Toxic Substances Legislation: How Well Are Laws Being Implemented?

The nineteen-seventies seem to be dedicated to the environment. After generations of benign neglect as well as nearsighted exploitation, it has become apparent that we are wreaking damage on our environment at considerable cost in terms of the quality of life and human health. Remedy comes slow, and is not without considerable cost of its own, but it looks as though we have entered an era marked by a new environmental ethic.

In the first years of this decade, the Environmental Protection Agency (EPA) and the presidential Council on Environmental Quality (CEQ) came into being. The environmental movement, which began in the 1960's as a protest movement among the well-educated, well-intentioned young, has matured into a forceful, reasonably well-financed lobby run by scientists and lawyers who are making successful careers out of environmental protection. Since 1970, Congress has passed more than a dozen pieces of environmental legislation.

Environmental protection means many things, from preserving the Alaskan wilderness to saving endangered species to reducing our exposure to toxic substances in the air, in water, in food, in the workplace, and at home. The problem of toxic substance control (especially with respect to agents that cause cancer) is at once particularly important and contentious. In recent years, we have witnessed a number of tragedies caused by toxic substances in the environment: asbestos, Kepone, polyvinyl chloride, and mercury come readily to mind. Leakage of chemical wastes buried underground has become an almost epidemic problem of the chemical age.

In an attempt to cope with the newly perceived crisis in toxic substances, Congress has put on the books eight laws specifically designed to regulate toxins in the environment. Perhaps the most complex and far-reaching of the eight is also the newest—the Toxic Substances Control Act (TSCA). Passed late in 1976, TSCA is meant to give the federal government control over chemicals not already regulated under other laws. Furthermore, it is written to give EPA a first-strike authority with respect to clearing an agent *before* it enters the marketplace, in addition to power to control existing chemicals if they are shown to be unreasonably hazardous. As President Jimmy Carter observed in his environmental message to Congress a year and a half ago, "The presence of toxic chemicals in our environment is one of the grimmest discoveries of the industrial era. Rather than coping with these hazards after they have escaped into our environment, our primary objective must be to prevent them from entering in the first place."

Can TSCA Be Implemented?

TSCA, in theory, does just that. Whether theory can match reality has become one of the predominant questions in environmental policy circles today. People are asking whether it is possible to administer the law.

In a series of articles beginning this week, the news sections of *Science* will address the myriad scientific and political issues that toxic substance legislation in general and TSCA in particular pose.

The EPA's first job under TSCA is to prepare an inventory of all the chemicals manufactured in or imported into the United States, one reason being that it cannot get into the business of premarket clearance of new chemicals or "significant new uses" of existing ones without knowing what chemicals are already in use. Although this sounds logical enough, the information-gathering requirements of TSCA are formidable and the inventory, originally scheduled to be published this fall, now is not expected to be ready until early next year (or later). For all practical purposes, TSCA cannot be implemented until the inventory is complete.

Of the estimated 4.3 million chemicals in existence, some 63,000 are thought to be in common use in this country. The sheer volume of chemicals alone is one indication of the magnitude of the problem of compiling an inventory, and it is complicated by the fact that many of them are produced in small quantities by small companies whose data are not in any central bank. But political issues beset the inventory in much the same way they beset the law itself, accounting in part, for the fact that TSCA languished in Congress for 5 years before winning approval.

At first, EPA was going to ask simply for a list of chemicals manufactured during the past 3 years, a position quite satisfactory to industry. As Jacqueline M. Warren of the Environmental Defense Fund pointed out in recent testimony before a congressional subcommittee, EPA's original plan did not even call for data on the names and addresses of the manufacturers. A compromise was reached in which EPA will collect information on chemicals and manufacturers but will not require data on what the chemicals are used for, thereby allowing industry to protect "use" information that it considers a trade secret. Although no one is completely satisfied, it can be said that when the inventory is finished, we will have for the first time a profile of the chemical industry in this country, and EPA can begin to regulate new chemicals under TSCA.

TSCA requires a manufacturer to notify EPA of his intention to market a new chemical; it requires EPA to answer within 90 days. Along with his notification, the manufacturer must supply any data on possible hazards. Then, taking costs and benefits into account, EPA is supposed to decide whether the new chemical presents an "unreasonable" risk to human health or the environment. It all makes very good sense. By requiring EPA to act quickly, the law intends to spare the manufacturer undue delay in getting his product on the market. However, EPA is understaffed. (A provision in the President's budget for next year calls for 600 new EPA employees.) Some estimates hold that 1000 new chemicals enter the marketplace every year, although some industrial sources say the figure is closer to 100 "significant" new agents. Already, TSCA is a nightmare of paperwork, some say a positive threat to trees. To keep up with that load, one EPA official told *Science*, the agency would have to rule on four new chemical applications every working day, which is clearly impossible. Therefore, will the harried administrator who, after 90 days, must say "yes," "no," or "more safety data, please," too often choose the latter?

Although EPA has principal responsibility under TSCA, it is by no means the

Federal legislation passed since 1970 regulating toxic substances.

- Clean Air Act, 1970
- Occupational Safety and Health Act, 1970
- Federal Environmental Pesticide Control Act, 1972
- Federal Insecticide, Fungicide, and Rodenticide Act, 1972
- Federal Water Pollution Control Act, 1972
- Safe Drinking Water Act, 1974
- Resource Conservation and Recovery Act, 1976
- Toxic Substances Control Act, 1976

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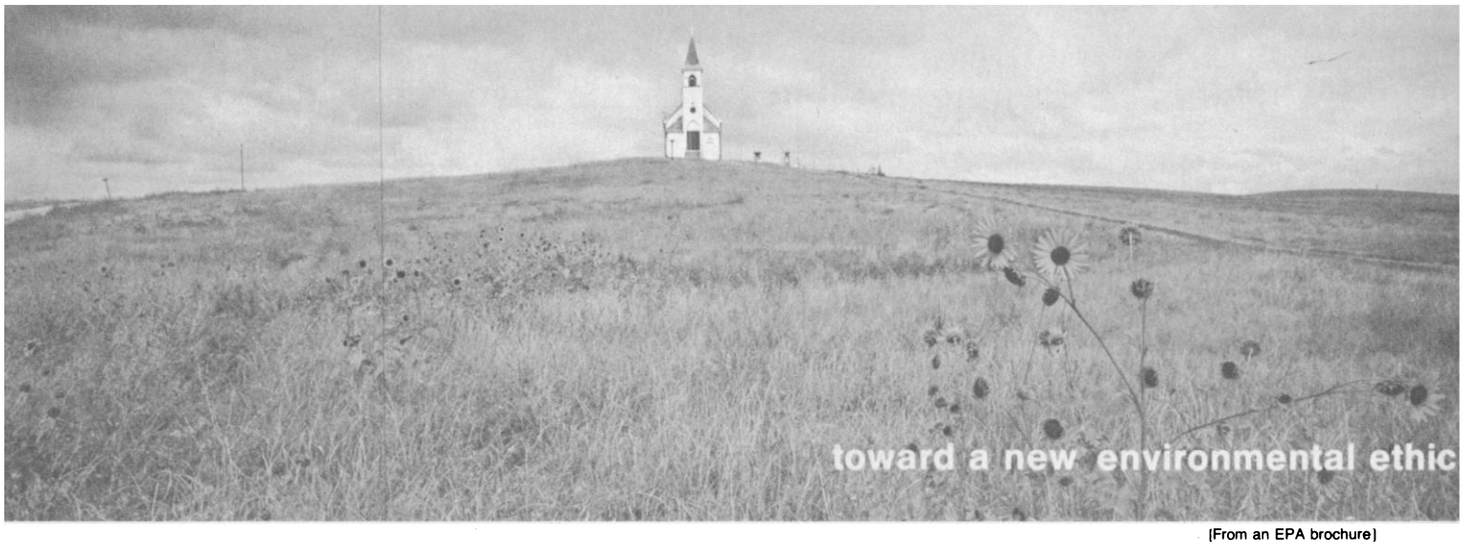

[From an EPA brochure]

only agency with tough regulatory problems under toxic substances laws. The Occupational Safety and Health Administration, which is in the midst of establishing a policy governing carcinogens in the workplace, is of equal importance.

Although environmental toxins cause a variety of human ills, including birth defects, miscarriage, heart disease, stroke, emphysema, and neurological deficits, it is fear of cancer that is at the heart of our commitment to a safer environment. For years, viruses and genetic predisposition stood at the top of the list of probable causes of cancer. But then, in the mid-1970's, the idea that "60–90 percent" of human cancers are "environmentally" caused gained currency, as did the idea that the incidence of cancer in this country is increasing. Whether either of these propositions is correct in toto or in part remains in doubt, but few would dispute the observation that they have had a powerful effect on society's attitude.

In many cases, it is a matter of interpreting data to suit one's point of view. For instance, in a speech several months ago, John F. Schmutz of E. I. DuPont De Nemours and Company, declared that "The incidence of cancer is not rapidly increasing. If the effects of cigarette smoking are excluded and statistics are age adjusted, cancer incidence and cancer deaths per unit population have remained about constant over the last twenty-five years." At about the same time, Gus Speth, a member of CEQ, told the League of Women Voters that "by 1960 cancer mortality in the U.S. was already about double that which might have been predicted on the basis of the increasing age and size of the population. It is clear, from statistics in other countries as well as our own, that something new is loose in the world."

Not surprisingly, industry rejects (and resents) the implication that what is loose is a host of carcinogenic chemicals, especially in light of data showing that the greatest increase in cancer is attributable to smoking and that dietary factors, alcohol consumption, and radiation are among the putative environmental causes of cancer. " 'Environment' does not equal industry," Schmutz stated. "Reliable experts estimate that 5 percent or less of cancer is industrially related."

Indeed, many "experts" have accepted that 5 percent figure as a reasonable one, and the argument has been made that it is simply easier for legislators and regulators to go after chemical manufacturers than heavy smokers. But then, only a couple of weeks ago, Health, Education, and Welfare Secretary Joseph A. Califano, Jr., weighed in with the opinion that a full 20 percent of human cancers are caused by industrial exposure. The secretary based his statement on a yet to be released National Cancer Institute–National Institute for Environmental Health Sciences study that says, "If the full consequences of occupational exposures in the present and the recent past are taken into account, estimates of at least 20 percent appear to be much more reasonable and may even be conservative." Until the data can be widely evaluated, no one is in a position to say whether the study is right or not.

At the heart of the challenge of controlling toxic substances is the fact that there are few uncontestable data. Uncertainty prevails in the regulatory arena. And so, it becomes necessary to act in the face of uncertainty, to make judgments and regulatory decisions on the basis of the best available data and hope that the cost turns out to be worth it. And cost it will. At the upper end of the predictive scale, there are estimates that TSCA will cost the chemical industry $2 billion a year, although most estimates are more conservative. With inflation as important an economic issue as it is now, President Carter has even asked his economic advisers to look at environmental regulations from an inflationary standpoint (much to the environmentalists' horror). TSCA itself explicitly allows the EPA administrator to consider costs in decision-making and, in comparison with other environmental legislation, is unusual in that regard.

As noted in the accompanying article on the scientific basis of toxic substances control, legislation rests on the "fragile premise that it is possible to identify which chemicals are hazardous . . . and which are safe and can be ignored." Accepting the necessity of acting in the face of uncertainty, it is sensible to conclude that we know enough to make an intelligent start. But it is equally pertinent to remember how much remains to be accomplished scientifically. The demands of TSCA and its companion legislation, which implicitly call for a pool of scientific manpower we do not have, reveal how imprudent it has been to let the disciplines of toxicology and epidemiology languish. It is indeed possible that one of the unanticipated benefits of toxic substances legislation will be a strengthening of these sciences. Federal support is gradually increasing, but some observers are going so far as to predict that the best toxicology in this country may soon be within industry, which is investing substantial sums in this area. At present, five chemical companies have strong toxicology laboratories and two more are being developed.

It is obviously important to begin an assessment of toxic substances regulation now, but, as Steven D. Jellinek of EPA has pointed out, it may well be 10 years before we can tell what its true impact has been.

—BARBARA J. CULLITON