

Water Pollution**Human Health Water Quality Criteria**

For the past several years, the Obama administration's Clean Water Rule, also known as the waters of the U.S. rule, has been the primary focus of water policy development. But while that saga has unfolded, another equally, if not more important, water policy debate has quietly developed—the calculation of human health water quality criteria and the fish consumption rate used to derive them. Author Jerry Schwartz argues the Environmental Protection Agency is imposing new, overly protective risk policies contrary to its own regulations and long-standing guidance that make clear states have the discretion to develop their own criteria as long as they protect designated uses.

BNA Insights: Human Health Criteria, Fish Consumption Rates—More Important Policy Implications Than Clean Water Rule?

BY JERRY SCHWARTZ

During the past several years, the Obama administration's Clean Water Rule, also known as the waters of the U.S. (WOTUS) rule, has been the primary focus of water policy development. But while that saga has unfolded, another equally, if not more important, water policy debate has quietly developed—the calculation of human health water quality criteria and the fish consumption rate used to derive them.

Like the Clean Water Rule, the human health criteria also center on the cooperative federalism that is the foundation of the Clean Water Act. Although some mistakenly perceive the development of criteria as confined to a state or region, it may have even more nationally significant and long-lasting policy implications than the Clean Water Rule because of the new risk policies the EPA has adopted. These upend the basic human health water quality criteria risk framework that has been in

place since at least the 1980s and result in unnecessarily stringent Clean Water Act permit limits. Some of those limits are unachievable, even with the expenditure of billions of dollars, and provide no measurable health benefit when compared to more reasonable alternatives. Moreover, there is a more scientifically advanced way of calculating human health criteria called “probabilistic risk assessment” that the EPA’s own scientists have been promoting for years.

As a matter of necessity, this paper discusses two sensitive issues related to fish consumption—cancer risks and tribal treaty rights. Everyone agrees even one additional cancer is too many, and society should do all it reasonably can to minimize cancer risks. To address this problem, resources should be deployed where they have the best chance of achieving actual cancer risk reduction. It also goes without saying that fish consumption has important cultural and religious significance for tribal members, and this paper is not intended to diminish that significance.

State and Federal Roles in Water Quality Standards, Human Health Criteria

The Clean Water Act gives states the primary responsibility for developing water quality standards. An important part of those standards is the “criteria” (usually a concentration limit for a pollutant) that are used to protect the “designated uses” of the water, such as fishing, swimming and other recreational activities.

The EPA issues national recommended human health water quality criteria under Section 304(a) of the Clean Water Act, and states use these as the starting point for developing their own criteria as part of their water quality standards. Importantly, under existing regulations (40 C.F.R. § 131.11(b)), states have three options when developing their criteria and submitting them to the EPA for approval: 1) adopt the EPA national criteria, 2) modify the national criteria to reflect site-specific conditions or 3) develop other “scientifically defensible” criteria.

Therefore, states are not required to adopt the national criteria or use the identical default values that the EPA included in the equations to derive them. The states’ criteria must protect the designated use and be based on “sound scientific rationale” (40 C.F.R. § 131.11(a)). If the EPA disapproves state criteria or determines that revised criteria are necessary, it can issue federal criteria for the state.

The Purpose of Human Health Water Quality Criteria. Water quality criteria are concentrations of pollutants allowed in a state waterway that protect a specified designated use. Waters not meeting water quality standards are considered impaired and require Total Maximum Daily Loads (TMDLs), cleanup plans designed to bring them back into compliance. These TMDLs will result in the establishment of Clean Water Act permit limits for municipal and industrial facilities discharging into those waters. Human health criteria also are used

to set permit limits even in the absence of TMDLs, using a “reasonable potential” analysis.

The fish consumption rate is often the most important element of the exposure individuals will have to pollutants; the higher the rate, the more stringent the resulting human health criteria.

Because of the prominence of fish consumption rates in the policy debate, some people confuse the human health criteria with standards to set fish advisories or to ensure that the water quality is adequately protective of the fish themselves, but that is not the case. The goal is human health protection. Specifically, the human health water quality criteria are set so that fish in the affected water body have levels of regulated pollutants low enough that when they are consumed by people (“organism only” criteria) or are consumed by people who are also drinking the water (“water and organisms” criteria), they do not pose unacceptable health risks to those individuals. The fish consumption rate is often the most important element of the exposure individuals will have to pollutants; the higher the rate, the more stringent the resulting human health criteria. Those criteria are then used to calculate permit limits, which control discharges such that pollutants will not cause health impacts to people consuming the fish or water from the receiving water.

EPA Requirements for Deriving Criteria

In October 2000, the EPA revised its “Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health” that provides the formula for calculating pollutant concentrations that are protective of human health. The formula includes several very conservative default values, including the fish consumption rate and the excess lifetime cancer risk (ELCR) level. These two values are the focus of the debate; other values such as the Bioaccumulation Factor (BAF) and the Relative Source Contribution (RSC) for non-carcinogens also are controversial.

In June 2015, the EPA issued “updates” to 94 human health water quality criteria; the majority were more stringent than the previous criteria—some many times more. The EPA stated it was doing nothing more than “updating” the 94 criteria to apply the 2000 methodology, but many commenters were not persuaded. Again, the bioaccumulation factors and the relative source contributions and several other elements of the exposure scenario used in the derivations of values were controversial.

Regarding the fish consumption rate, the EPA selected 22 grams per day (g/d) and changed how it identified certain fish as “nearshore” (and thus counted in

To request permission to reuse or share this document, please contact permissions@bna.com. In your request, be sure to include the following information: (1) your name, company, mailing address, email and telephone number; (2) name of the document and/or a link to the document PDF; (3) reason for request (what you want to do with the document); and (4) the approximate number of copies to be made or URL address (if posting to a website).

the fish consumption rate) or “marine” (not counted) and made other changes. The EPA also changed the drinking water default value to 2.4 liters per day. It is still unclear how the agency made these demarcations and how it derived some of the values.

State Risk Management Discretion. The methodology is very clear about three risk management points, all of which the EPA has changed. First, setting water quality criteria is a risk management policy decision left to the discretion of the states. As indicated in the foreword to the methodology, “EPA believes that ambient water quality criteria inherently require several risk management decisions that are, in many cases, better made at the state, tribal or regional level.”

Second, the EPA has long considered excess lifetime cancer risk levels of either 10^{-6} or 10^{-5} as being adequately protective. “Adoption of a 10^{-6} or 10^{-5} risk level, both of which states and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes,” the methodology said. The fact that there is no measurable difference in expected cancers in Washington State using criteria based on a 10^{-6} or 10^{-5} risk level demonstrates that they are equally protective.

Third, it is within the states’ risk management policy discretion to choose excess lifetime cancer risk levels of 10^{-6} or 10^{-5} for the general population and a different, ostensibly less-stringent level for high fish-consuming subpopulations, such as tribes or subsistence fishermen. Specifically, the methodology states “EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as states and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level.” This also was the risk policy the agency used in policies as early as 1990, when it adopted the National Toxics Rule in 1993 and the Great Lakes Initiative (GLI) in 1995.

This bifurcated approach to setting cancer risk levels may seem counterintuitive. Indeed, many people have the same reaction upon hearing it for the first time: “Wait a minute. You are setting criteria for high consuming populations like subsistence fisherman using a less protective risk level? That doesn’t seem right.”

The EPA established this policy because it has consistently recognized (with the exception of the current EPA Region X administrator) that it is not possible to ensure everyone faces the same risks because people engage in different behaviors that present different risks. If one person is consuming more fish with the same levels of pollutants as someone else, then that person faces a higher risk (it is a theoretical risk because the criteria more than adequately protect both people due to the “compounded conservatism” underlying those standards). The EPA recognized this in the preamble to a 1998 advance notice of proposed rulemaking on revisions to its 1988 water quality standards rule: “Given the wide variations in consumption patterns, it would not seem to be possible for States and Tribes to provide the same level of protection from contaminated fish for all consumers” (63 Fed. Reg. 36,741; . Similarly, the methodology states, “[t]he point is that the risks for different population groups are not the same.” This should not be controversial; people who drive more

miles per year inevitably will face a higher risk of traffic accidents, regardless of the safety measures used in building cars and highways.

‘Compounded Conservatism’ in the Human Health Criteria. To assess the risk from pollutants, one must consider both hazard and exposure. While this paper discusses only the human health criteria formula values for exposure, there also are conservative assumptions and “safety factors” built into the toxicity values used in the formula.

The National Council of Air and Stream Improvement, ARCADIS and Integral Consulting issued a paper describing in detail a concept known as “compounded conservatism” in assessing exposure and how the assumptions compound each other; the two examples below help illustrate this concept. The first is an analogous example in which the data used are not real but intended to be illustrative; the second describes the EPA’s national human health criteria.

An agency is developing standards to protect people from falling down steps in their homes and available data identify several factors that make it more likely a person will fall. Because older people fall more often, the agency decides to be extra conservative (protective) and bases its standards on the assumption that everyone is at least 85 years old. Similarly, because more people fall when they do not clearly see the steps, the agency assumes that stairs are used only after dark without adequate lighting. Finally, because falls increase with step use, the agency assumes that everyone uses the steps in their homes at least 50 times per day.

Compounded conservatism means that the agency will base its standards on the assumption that *everyone* exhibits ALL of these characteristics. Yet, we know that only 3 percent of the people actually are at least 85 years old, only 25 percent actually use steps in low light and only 1 percent actually use the steps at least 50 times per day. Based on compounded conservatism, the agency develops a “stair use standard” limiting the number of steps a person can take on staircase to 10 a day. To comply with this standard, homebuilders must install expensive elevators or build only single story homes.

Actual Values EPA Used to Develop Human Health Criteria. The actual values from five areas used to derive national human health water quality criteria are outlined below and come from the 2000 methodology (note the drinking water value and the fish consumption rate were updated in 2015)

- **Drinking Water Consumption.** The criteria assume that everyone drinks 2.4 liters (about 2.5 quarts) of water per day; this is more water than what 90 percent of the people in the U.S. drink. The EPA also assumes that each person is drinking water directly out of a lake or stream or other surface water—and that the water has not been filtered or treated to remove any pollutants. The EPA states this latter assumption is not based on science but is to further a “pollution prevention policy.”

- **Exposure Concentration.** The equation also assumes that the concentration of the pollutant in the drinking water is equal to the criteria level ultimately calculated and is at that concentration 100 percent of the time.

■ **Duration of Exposure.** The criteria assume that the people never move and are exposed every day for 70 years.

■ **Body Weight of a Person.** The EPA's default assumption is that a person weighs 80kg (about 176 pounds) or about the arithmetic average of the U.S. population.

■ **Cooking Loss.** The equation implicitly assumes zero loss from cooking the fish. This is conservative, because we know that for many of the pollutants of concern, there is a significant amount of pollutant lost during cooking.

Fish-Consumption Rate. Because the fish consumption rate has garnered such attention, it is discussed separately from the other values. As a result of the 2015 update, the EPA's national default fish consumption rate is 22 g/d (less than an ounce). This is more fish and shellfish from inland and nearshore waters than is consumed by 90 percent of the U.S. adult population 21 years of age and older. The purpose of the criteria is to set water quality standards that become the basis of Clean Water Act permit limits for discharges into local waters and to protect people who are consuming fish and water from those local waters. Nonetheless, the EPA policy is to include in its calculation fish and shellfish from multiple local, commercial, aquaculture, interstate and international sources (except marine fish), including fish bought in supermarkets or imported from other countries. In effect, the EPA assumes that all the fish from inland and nearshore waters that these high fish consumers eat is locally-caught fish, despite knowing that is untrue for the vast majority of them.

Understanding the implications of compounded conservatism, we can begin to form a more rational approach to risk management.

The EPA also assumes that all of those fish are taken from waters that contain the pollutant at a concentration equal to the human health criteria and that all have resided in those waters long enough to bioaccumulate the pollutant to the maximum extent. The agency is intentionally using a rate of consumption of both contaminated and uncontaminated fish to represent consumption of maximally contaminated fish.

Compounded Conservatism in Human Health Criteria. Understanding the implications of compounded conservatism, we can begin to form a more rational approach to risk management. In its Cancer Risk Assessment Guidelines, the EPA cautioned that piling on multiple conservative values in criteria is of limited value to decision makers. In summary, the equation used to derive the national water and organism criteria assumes that the concentration of a pollutant in all waters is always equal to the criteria *and* that everyone in the U.S.:

- is of average weight;
- drinks 2.4 liters of unfiltered and untreated water from rivers, lakes, and streams every day for 70 years *and*

- eats 22 grams of locally caught fish every day for 70 years, all of which are contaminated at the criteria level.

The equation also assumes that none of the pollutants in the fish were lost due to preparation or cooking.

My colleagues have estimated that less than 1 percent of the population has these characteristics, yet it is reasonable to conclude that this is conservative because no one has all—or even most—of the exposure characteristics listed above, which are the basis for the EPA's national default human health criteria. The EPA's new policy uses even more extreme values to derive criteria for the states at issue.

When deriving discharge permit limits for a pollutant, the EPA further compounds the conservatism by assuming that all of the elements of the national exposure scenario for the criteria are occurring, but only with respect to the particular water body that will receive the permitted discharge. Based on the information above, we know this is extremely unlikely.

EPA's New Policy

In Oregon, Washington, Idaho and Maine, the EPA has advanced a new policy without public notice and comment based on tribal treaty fishing rights and how they must be accounted for in establishing state human health criteria. (In a meeting with EPA Office of Water leaders, they claimed the policy is not “new” but that the existing policy has “evolved.”) The rationale for the EPA's new policy is not clear enough to easily identify other states that may be subject to it. Nonetheless, at least 10 states have tribes with treaties similar to those at issue in Washington, and in total, 40 states are home to tribes with treaties. Further, in late 2014, EPA Administrator Gina McCarthy issued a memorandum to the regions directing them to continue promoting tribal treaty rights as they implement the nation's environmental laws.

Oregon and Maine. In the Northwest, the EPA's basis for pressuring states to adopt more stringent human health criteria (i.e., including a fish consumption rate of 175 g/d or .39 pounds and a lifetime cancer rate level of 10^{-6}) has varied over the years from environmental justice, “regional consistency” (even though there is no Clean Water Act requirement that regions have “consistent” standards) and tribal treaty rights. In 2011, Oregon became the first Northwest state to adopt revised human health criteria based on the EPA's preferred fish consumption rate and excess lifetime cancer risk values. Some five years later, Oregon has not yet issued major permits based on these criteria, so the issue has not peaked in that state.

In Maine, the federal 1980 Maine Indian Claims Settlement Acts and a related state statute that resolved tribal claims over lands in the state complicates the issue, but the EPA's basic policy is the same. The agency disapproved Maine's water quality standards based on that policy in 2015 and in April 2016 issued a proposed rule for “Indian lands” in the state (81 Fed. Reg. 23,239; 77 DEN A-17, 4/21/16). Based on tribal treaty rights the fish consumption rate is 286 g/d, which EPA says represents “present day sustenance-level fish consumption, un-suppressed by pollution concerns” for the relevant tribes. The EPA cites a Frequently Asked Questions (FAQ) document as authority for choosing an “un-suppressed” rate. Maine has sued the EPA over the disap-

proval, and the case has not yet been resolved (132 DEN A-14, 7/10/14).

Washington. EPA Region 10 also has consistently made clear that Washington state’s human health criteria were no longer acceptable, most importantly because they were based on the agency’s earlier National Toxics Rule, which included an FCR of 6.5 g/d.

In 2013, Washington began a rulemaking that included a comprehensive stakeholder process to develop protective and achievable standards, but it did not achieve consensus, partially because the EPA made clear that it would reject the more reasonable alternatives being considered. Subsequently, on Sept. 14, 2015, the EPA proposed a federal rule that would impose stringent human health criteria on the entire state of Washington except “Indian lands”—even more stringent than Oregon’s (80 Fed. Reg. 55,063; (172 DEN A-14, 9/4/15).

The state recently restarted its regulatory process to develop a proposal acceptable to EPA. If the agency accepts the proposal, it will withdraw its proposed federal rule.

The proposed rule has several different explanations for how the treaty rights should be accounted for in deriving water quality criteria. EPA says the rights must be “consider[ed],” and “inform” the criteria, and that the proposed criteria are needed to “effectuate and harmonize those rights . . . with the CWA.” The exact role of the tribal treaty rights in human health criteria, therefore, is unclear.

The proposed rule states that treaties with the U.S. provide Washington tribes with reserved rights that must be accounted for and protected in the state’s criteria. Specifically, the tribes have the right “to take fish for subsistence” and other purposes, including “rights to take fish at all usual and accustomed fishing grounds and stations in waters under state jurisdiction. . . . Such rights . . . necessarily include an attendant right to not be exposed to unacceptable health risks by consuming those fish.” As commenters on the proposed rule pointed out, EPA did not provide any legal authority for this proposition. Moreover, the agency took the opposite position in previous litigation over Washington’s tribal treaties that had been resolved in EPA’s favor. EPA argued, and the court in agreed, that any trust responsibility owed by EPA to tribes based upon treaty fishing rights was discharged by EPA’s compliance with the Clean Water Act, the aim of which is to protect the water quality for the entire population (*Sierra Club v. McLarren*, W.D. Wash., No. 2:11-cv-01759, 3/16/15).

The proposed rule has several different explanations for how the treaty rights should be accounted for in de-

veloping water quality criteria. EPA says the rights must be “consider[ed],” and “inform” the criteria, and that the proposed criteria are needed to “effectuate and harmonize those rights . . . with the CWA.” The exact role of the tribal treaty rights in human health criteria, therefore, is unclear.

It is clear, however, that contrary to the 2000 methodology and long-standing EPA policy on state risk management discretion, EPA is asserting that the criteria must treat the subpopulation of high-consuming tribal members as if they were the general target population. Thus, the EPA’s proposed criteria assume that everyone in the state has all the exposure characteristics discussed above—except for the fish consumption rate, for which the EPA has substituted a rate of 175 g/d, reflecting the amount of fish consumed by only 5 percent of the people in a surveyed tribe in the region. EPA again cited the same FAQ document to support its recommendation for an unsuppressed fish consumption rate.

The proposed criteria also require that this high-consuming tribal subpopulation be protected at an excess lifetime cancer rate of 10^{-6} , not the 10^{-4} level required by the 2000 methodology, which would be adequately protective because of the compounded conservatism on which the criteria are based.

Idaho. EPA also rejected Idaho’s human health water quality criteria in 2010 primarily based on asserted deficiencies in the state’s fish consumption rate. Over the last few years, the Idaho Department of Environmental Quality has undertaken a transparent stakeholder process based on clear analyses and well-documented choices to develop new criteria. Based on a recent fish consumption survey of its general population and an EPA tribal survey, Idaho chose a fish consumption rate of 66.5 g/d. That number represents the 70th percentile of the Nez Perce tribal consumption and included salmon and steelhead trout, both conservative assumptions, considering the general population mean consumption of all fish is 22 g/d, or 2.3 g/d if salmon and steelhead trout are not included. Idaho also only counted certain fish species, excluding most market fish from the rate based on information about Idahoans fish consumption. As Idaho DEQ stated in a presentation on its human health criteria, “it is reasonable to conclude that nearly all fish purchased in the market are marine fish or estuarine fish from outside of Idaho and that Idaho water quality standards will have little or no effect on their contaminant burden and risks to health in Idaho.”

Consistent with the 2000 methodology and the risk management policy discretion it provides, Idaho used a 10^{-5} risk level to derive its criteria. Idaho specifically recognized that “risk can never be made the same for everyone” and that its criteria were adequately protective for both the general population and higher-consuming subpopulations.

Idaho has not yet officially submitted its standards package to EPA for approval, but EPA comments during the rulemaking indicate that the agency believes tribal treaty rights compel DEQ to adopt criteria in line with the agency’s preferred criteria for Oregon, Washington and Maine—criteria based on 175 g/d and an cancer risk level of 10^{-6} . Idaho’s departure from EPA’s stated preferences suggests that the agency will reject that package, and it is likely that Idaho will challenge

that decision, as has Maine. It would seem that Idaho's human health criteria are adequately protective and consistent with EPA's regulatory requirements for approval.

Benefits and Costs

Comments submitted on EPA's proposed rule for Washington demonstrate that implementation of those more-stringent criteria do not produce a measurable health benefit. Based on Washington's 2014 population and information from the American Cancer Society, with criteria based on EPA's preferred excess lifetime cancer risk level, the theoretical annual incidence rate of cancer is predicted to increase from 38,230 to 38,230.01, a tiny fraction of a cancer case per year. Criteria based on a more reasonable risk level, which EPA arbitrarily told states it would reject (i.e., 10^{-5}) but is specifically allowed by EPA's existing guidance, results in a theoretical increase in annual cancer incidence in Washington from 38,230 to 38,230.1, again a tiny fraction of a case per year. Both of these theoretical cancer rate increases only would occur if people have all of the exposure characteristics underlying the human health criteria (e.g., drinking 2.4 liters of unfiltered and untreated surface water every day). Because few, if any, people have those characteristics, any actual change in cancer incidence will be much, much lower than even these tiny fractions and may, in fact, be zero.

One study found that if the Oregon standards were applied to Washington State, industries and municipalities would not be able to meet all the resulting Clean Water Act permit limits and the potential cost to attempt to attain compliance would be in the billions of dollars.

In 2013, a coalition of Washington stakeholders issued a report in 2013, "Treatment Technology Review and Assessment," by HDR Engineering, Inc., that found if the Oregon standards were applied to Washington State, industries and municipalities would not be able to meet all the resulting Clean Water Act permit limits and the potential cost to attempt to attain compliance would be in the billions of dollars. For example, when Washington was developing its criteria, in a Dec. 5, 2013, meeting of the Governor's Informal Advisory Group, the mayor of Bellingham stated that it could cost more than \$1 billion over 30 years for her community alone to meet similar state standards (but less stringent standards than those in EPA's proposed rule), raising monthly sewer bills for every resident from \$35/month to \$200-\$250/month.

In short, EPA's choice of a 10^{-6} target risk level results in no measurable improvement in public health (compared to the choice of 10^{-5}) but imposes potentially exorbitant costs on all Washington residents. Comments filed in Idaho's rulemaking show similar misalignment of benefits and costs, even though Idaho DEQ has chosen to adopt much more reasonable fish-

consumption rates and excess lifetime cancer risk levels for its human health water quality criteria.

EPA's Role and the Basis for Approving State Criteria

The Clean Water Act gives states the primary role in setting water quality criteria and standards, and they have discretion to make their own scientific and policy choices. In the case of Washington, the difference in the cost of its risk policy choices versus the theoretical excess cancers demonstrates why the regulations give states the discretion to weigh these factors. The EPA's preferred values could result in similar costs and benefits in Idaho.

As stated by the National Association of Clean Water Agencies in comments on EPA's proposed rule for Washington:

[T]he language in the CWA and the implementing regulations was not intended to give EPA authority to disapprove standards because the state's science and policy decisions are not identical to [EPA's] preference, policies and guidance. . . . In the case of Washington's proposed rule . . . EPA appears to ignore the flexibility afforded to states in its own guidance by insisting that the state's program conform to EPA's preferred approach. These tactics are inconsistent with the CWA's cooperative federalism foundation and history that provides the states the responsibility for developing and approving water quality standards. . . . The structure established by the CWA—where EPA provides criteria recommendations and guidance and the states develop water quality standards based on that information as well as state policy and risk decisions (where a range of acceptable CWA options exist)—must be preserved to ensure that federal preference and the criteria recommendations do not become de facto regulations.

EPA's national default criteria are based on a number of extreme and unrealistic assumptions and are a perfect example of "compounded conservatism."

The EPA's regulations (40 C.F.R. § 131.11(a) (1)) also are clear that the agency must approve criteria based on state science and policy choices if the resulting limits are protective of designated uses. The choices may differ from the EPA's preferences, but they still must be approved if they reflect "site specific conditions" or are "scientifically defensible." If the EPA rejects Washington's or Idaho's criteria, could the EPA meet its burden of proving in the ensuing litigation that the criteria do not meet either of these standards? The EPA's national default criteria are based on a number of extreme and unrealistic assumptions and are a perfect example of "compounded conservatism." The EPA's preferred human health criteria for Washington and Idaho are even more conservative and violate existing agency policy. Further, those states can demonstrate that some of those default values result from policy choices, not requirements based on science—such as the assumption that people are drinking 2.4 liters of untreated water from lakes and streams every day. Instead of adopting criteria based on national default values, Idaho undertook a transparent stakeholder process and adopted

limits based on data reflecting the conditions of the state's population and explained why they were "scientifically defensible." It seems that the EPA would have a hard time proving the contrary in litigation. Moreover, if the EPA argued its rejection was required because of tribal treaty rights, it would also have to argue that its new policy somehow trumps long-standing regulations, which would be an equally difficult argument.

A Better Way—Probabilistic Risk Assessment

Environmental practitioners are familiar with the conservatism inherent in setting environmental standards. For instance, standards for Superfund cleanups assume that for 350 days per year children eat 200 milligrams of dirt while playing in the soil at a site. It made sense decades ago to embody "compounded conservatism" in standard setting. Available risk assessment tools were not as sophisticated, and we could not accurately make measurements in the ranges needed to detect and quantify low levels of pollutants. At that time, we also were attacking much more significant problems than we are today. But today we can make measurements in the parts per quadrillion range, some of our standards approach background levels and we are attacking the remaining small percentages of the problem—the low hanging fruit is gone, the benefits are few and the costs are enormous. EPA's new policy takes an already excessively conservative approach one step further and assumes that every person in the state has exposure characteristics that few if any people in the state exhibit—tribal members or otherwise.

Setting human health water quality criteria based on exposures represented by one value on the high end of the range of possible values is called a "deterministic approach." In contrast, a "probabilistic risk assessment" approach gives policy makers an understanding of the central tendency of estimated risk and the probability that actual risk will be on the high end of the range. The probabilistic approach is more scientifically advanced as it addresses compounded conservatism, links risk targets with environmental concentrations,

improves transparency and makes greater use of available data. Numerous offices and bodies within the EPA have endorsed or used the probabilistic approach for several years, and the agency recently released a Risk Assessment Forum White Paper on that method. The agency's recent draft update to the Guidelines for Human Exposure Assessment also recognizes the value of that approach. The EPA should be deriving its own human health criteria recommendations using the probabilistic approach, encouraging states to do so, and then approving the resulting criteria based on that method, as they certainly are "scientifically defensible."

Finally, it should be noted that a probabilistic risk assessment approach is not a panacea. Those using it still must make reasoned policy choices regarding exposure and risk, just like with a deterministic approach. Otherwise, we will again be deriving criteria with an excessive level of conservatism that is not needed to protect human health.

Conclusion

Similar to the concerns many have raised with the WOTUS rule, the EPA is rewriting the rules governing its role and that of states under the Clean Water Act. In this case, the EPA is imposing new, overly protective risk policies contrary to its own regulations and long-standing guidance that make clear states have the discretion to develop their own criteria as long as they protect designated uses. The EPA may prefer that the states adopt its science and policy choices, but states can choose not to do so when developing their human health criteria as long as those choices reflect site-specific conditions or are scientifically defensible. Considering the compounded conservatism inherent in the EPA's national default criteria, the absence of measurable benefit, and the billions of dollars in compliance costs that the new policy would impose, it is hard to see how the EPA could successfully defend rejection of state criteria simply because they do not reflect its latest policy preferences.

