Study of the benefits of consuming seven fish meals per week in lowering risk of coronary heart disease in women. Bernstein et al., *supra* note 13, at 881–82.

420. HARPER ET AL., *supra* note 327; Harper et al., *supra* note 18.

general population.[421] As a consequence, if environmental standards for these places and resources are set at a level that would protect tribal members engaging in traditional lifeways, they likely will also protect non-tribal people for whom healthful practices entail lesser exposures (although there may be some exceptions). Or perhaps it is more accurate to say that by supporting the heritage-based practices of American Indian tribes whose uses pertain to a particular area, environmental standards would at least support the option of place-appropriate uses to all, whether indigenous or immigrant. That is, such standards would support practices that particular ecosystems on this continent in fact once supported—and, so, realistically might be capable of again supporting. If this is so, there may not need to be detailed investigations into what constitutes a healthful practice or use for each individual or non-indigenous group in the U.S.[422] This last point, note, may help assuage process concerns for the delay that would be occasioned by an initial re-tooling of exposure assessment method.

2. Eschewing the Advantages of the "Actual"

While there are problems with relying on people's contemporary circumstances of exposure to set environmental standards, a focus on people's actual behaviors is not without its strengths. The quotidian activities people in fact undertake, the foods they in fact eat—people's actual behaviors—can in theory (and, increasingly, in practice) be directly measured or observed. To the extent that our confidence in the accuracy of "the factual base"[423] describing exposure is increased where behaviors can be measured or observed, the credibility of the resulting risk assessment will be enhanced. A concern for the credibility of the scientific assessments that support

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421. NAT'L TRIBAL TOXICS COUNCIL, *supra* note 321, at 3–6. The NTTC also emphasizes an additional dimension of understanding tribal exposures, that "impairment of natural resource uses affects tribal social and cultural well-being beyond nutrition and physical health." *Id.* at 3.

422. As noted above, many tribes have already made considerable progress in undertaking scenario-based assessments of exposure and, in some cases, used these as a basis for tribal regulatory standards. *See* Elizabeth Ann Kronk Warner, *Tribes as Innovative Environmental "Laboratories"*, 86 U. COLO. L. REV. 789, 831–32 (2015) (observing that tribal governments have frequently been leaders in undertaking innovative environmental regulation); Rebecca Tsosie, *Tribal Environmental Policy in an Era of Self-Determination: The Role of Ethics, Economics, and Traditional Ecological Knowledge*, 21 VT. L. REV. 225, 288–300 (1996) (discussing role of tribes' unique world views in tribal environmental management decisions).

423. THE RED BOOK, *supra* note 29 (defining risk assessment as "the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations").

agencies' regulatory decisions was a key motivation, recall, for the publication of *The Red Book* in 1983;[424] this concern continues to animate EPA method and practice.

Additionally, people's actual behaviors are thought to be useful indications of the practices that are preferred by, and enhance the well-being of, these individuals. Economists argue that human welfare is "a function of individuals' well-being," which, in turn, is to be determined by "relying on individuals' existing preferences, as revealed by their behavior."[425] Without delving into whether or not welfare maximization ought guide environmental policy,[426] economists' disciplinary emphasis on people's actual behaviors may stem from impulses that are relevant to exposure assessment. First, there is humility in economists' belief that an individual is the best or most legitimate arbiter of what is good for himself or herself. As Louis Kaplow and Steven Shavell put it, economists assume "that individuals comprehend fully how various situations affect their well-being and that there is no basis for anyone to question their conception of what is good for them."[427] Arguably, there is no basis to second guess what people are choosing to do and eat and drink—nor to second guess what they are refraining from doing by adopting averting behaviors. Second, there is a respect for unmediated information about how human beings are in economists' reference to people's existing behaviors as their basic source of data. While economists go on to take these behaviors as having revealed people's preferences—a conversion that, as Mark Sagoff has pointed out, requires a move from the observable (behaviors) to the constructed (preferences)[428]—their starting point is tangible. Indeed, economists here join scientists of all stripes who understand the value of observable, tangible facts as a guard against subjectivity in our analyses.

In considering a reframed exposure assessment, the concern for accuracy of the factual base can be readily addressed. There is no reason to think that the methods involved in depicting healthful or heritage practices are less reliable than those portraying people's contemporary practices. Whereas exposure assessment as practiced draws on a host of methods from a variety

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424. *Id.* at 49.

425. Louis Kaplow & Steven Shavell, *Fairness Versus Welfare*, 114 HARV. L. REV. 961, 1329 (2001).

426. As observed *infra*, where the relevant standard calls for an approach enlisting health-based standards, Congress has answered this question in the negative. For a thoughtful and thorough response to the view that welfare maximization ought guide environmental policy, see MARK SAGOFF, PRICE, PRINCIPLE, AND THE ENVIRONMENT (2004).

427. Kaplow & Shavell, *supra* note 425, at 984.

428. *See* SAGOFF, *supra* note 426, at 57–79 (considering "Should Preferences Count?").

of fields, a reframed exposure assessment would need to enlist the methods and expertise of a different (although overlapping) roster of disciplines. But there is no reason to suppose that, say, a sociologist who analyzes time-activity pattern diaries is better suited to producing trustworthy data than, say, a nutritional anthropologist who analyzes historical and contemporary evidence of a tribe's dietary practices. So long as the relevant experts provide data from within their areas of expertise, in accordance with its methods and protocols, there is no reason in theory that a future-oriented scenario-based exposure assessment would be less scientific than exposure assessment as practiced. Nor is there any reason to think that environmental agencies or the public would be less well situated to oversee the new roster of disciplines (although it might take some time for agencies and the public to develop the requisite familiarity with new methods and disciplinary conventions).[429]

And, of course, there is no use in discerning with great accuracy an answer to a question that is not relevant to the inquiry at hand. With technological advances in our ability to obtain real-time-and-place data about individuals' actions, exposure assessors could soon be able to produce quite accurate depictions of contemporary exposure—a breath-by-breath snapshot of a person's inhalation of particulate matter or a bite-by-bite record of a person's intake of particular species of fish. But such increasingly accurate and fine-grained measurements of contemporary behaviors still do not tell us about healthful or vital behaviors. Such data do not help answer the question "what is it healthful for people to be able to do?"

The argument that an individual is the best judge of the practices that are best for him or her requires more discussion. First, it is possible that people's contemporary behaviors are not, in their view, "constrained." If so, it is arguably inappropriate to suggest that people's current practices are untethered to what would be "healthful." They may eat no fish, for example, because they are allergic to fish or because they choose to maintain a vegan diet. In either case, such fish intake practices—while at a rate of 0 grams/day are far off the 227 grams/day that studies show to be protective of cardiovascular health—might indeed be healthful for these individuals. And, importantly, having "[understood] fully how various situations affect their well-being," their choice to abstain from fish ought not be assumed to be unhealthful.[430]

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429. *See generally* Sidney A. Shapiro, *The Failure to Understand Expertise in Administrative Law: The Problem and the Consequences*, 50 WAKE FOREST L. REV. 1097, 1099 (2015) (discussing agencies' use of "craft expertise"—a type of expertise "in reconciling and accounting for conflicting evidence and arguments, disciplinary perspectives, political demands, and legal commands" developed chiefly through experience).

430. Kaplow & Shavell, *supra* note 425, at 984.

The response to this first point is twofold. There is indeed an important sense in which an individual's choices should be respected as an indication of what advances his or her health and well-being. Among other things, this point might suggest caution in ascribing a rationale to people's apparent averting or compensatory behaviors. That said, it has long been recognized that people's preferences are exogenously influenced, such that it is not possible simply to defer to their behaviors or statements about their behaviors as evidence that they are the product of unconstrained choice.

Regardless, given that health-based standards are generally set to protect the most exposed individual in a population—in recognition that others exposed to a lesser degree will necessarily also be protected—the need to support healthful practices for those whose behaviors have been constrained will drive the resulting standards. In the case of fish intake, for example, the Spokane tribe's water quality standards support fish consumption up to 865 grams/day in order to ensure that the waters are clean enough not to constrain those who would consume fish at this rate, but have been thwarted in doing so by depletion and contamination. Those who would consume fish at any lesser rate are also protected—and their judgments that these lesser rates of intake are those that enhance their well-being effectively honored.

A second point stems from a respect for individuals' actual behaviors as the best indication of their well-being: it is folly, and thus inefficient as a matter of social policy, the argument goes, to presume that people will change their behaviors to embrace those that are healthful. Even if people claim in all earnestness that they would eat more fish if the fish were again plentiful and safe to eat, there is no guarantee that they would actually do so in the future. As one commentator put it during a public meeting on Washington's water quality standards: people say that they will stop eating potato chips and adopt healthier habits, but how many will actually do so? What people are doing, in other words, is the best evidence of what people will do.

The response to this point is that the aim of heath-based standards is to provide environmental quality sufficient to support healthful options. Agencies' standard-setting method should be designed to produce environmental conditions that support those options and, crucially, that do not penalize those who do maintain or adopt healthful practices. Whatever public health professionals' and tribal leaders' hopes, it may be that not everyone in fact embraces more healthful behaviors or traditional lifeways. But this is a matter for those public health professionals and tribal leaders to address;[431] the role of environmental standards is to ensure that their public health goals are not rendered hazardous or impossible for people to reach, because of environmental degradation.

As to the suggestion that this aim of health-based standards is inefficient, an important response is that this is nonetheless the aim that Congress has chosen. Health-based standards are tied not to a level of environmental protection that is optimal, in the sense that economists use the term, but to a level of environmental protection that is healthful for humans.

CONCLUSION

Environmental agencies determine the future state of our air, waters, and soil by reference to people's recent-past practices. Agency exposure assessors inquire "to what are people exposed?" and then set health-based standards accordingly. That is, they require environmental conditions to support only people's contemporary pursuits. Exposure assessment in this way defines the scope of future human endeavors.

Exposure assessment, however, is not tethered to human behaviors that are healthful or vital. Nor, as an examination of the method's development reveals, was it ever tied in any particular way to an inquiry into human health and well-being. In the early years, EPA availed itself of the data at hand—data that depicted people's then-contemporary activities and resource uses. These initial exposure assessments became the template for the method that is used today, irrespective of the purpose for which an understanding of human exposure is needed.

While people's practices back in the 1970s were likely shaped by environmental degradation, conditions are only somewhat better today. People's behaviors may be constrained by contamination and depletion. A method that takes these behaviors, automatically, as the premise for the resulting standards may render "health-based" a misnomer. Indeed, as experience has shown, exposure assessment as practiced often fails to advance—and may undermine—the restorative and preventive aims of our foundational environmental laws and the rights-based claims to robust resources contained in treaties and other laws.

431. They might enlist any of a panoply of tools to this end. *See, e.g.*, PRESIDENT SHELLY SIGNS HEALTH DINE' NATION ACT OF 2014 INTO LAW, NAVAJO NATION (Nov. 21, 2014), http://www.navajo-nsn.gov/News%20Releases/OPVP/2014/nov/Healthy%20Dine%20Nation%20Act%20of%202014.pdf (imposing 2% tax on "gross receipts for minimal-to-no-nutritional value food items sold" and using revenues to fund gardens, farmers markets, exercise equipment, and health classes).

The history uncovered in this Article shows the method's recent-past orientation to be more an artifact of its formative years than the product of considered judgment. Given exposure assessment's serious shortcomings, it is time to consider asking a better question—one aligned with the purpose of health-based standards.