Water Act Revision Complete

Congress was expected in early December to endorse and send on to the President the 1977 amendments to the Clean Water Act of 1972. The measure, commonly referred to as the act's "midcourse correction" on the road to "zero discharge," has been subjected to 2 years of deliberation. Environmentalists and industry both appear to be reasonably satisfied with the results, which include a 1-year extension of interim deadlines for industrial waste cleanup.

The two most controversial aspects of the new bill relate to industrial point source polluters and to the dredging and filling of wetlands.

The bill breaks pollutants into three categories: "conventional" (dirt, sewage, organic waste); "toxic" (the Environmental Protection Agency has a tentative list of 129 toxic chemicals); and "nonconventional"—a new category of chemicals, including some pesticides and heavy metals, whose toxicity is yet to be determined. The deadline for installation of "best available control technology" (BAT) for conventional pollutants has been moved from 1983 to 1984, although waivers may be applied for in cases where BAT is not deemed to be cost-effective. For toxic pollutants, the deadline is 1984, with no exceptions.

Some environmentalists are concerned that dangerous chemicals may stay interminably on the unconventional list, thereby escaping the stringent controls applied to those on the toxic list. However, an EPA official says the bill has been designed, through elimination of formal hearing requirements and additional discretion given the EPA administrator, so that it will not be as difficult as it has been in the past to have a chemical regulated as "toxic."

Compromise on Wetlands

As for wetland dredging, the House-Senate conference committee made a major concession to the House when it voted that permits would not be required for discharge of dredge or fill in projects "specifically authorized by Congress." This covers many of the big government stream channelization and dam projects. Instead of getting a permit, the agencies involved will be required to submit environmental impact statements (EIS's) to the relevant congressional committees. Environmentalists consider this exemption outrageous, and the EIS provision silly since the committees are scarcely equipped to evaluate such statements. An EPA official explains that members of Congress "don't want EPA and the Corps of Engineers [the permit-granting authorities] second-guessing Congress and the President" on big projects, or jumping in to halt half-completed ones.

Otherwise, the bill embodies a continuing evolution of the original wetlands policy. States will be given control over permit programs on other than major bodies of water if they have a plan approved by the EPA. Also, the bill resolves a controversy that began a couple of years ago when the Corps put out a press release saying that farm plowing might require a permit (the plow being a "point source," and the dirt "fill"). The law now specifically exempts discharge activities in what are defined as "normal" farming, mining, and timbering practices.

Finally, there is a new, futuristic clause that would permit states to forget about permits altogether if they submit to EPA an acceptable statewide regulatory scheme covering all point source dredging and filling operations.

Among other items covered in the bill is continuation of the federal grant program for sewage treatment plants, with $24.5 billion authorized over the next 5 years. The federal share of the cost of treatment facilities is 75 percent, but that can go up to 87.5 percent in cases where "alternative or innovative" treatment technologies are being tried.

The need to renew the sewage grants was the main reason Congress wanted to get the bill out this year. Jim Banks of the Natural Resources Defense Council adds that environmentalists are pleased that the extension was for 5 rather than 2 years—not only because it helps cities to plan, but because the water act is less likely to be brought up for tinkering and possible weakening before the expiration of the sewage authorization.—C.H.

George Mann of Vanderbilt University, a forceful critic of the diet-heart disease hypothesis, believes that the LRC results could not be extrapolated to the general population because they involve a select group of high-risk men who are not representative of the rest of the population. Moreover, cholesterol is lowered with a drug, not by a diet alone, which further confounds the results.

According to Mann, at least one planner of an NHLBI prevention trial admits privately that the trial he is involved with cannot produce meaningful results. But, Mann says, the planners of these prevention trials "get so involved in obtaining financial support that they'll do and say just about anything to keep their trials going."

Closely related to the problem of deciding whether to start a randomized, controlled clinical trial is the problem of deciding when such a trial should begin. Usually, a randomized controlled trial is suggested on the basis of presumptive evidence that a particular treatment or preventive measure is useful. However, Chalmers estimates that fewer than 20 percent of trials testing new therapies are well-controlled. And this percentage can be far smaller than 20. A few years ago, Chalmers surveyed the clinical-trial abstracts submitted to the annual meeting of the American Gastroenterological Association. He noted that only 4.5 percent of those trials appeared to be well-controlled.

Many physicians prescribe treatments on the basis of results from uncontrolled or poorly controlled studies. They often come to believe in the efficacy of those treatments and feel ethically constrained from allowing their patients to participate in randomized controlled trials. They cannot in good conscience risk denying a patient what they believe to be the best treatment, even if their belief is not scientifically justified.

Clinical investigators are often in a quandary when they must decide when to start a randomized controlled trial. To start when a great deal of presumptive evidence favoring a treatment has been published is to risk fighting physicians who already believe in the treatment. To start too soon is to risk wasting years and a great deal of money testing a treatment that, by the time the trial results are out, has been modified, replaced, or discarded. Both of these difficulties arose when investigators planned randomized controlled trials of the effects of coronary bypass surgery.

Recently, investigators at the NHLBI initiated a randomized controlled trial to