RISK ASSESSMENT

EPA Analysis of Radon in Water Is Hard to Swallow

For much of the past year, a group of scientists in the Environmental Protection Agency (EPA) has been at the center of a gathering storm of controversy. Their work on the potential health risks from radon in water, culminating in a report suggesting that strict limits should be imposed, rejected advice from the agency's own science adviser and drew fire from an outside panel of experts. But the scientists have at least one powerful friend: Senator John Chafee (R–RI), who has accused critics of trying to undermine EPA's science to further their own policy agendas.

The issue is what, if any, steps should be taken to keep radon out of the nation's drinking water. The answer could involve hundreds of millions of dollars in new purification technology, so it's no surprise passions are aroused. But additional ingredients have raised the temperature of the debate. For one thing, virtually nobody believes that, in comparison with many other environmental contaminants, radon in drinking water poses a major threat to public health—EPA's own analysis indicates fewer than 200 people die each year from ingesting or inhaling radon from drinking water. And for another, uncertainties in the science underlying the risk analysis provide room for different interpretations and divergent views on regulation.

To EPA's critics, this case is a prime example of how hard it is for the agency to incorporate science into decision making. Last year a committee of outside experts, established by then-EPA Administrator William Reilly, said the agency's scientific priorities are out of sync with the major health threats facing the country. The panel also said EPA's "policies and regulations are frequently perceived as lacking a strong scientific foundation." But perhaps most of all, the events of the past few months show how EPA's scientific priorities are determined by Congress. "It troubles me the extent to which science is largely treated as an afterthought" in developing regulations, says Richard Sextro, a physicist at Lawrence Berkeley Laboratory who serves on the radiation advisory committee of EPA's Science Advisory Board (SAB). "Policy is arrived at largely for ascientific reasons," he says.

Congress wants to know. Radon, an invisible, radioactive gas that seeps out of the ground, has long been regarded as a health hazard associated with indoor air; each year, according to EPA, radon causes an estimated 13,600 U.S. deaths from lung cancer (see box). EPA's efforts to come to grips with the problem of water-borne radon go back at least 7 years, when Congress, in reauthorizing the Safe Drinking Water Act, gave EPA 3 years to propose standards for 83 contaminants (including radon) in drinking water. EPA came up with a proposal in 1991 but never implemented it. Last year, two senators, Chafee and Frank Lautenberg (D–NJ), desiring to see EPA finalize regulations that govern water-borne radon, directed EPA to produce a report within 9 months on the risks the element poses in drinking water. This report, which will form the scientific basis for regulations, was supposed to be completed by 31 July; however, as *Science* went to press EPA officials had not yet sent the report to the White House Office of Management and Budget (OMB) for clearance before its transmittal to Congress.

The task of preparing the report fell to scientists in EPA's Office of Water, which got help from other EPA program offices. In July top EPA officials cleared a draft estimating that radon in drinking water causes 192 excess cancer deaths in the United States each year. That figure was based primarily on an unpublished study by radiologist Jack Correia and others at Massachusetts General Hospital on the organ distribution of radioactive xenon (like radon, a noble gas) in humans. Douglas Crawford-Brown, a radiation biophysicist at the University of North Carolina, Chapel Hill, who prepared EPA's ingested radon risk estimate, says it was the best study EPA could find to approximate the movement of radon in the body. Decades-old studies on radon ingestion in humans were deemed unsuitable because they had not as thoroughly measured the amount of radon deposited in specific organs, he says.

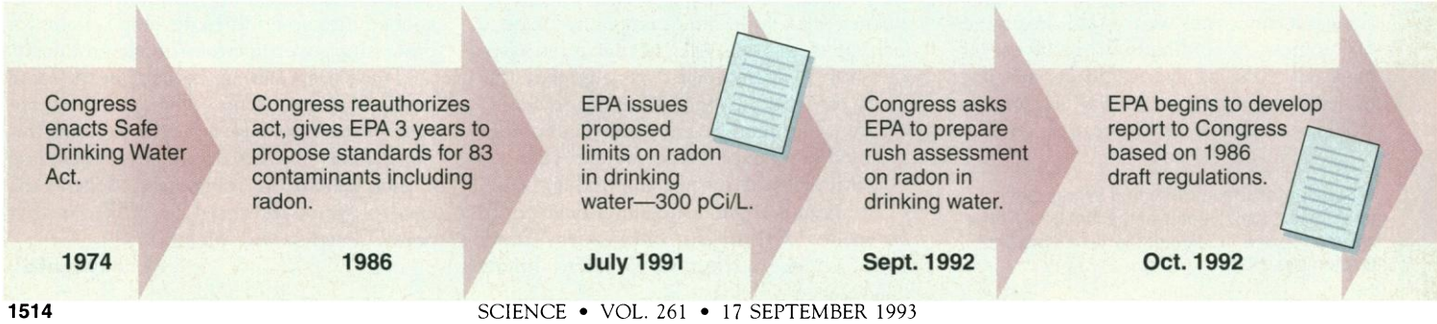
Although the total number of deaths may seem small, the draft report recommends that EPA set a strict regulation for radon in drinking water. It says sticking to the radon limit the agency had proposed in July 1991, a maximum contaminant level (MCL) of 300 picoCuries per liter (pCi/L), would reduce lung cancer fatalities to an estimated 107 per year at an annual cost of $272 million, or $3.2 million per cancer fatality avoided. Stephen Page, director of EPA's radon program, says this figure is "within the range of most EPA programs."

The analysis was questioned within EPA even before the draft report was completed. The agency's science adviser, William Raub, was first to sound the alarm after reviewing the documents the water office was using. In February he urged EPA scientists to consider the "enormous uncertainty" that underlies risk estimates of radon. Expressing sentiments shared by outside researchers, Raub said there were "inconclusive epidemiological findings as to whether radon (either ingested or inhaled) actually presents an appreciable risk within the typical American household if none of the occupants smokes tobacco products."

Raub suggested EPA should set a maximum exposure to radon in water equal to that from radon in outdoor air—a "relative-risk" approach that allows regulators to tackle the most pressing health risks first. This approach would result in an MCL in the range of 1500 to 2000 pCi/L, Raub said. But EPA regulators rejected Raub's advice and suggested a level five times lower than his lowest recommendation.

Raub's concerns got some high-level support when EPA submitted its findings to the SAB, the report's last stop before OMB and Congress. The SAB slammed the report's conclusions, arguing that "there is no direct epidemiological or laboratory animal evidence of cancer being caused by ingestion of radon in drinking water." As a result, "it is not possible to exclude the possibility of zero risk from ingested radon."

In a 30 July letter to EPA Administrator Carol Browner, Roger McClellan, president of the Chemical Industrial Institute of Toxi-



Radon Risks Up in the Air

The Environmental Protection Agency (EPA) is fighting a war on two scientific fronts in its efforts to develop regulations governing exposure to radon. Just as intense as the battle over drinking water standards (see main text) is a dispute over the health effects of radon in indoor air.

EPA is at odds with scientists at the Department of Energy (DOE) and elsewhere over whether the effects of high doses of radon can be extrapolated to the low levels found in homes. The debate centers around epidemiological studies that found uranium miners exposed to radon and radon daughters—the radioactive decay products of radon—were more likely to get lung cancer than people who never worked in a uranium mine. EPA argues these studies imply that indoor radon causes between 7000 and 30,000 lung cancer deaths per year, with 13,600 as a best estimate—a view supported by a 1988 report from a National Research Council (NRC) panel, which concluded that such an extrapolation is reasonable.

But critics believe the agency needs to temper its radon warnings with an acknowledgement of the uncertain state of the science. Even the NRC panel, for example, stated that differences between mining and domestic environments, as well as the interaction between cigarette smoke and radon, "remain incompletely resolved." And David Smith, director of DOE's health effects and life sciences research division, argues that "even though there's better data on radon than on many other carcinogenic agents, that doesn't mean it's scientifically sound to extrapolate from miners to homeowners."

For Smith and others, the jury is still out on radon's effects at low levels of exposure. "You probably can't draw a straight dose-response line from high-dose to low dose," contends Marvin Frazier, a radiation biologist in Smith's shop. Frazier insists there's evidence to support a model in which low doses of radon cause fewer lung cancers than estimated, pointing to animal studies that suggest the body has two ways to repair cellular damage from radon daughters. At the same time, Frazier says, some animal studies suggest low doses of radon may cause proportionally more cellular damage than high doses. The bottom line, says Smith, is "we just don't know what the health risk of radon is in the home...these uncertainties tend to get lost in setting policy."

Another critic of EPA's approach is Michael Reimer of the U.S. Geological Survey, which helped EPA draw up a map of nationwide radon levels. In an 11 June 1992 letter to Michael Shapiro, EPA's deputy assistant administrator of the Office of Air and Radiation, Reimer says that "scientists prefer a positive, open, honest, and thorough treatment" instead of the "negative, scare-tactic, minimal information approach" that EPA has taken. Adds Smith: "We don't think it's right to frighten the public when there's so much uncertainty."

For the most part, EPA officials brush off these criticisms. They "aren't really criticizing science, they're criticizing policy," says engineer Margo Oge, director of EPA's Office of Radiation and Indoor Air, which oversees the radon program. Oge acknowledges that EPA "has had a very strong ad campaign that's really offended people in the scientific community," but she says it was necessary to rouse the public from its apathy to radon risks.

Those in Congress who follow the radon issue are troubled by the conflicting messages from DOE and EPA and would like to see more cooperation among government agencies. Representative Ron Wyden (D–OR) is considering tacking on an amendment to a bill called the "Radon Awareness and Disclosure Act" that would create an interagency committee to set a federal agenda for radon research. "We're tired of the pissing match between EPA and DOE," complains one congressional staffer. "We just want to see the research get done right," he says.

Neither EPA nor DOE officials like Wyden's proposal, however. Smith says he would prefer to receive guidance from the Committee on Interagency Radiation Research and Policy Coordination, chaired by U.S. Department of Agriculture biotech chief Alvin Young, which monitors radon legislation and already has studied the NRC report and EPA's proposed drinking water regulations for radionuclides. Meanwhile, Oge says current efforts to coordinate research are proceeding smoothly. "We don't need the legislation—we've already established a dialogue with other agencies to get together and develop a strategy," she says.

Judging from the tension between EPA and DOE, however, that dialogue needs to be improved before the government can agree on the health risks of radon.

–R.S.

cology and chairman of the committee that reviewed the report, said the document failed to acknowledge the agency's disagreement "with interested parties"—outside scientists, other federal agencies, and water utilities—over the extent of exposure, risk, and mitigation costs of water-borne radon. "We cannot emphasize too strongly the SAB view that a relative risk orientation should be applied to the decision-making process," McClellan stated. In SAB's view, an MCL of 3000 would be justified.

The SAB's attitude is no surprise. Last year, in a letter to Reilly, the board urged EPA to "apply our limited resources to more important risks." Repeating phrases from an earlier report, the board added, "Frankly, radon in drinking water is a very small contributor to radon risk."

But McClellan's conclusions didn't sit well with Senator Chafee. On 5 August he fired off an angry letter to the chair of the SAB's executive committee, University of Texas, Austin, environmental engineer Raymond Loehr, who had co-signed the McClellan letter. "The effectiveness of the SAB as a science adviser may well be undermined," Chafee fumed, "if members use it as a platform to advocate policy positions that have little to do with the quality of the scientific assessments

Raub

EPA science adviser stresses uncertainty.

Feb. 1993

McClellan

Loehr

EPA's Science Advisory Board (SAB) gets indigestion.

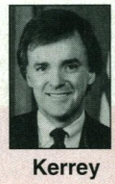
July 1993

Chafee

Congress blasts the board.

Aug. 1993

Clinton proposes changes to law, Senate passes amendment that delays implementation of radon regulation at least 1 year; risk-assessment report expected to go to Congress later this month.



Kerrey

9 Sept. 1993

relied upon by EPA." Although disavowing an opinion on EPA's proposed rule, Chafee said "any policy maker would find [the report contains] enough information...to make a scientifically justified decision to regulate radon in drinking water."

On 24 August Loehr answered that the board was simply trying to give EPA information "that has the least uncertainty and best scientific basis." As McClellan explained, "I didn't have any particular ax to grind—we just called it as we saw it."

EPA officials are now preparing a reply to the McClellan report. Jim Elder, director of the water office, says EPA is revising the report to respond to SAB's concerns. "When you take this piece of data and that piece of data and put it all together, you end up drawing conclusions that look more sound than you intended them to," says Elder. "We're admitting it wasn't perfect," he says.

In the meantime, Congress once again has interceded: Last week, the Senate appropriations committee passed an amendment to EPA's 1994 budget that would delay until October 1994 the implementation of EPA's proposed MCL for radon. The legislation came from Senator Bob Kerrey (D–NE), who argued that the cost of installing equipment in Nebraska water systems to remove radon "would accomplish practically nothing." The amendment, he said in a statement, "gives the federal government more time to evaluate compelling scientific evidence which casts serious doubt on the need for the new regulation."

Kerrey's amendment "would give EPA the breathing room to reconsider its proposed standard," says a Senate staffer. And some more pressure on EPA to rethink its radon policy is in the offing: *Science* has learned that the Office of Technology Assessment (OTA) plans later this month to release a report called "Research on Health Risk Assessment" that criticizes EPA's radon policy. Like many observers of the radon saga, the authors of the OTA report view EPA's troubles with water-borne radon as a symptom of the agency's problems in translating its science base to policy—problems Browner has pledged to fix without saying how.

–Richard Stone

CONFLICT OF INTEREST

White House Seeks Uniform Policy

The Clinton Administration has sent the two leading science agencies back to the drawing board in search of a single, government-wide policy on financial conflicts of interest by federally funded researchers. White House officials have asked the National Institutes of Health (NIH) and the National Science Foundation (NSF) to rewrite proposals that have been years in the making, with the goal of developing one set of regulations that apply to any researcher, regardless of the source of funding.

The new plan, spearheaded by the White House Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB), would reconcile differences in current draft regulations written by NSF and NIH. It would jettison NSF's proposal to require institutions to inform the funding agency of the financial holdings of every federally funded researcher as well as NIH's plan to collect such information only for those whose holdings exceed a certain level. The new guidelines would give institutions the authority to review all financial holdings and resolve any potential conflicts before submitting grant proposals, and to certify to the funding agency that they have done so. Each agency would conduct random audits to ensure that the policy is working.

The new policies, if adopted, would mark a change for both agencies. NIH, in its latest draft, had intended to ask institutions to clear with the agency any instance in which an investigator held stock valued at more than $50,000 in a company related to his or her research. The draft, written as a formal rule that has gone through more than a dozen incarnations over the past 5 years (including the release and subsequent retraction of one version), has not yet been published for public comment.

NSF was closer to issuing a final policy. The agency has already published a version for public comment in which it proposed to review grant requests internally for potential conflict, based on financial disclosures supplied by the individual applicants. But NSF received hundreds of letters from researchers and institutions objecting to the effort needed to satisfy such a detailed reporting requirement. In response, the agency has revised its policy to allow institutions to certify their own investigators as conflict-free.

Both agencies submitted their proposed drafts for Administration clearance earlier this year with the hope of publishing them in September. But last month OMB, with OSTP's prodding, decided instead to revisit the entire conflict issue and called in officials from both agencies. Armed with new marching orders, NSF and NIH officials are rewriting their versions of the guidelines to conform to one another and to the outlines of the proposed common federal policy.

This process is being hailed by research organizations such as the Association of American Medical Colleges as a long-needed clarification of federal conflict policies and a simplification of the reporting requirements for individual scientists. Under the proposal, researchers would typically disclose their financial holdings only to their own institutions, which would review them and resolve any potential problems before certifying to funding agencies that they have done so. Agency officials are likewise pleased with the idea of uniform policies, says NSF associate general counsel Miki Leder.

The initial reaction from Congress was generally positive. Steve Jennings, an aide to Representative Ron Wyden (D–OR), says that the broad outline of institutional screening backed by federal oversight "is a vast improvement over what we have now—which is nothing." Jennings, who investigated research conflict of interest in the course of taking the Scripps Research Institution to task for a proposed $300 million agreement that would have given Sandoz Corp. first rights to NIH-funded research at Scripps, says NIH must still set some clear guidelines on what constitutes a potential conflict. But once that is done, he says, "it makes more sense for NIH to monitor each institution than to monitor [the financial holdings of] each and every grant recipient."

The revised rules are expected to be issued around the end of the year and serve as a model for future conflict-of-interest rules issued by any agency that awards research grants. This schedule could push NIH past a 7 December deadline imposed by Congress in legislation passed this spring. But NIH officials believe the delay is a fair tradeoff for a government-wide conflict policy and they do not expect trouble from Congress.

But even as the top two research agencies join hands on a common policy, at least one other agency is heading off in quite a different direction. Last week, the Food and Drug Administration's (FDA) science advisory board recommended that the agency develop conflict-of-interest rules requiring full financial disclosure by individual investigators whose research data is submitted as part of an application for FDA drug or product approval. FDA hopes to issue draft regulations covering such research later this year; research that FDA itself funds would fall under the NIH rule, which will apply to all research sponsored by the Public Health Service.

FDA's harder line on clinical research, agency officials and congressional staffers say, reflects the fact that it, unlike NSF and NIH, is a regulatory agency that must protect the public from the consequences of a scientist testing a product in which he or she holds a financial interest. "FDA is going to have to make material judgments on the basis of data submitted by these researchers," says Jennings. "It's a matter of public health, and that ratchets up the level of oversight needed."

–Christopher Anderson