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NEWS AND COMMENT

EPA and Toxic Substances Law: Dealing with Uncertainty

The associate administrators of the Environmental Protection Agency (EPA) often gather at breakfast Monday mornings for an informal exchange on the ongoing battle to protect the environment. So frequently have the Sunday papers carried a story indicting yet another chemical as a threat to health and the environment that the offending substance has come to be ruefully referred to as the "chemical of the week."

The point underscored is that chemicals are ubiquitous in the environment and that some of them are dangerous. Chemicals also contribute significantly to American living standards, and regulating them involves substantial economic consequences. In 1976 Congress put EPA in charge of resolving this dilemma when it enacted the Toxic Substances Control Act (TSCA), which provided for the first comprehensive regulation of the chemical industry.

EPA's most obvious problem is the estimated 63,000 chemicals already in commerce and others coming into use at a rate of perhaps 1000 a year. The real difficulties for EPA, however, lie in the fact that the means of establishing long-term effects of these chemicals are imperfect. In regulating toxic substances, therefore, EPA must contend with a considerable measure of scientific uncertainty. At the same time, if the agency is not to be overwhelmed by sheer numbers of chemicals, it must set workable priorities for determining which chemicals to test and how to test them. It is not surprising, therefore, that now, at the end of the second year since the passage of TSCA, questions are being raised as to whether the law is enforceable or, to put it another way, whether EPA is capable of enforcing it.

TSCA is complicated and controversial legislation. The complexity is in part a product of the controversy. Six years of negotiations and debate were necessary before Congress passed it. Adversaries throughout the process were representatives of chemical industry and environmental groups. The tension persists, with the former group typically arguing that EPA is being too tough and the latter that the agency is not tough enough.

When it passed, TSCA was regarded as a substantial improvement on previous environmental laws: second-generation environmental legislation that built on experience. The major departure from earlier law were the provisions aimed at preventing cancer-causing substances from ever reaching the environment. As EPA administrator Douglas M. Costle is fond of saying, TSCA makes EPA a preventive health agency as well as an environmental agency. To protect EPA from being swamped by the sheer number of chemicals, the new law was designed to give the agency greater leeway in setting priorities for choosing which chemicals to regulate—enabling it, so to speak, to deal with worst things first.

TSCA is second-generation legislation also in the sense that it reflects the reaction of recent years against no-holds-barred federal regulatory activity and requires EPA to perform a balancing act between economic and environmental imperatives.

For a federal agency, the heart of any law is the section which sets forth its authority. TSCA states that the act's authority over chemicals "should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

The law does not define "unreasonable risk" and, in the nearly 2 years since TSCA was signed into law, EPA has been mainly engaged in adding flesh to the spirit of the statute through the tortuous and time-consuming process of writing administrative regulations aimed at giving "unreasonable risk" a definition which is defensible.

To be sure, other circumstances have contributed to the slow pace of TSCA implementation. TSCA was enacted at the end of the Ford regency. It was not until nearly a year after the bill became law that EPA filled the post of director of its Office of Toxic Substances (OTS) with the appointment of Steven D. Jellinek, who came to EPA from the post of staff director of the Council on Environmental Quality. The last year has been spent hiring staff, including most of the upper and middle management, while at the same time formulating policy and get-

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ting under way with writing regulations. OTS was also under pressure to move forward with the control of suspect chemicals already in the environment—termed "existing chemicals." TSCA mandated action on PCB's and fluorocarbons. OTS was also afflicted with chronic EPA problems of coordination with other divisions within the agency and cooperation with other environmental agencies. And, since EPA is in the throes of a severe space problem, there has been literally no place to put people as OTS "staffed up" to administer the act. The TSCA budget for the fiscal year just ended was $29.2 million and would rise to $58 million next year under the terms of the appropriations bill passed by Congress. OTS staff now numbers 200, up from about 100 a year ago. The staff is scheduled to double again in size in the next year if the money bill is signed and the agency can find space for the new people. Meanwhile, there is a formidable manpower problem afflicting OTS, because of the current shortage of professionals trained in the appropriate specialities, particulary toxicology. Ironically, the buildup by industry of its scientific capacity to comply with TSCA's requirements has made it difficult for OTS to find the professionals needed to make the scientific judgments required to implement the law. Of immediate concern is the government freeze on federal employment which environmentalists say will stymie OTS hiring at a crucial time.

Initially, however, the main pressures on OTS have arisen from the task of developing policies and procedures for a complex law while building a bureaucracy to administer it. EPA's first administrator, William Ruckelshaus, likened the start-up phase of the agency to having an appendix removed while running a hundred-yard dash. Something of the sort could be said of OTS.

OTS has concentrated mainly on two sections of the law, one providing for an inventory of existing chemicals and the other setting out procedures for premanufacturing notification, the key section for preventing dangerous chemicals from reaching the environment. It is generally agreed that only if OTS does a good job in implementing these sections will there be a solid foundation for administering TSCA.

TSCA divides the universe of chemicals into "old chemicals" listed in the inventory and "new chemicals" subject to premanufacturing notice. With old chemicals, the burden of proving that they pose unreasonable risk will fall largely on EPA. With new chemicals, the manufacturers will be expected to provide information indicating that they do not constitute such a risk.

The law mandated that the inventory be completed 315 days after passage of the law, but the deadline has slipped more than a year and publication is now scheduled for March. The delay is attributable in part to the wheel-spinning caused by the change of administrations. But after the Carter Administration assumed office, the new management at EPA decided that more information was needed for the inventory than had originally been asked from manufacturers. A decision had been made, partly because of time pressures, simply to produce a list of what chemicals were being produced. Environmental groups argued that such an inventory would be virtually useless for regulatory purposes and urged that more information—on production sites and volumes of chemicals produced, for example—be required. EPA Adminstrator Costle in June of 1977 agreed to a broader approach. Industry expressed opposition to this on a number of counts ranging from objections to the expense of complying with altered reporting requirements to worries about increased threats to proprietary secrets involved in the new inventory questions. Vigorous negotiations produced a compromise, which did require information on sites and on production volume, but eased some proposed requirements and gave tighter assurances of confidentiality. The information for the inventory was collected last spring.

Premanufacture Notice

The law prescribes that publication of the inventory will activate the premanufacturing notification process. This requires that anyone intending to manufacture or import a new chemical must file a premanufacture notice with EPA at least 90 days before introducing the substance into commerce. If the EPA does not ban the chemical, limit its use, or ask for more information within the 90 days, the substance can be marketed.

An important facet of TSCA is that Congress deliberately did not give EPA authority to require testing of all new chemicals. It is up to the manufacturer to decide what tests to conduct for a new chemical or whether, in fact, tests are necessary. However, section 5 of the law, which deals with the premanufacturing notification process, does say that manufacturers must provide EPA with any test data in their possession or control and any other information pertinent to establishing the substance's effects on health and the environment.

EPA must decide whether it has sufficient information on a chemical to make an assessment of risk. If the agency conclude that the data are inadequate, the law directs that it go to court to get the information required. Litigation on individual cases may occur at two stages of the process—when the agency decides more information is needed and if it decides that a chemical poses an unreasonable risk. The intention of Congress was to structure the law to minimize litigation by rejecting a comprehensive testing requirement, but to what extent it will actually have that effect is by no means certain.

When OTS officials began working on rules for section 5 they quickly concluded that it would be necessary to let manufacturers know what information EPA considered necessary if the agency was to make informed decisions on new chemicals or on new uses of old chemicals.

Much effort in OTS, therefore, has gone into drafting guidelines, a delicate operation since such guidelines had to be "nonmandatory" because of the law's provisions on testing.

Early in their deliberations EPA officials concluded that it would be impracticable to put forward standardized testing procedures. None of the schemes proposed were adequate for all the chemicals which will have to be evaluated. Jellinek and others do say that the objective is to develop a well-reasoned, "tiered" testing system, beginning with relatively quick and inexpensive tests and moving on to a larger scale and more expensive ones.

OTS has been saying that it would soon "propose" these guidelines for wider discussion through publication in the *Federal Register*, but in the first week in October a decision was made to back away from taking this step, which is regarded as a formal part of the rule-making process.

OTS officials say that the idea of the guidelines is not being abandoned. The reason cited for the change in plans is simply that those in charge are not satisfied with the present draft. One insider said that time constraints have been a major factor. Some of the people in upper echelon jobs in the agency had been dealing with TSCA for too short a time to fully understand the intricacies of the premanufacturing notice. Now everybody understands the problems, but there are still some differences of opinion on how to resolve them.

Current EPA plans are to publish in the *Federal Register* by year's end a discussion of major testing issues and guideline alternatives being considered

by the agency. Also included would be a description of test methods which EPA regards as appropriate for estimating a range of health and ecological effects.

Since industry from the start has argued for a minimalist policy on testing requirements and specifically, on the guidelines, the delay in getting out the guidelines will inevitably be regarded as pleasing to the industry side.

Environmentalists are now expressing concern that the OTS decision on publication of the lines may foreshadow an eventual abandonment of the idea of formal guidelines. If this did occur, manufacturers would not be left with a total option in providing information. The premanufacturing notification form itself requires a fair amount of information, most of which is prescribed in the law. It is a three-part form with two mandatory sections. The first of these asks for general information on things such as the chemical identity of the product and production and marketing data. The second part is meant to elicit data to aid in risk assessment and requires information on the chemical properties, fate characteristics, and effects. The optional third part requests information in areas such as a chemical's structure-activity relationships, engineering safeguards, and industrial hygiene provisions, and information which might militate in favor of restricted use. The incentive for the manufacturer to supply maximum information would be to help EPA make its "reasonable evaluation."

Testing will continue to be a central issue for TSCA. Other sections of the law provide EPA with more specific authority to require testing than does section 5, but these sections still lack the ballast of regulations. Testing has very substantial economic implications, both in respect to the costs of full-scale evaluation of chemicals and, of course, to the consequences of adverse results. EPA is still wrestling with the special problems of the costs of testing by small manufacturers, and also those of testing new chemicals likely to be manufactured only in small quantities.

Then there is the scientific dimension. The means of measuring long-term effects of small quantities of toxic substances under variable conditions of exposure are still limited. There is considerable optimism that scientific sophistication in this sphere will advance rapidly, strengthening EPA's hand in the future, but the uncertainties with which EPA must now contend are the chief reason that implementation of EPA must be a step-by-step, evolutionary process.

Rule-making has really only begun for TSCA. Inasmuch as no new chemicals have yet been regulated under the law, it would be premature to venture any sweeping judgment on EPA's record on implementing TSCA.

At this point, it is fitting, therefore, to speak in comparatives rather than superlatives. Internal coordination among the divisions of EPA seems to be better than it was. At least under Costle the assistant administrators are talking to each other and machinery for coordination at lower echelons is in place. Cooperation between EPA and the other agencies also appears decidedly improved.

Office of Toxic Substances' Spot on the Learning Curve

The Office of Toxic Substance's prospects for administering TSCA are, of course, influenced by its being part of the Environmental Protection Agency (EPA), an agency with a particular set of institutional problems and peculiarities. A perennial criticism of EPA since it was created in 1970 has been that it is too compartmentalized. EPA was assembled by transferring environmental programs and their staffs from other agencies. The principal ones were the pesticide regulation program from the Department of Agriculture (USDA), the air pollution program from Health, Education, and Welfare, and the water quality program from Interior. Each group brought its own attitudes and regulatory mores with it. New and complex environmental laws passed by Congress forced these groups to plunge into regulation writing when they arrived at EPA, and there was no time at the beginning to talk across program boundaries.

Critics say that EPA remains a bureaucratic Balkans, with the divisions reinforced by agency organization. The original intent was to structure the agency along functional lines with research, standard setting, and enforcement activities cutting across the boundaries of individual programs. As it turned out, however, the 1000 new job slots provided when EPA was set up were used largely to create big administrative and enforcement sections, the old programs being left substantially intact. The critics say that there continues to be relatively little mobility of staff between programs and little serious effort to retrain staff to cope with evolving problems. The practice in EPA by and large has been to hire new staff for new programs and this, largely, is what has occurred with TSCA.

A direct legacy from the past is the presence in OTS of the pesticide program. Pesticides are chemicals, of course, but chemicals covered by the pesticide and the food and drug laws are excluded from TSCA's authority. Administration of pesticide laws was made part of Steven D. Jellinek's responsibility as head of OTS.

Experience with pesticide legislation was influential in shaping TSCA, though principally, perhaps, in a negative way. Pesticide laws date from the late 1940's and were modeled on criminal justice procedures. Pesticides, so to speak, were presumed innocent until proven guilty. The laws were conducive to protracted litigation.

The original legislation was written at a time when the major threat of pesticides was seen in their potential to cause acute toxicity. Perceptions of these problems changed as techniques for detection of pesticide residues advanced and the understanding of long-term biological effects improved. This awareness contributed to 1972 amendments to the pesticide law requiring reevaluation of all pesticides on the market.

The effect of reregistration did not give EPA its finest hour. Reregistration has been dogged by false starts, delays, and general embarrassment. Part of the problem was the technical data on which registration was originally based. When EPA was formed, USDA trucked over a million documents including 300,000 toxicological studies. These were not indexed and it took 2 years to bring order out of this disarray. Then, when the data were examined, says Jellinek, it was realized that there were "tremendous gaps."

In addition, the pesticide law required that products be registered on a label-by-label basis, and the agency was confronted with the daunting task of considering one by one the thousands of products on the market. Belatedly, the agen-

As for the actual implementation of TSCA, things have moved very slowly. The OTS explanation for this caution is that great care is being taken in laying the groundwork with the early sections of the law so that interconnections with other parts of the TSCA will be well designed and the whole law will work properly. The caution will be justified if this eventually proves to be the case.

On the negative side, the two main groups of critics state similar concerns, but from points of view diverging by 180 degrees. Industry apparently feels that EPA has tilted toward the environmental side at the expense of economic values in gearing up to administer TSCA. At oversight hearings on the law held by the Senate subcommittee on environmental pollution chaired by Senator Edmund Muskie (D-Maine), Ralph Engel, president of the Chemical Specialties Manufacturing Association, expressed concern about the agency attitudes in respect to the protection of proprietary information. He cited several specific actions which, he said:

> illustrate our belief that EPA has in these initial TSCA actions, not followed the clear language of the act nor congressional intent. It rather has adopted the posture of an advocate so as to effectively assume a position which precludes proper administrative practice and goes beyond the mandate from Congress that the act be carried out in a reasonable and prudent manner.
>
> It is difficult for regulators to fully understand the absolute importance of protecting trade secret and confidential information owned by the regulated company. Growing industry concern for the continuing confidentiality of sensitive business data was heightened by the final inventory reporting rules.

Environmentalists have been critical of EPA's manner of dealing with suspect existing chemicals, saying that the agency was dilatory in identifying a group of such substances and that there is still little sign of action. A more general sort of criticism has been directed at EPA for not demonstrating a clearer "sense of mission" as an environmental agency. At the same Muskie subcommittee hearings, Jacqueline Warren of the Environmental Defense Fund cited negotiations over the inventory as an instance in which EPA had "advocated the narrowest possible interpretation of the law." Arguing that EPA had an "affirmative mandate" to regulate unreasonably hazardous chemicals. Warren said:

> Throughout the deliberations about what the inventory should contain, EPA played the role of a neutral arbitrator of the disagreements between the chemical companies on one side and the environmental protection advocates on the other. The agency appeared to have no views of its own or sense of its role in carrying out Congress' intent. This attitude has been apparent in other areas of EPA's jurisdiction in recent years, but never so blatantly as in the development of the inventory regulations. As one who attended most of the public meetings, it was often the case on disputed issues that EPA seemed to be taking a head-count of the industry and environmental representatives to resolve the issue, and the tally was usually 50 to 3.

While the critics continue to espouse diametrically opposed views, EPA has managed to maintain a working relationship with the interest groups. A likely reason is that the agency has followed an "open" policy in its rule-making, involving interested parties through advi-

Influenced by EPA's Origins and Subsequent Experience

cy decided to divide the pesticides into manageable groupings according to active chemical ingredients. To do this, the agency first had to get congressional permission. Six years have elapsed and the first reregistrations are only now in the offing.

The pesticide experience also points to what some observers regard as EPA's Achilles heel—its data processing capacity. EPA's record in this sphere is generally regarded as very weak. Its troubles with handling pesticide data raises questions about whether the agency will be able to cope with the masses of information that will pour in as testing results are obtained. As the critics say, there is little point in having data on hand if you can't find them, and that too often in the past has been exactly the case. The data processing side of EPA is said to be getting stronger these days and OTS officials seem to be optimistic that they won't be swept away by the data they need to make decisions.

While handling of information has been a vexing problem for EPA, the validity of its scientific information is the make or break factor for the agency. And EPA's scientific capabilities are seen by knowledgeable critics as chronically weak. The agency's research capacity was in large measure also part of the agency's dowry. Much of that capacity came in the form of field laboratories established to carry out fairly narrow testing and monitoring activities. There are persistent complaints that many of these labs have not kept pace scientifically or developed sufficient competence in managing research contracts. EPA is heavily dependent on the National Institute of Environmental Health Science in Research Triangle Park, N.C., in gaining a fundamental understanding of how pollutants affect human health and the environment. NIEHS, however, is seen as heavily committed to long-term basic studies with the result that EPA often has nowhere to turn for technical information required to make specific decisions. NIEHS is part of HEW's National Institutes of Health and looks ultimately to NIH for policy direction as well as budget.

The internal rigidities of EPA doubtless contribute to the problem. At TSCA oversight hearings in July before Senator Edmund S. Muskie's subcommittee on environmental pollution, Jellinek frankly acknowledged that the system for coordination between OTS and the EPA office of research and development had not always worked well. Research results had been delivered late or not at all. Final results sometimes addressed problems different from those originally agreed on. In general there were problems in philosophy, management, and communication. Jellinek did see the "nonconstructive tensions" of past years lessening, and said that TSCA permitted a fresh start involving new people who were less encumbered with the problems of the past.

Jellinek, like other commentators inside and outside the agency, thinks that TSCA provides the mechanism to make EPA "act like an agency rather than a loose confederation." The act mandates intra-agency collaboration with a section which says that action to regulate an unreasonable risk cannot be taken without consultation with other sections of the agency. A toxic substances priorities committee has been formed and has begun its meetings. Earlier mechanisms created to promote liaison and review within EPA have functioned imperfectly, but partisans of TSCA are counting on a common interest in toxic substances across the agency to make the new machinery operate successfully.—J. W.

sory committees and public meetings and by encouraging officials to be accessible to outsiders. This has increased the burden of EPA officials directly involved in the endless round of meetings and memos which move forward the rulemaking process. A hard-working group of bureaucrats, these officials have been lashed to the mast for nearly a year working long hours, often 7-day weeks; many have had no vacations since the push began. A source of restraint among the critics is the awareness that the regulators must contend constantly with ambiguity. As Muskie said in the recent hearings, "the Agency will be required to develop a program and a set of regulations based on many 'unknowns.' "

In dealing with toxic substances, EPA must administer a law which Congress left unspecific on many points. The agency's line of authority is often less than clear and the science uncertain. As Jellinek and other EPA officials have said, reaching a decision on unreasonable risk will be to some extent subjective.

If the regulators must live with ambiguity, the goals are clear enough. As one assistant administrator put it, "the ultimate test of success is whether we can cut down the number of after-the-fact calamaties, and the sad jokes about the chemical of the week."—JOHN WALSH

Industry Council Challenges HEW on Cancer in the Workplace

Health, Education, and Welfare Secretary Joseph A. Califano made headlines in September when he released a report that projects a massive increase in cancer due to occupational exposure during the next two decades. Last week the American Industrial Health Council (AIHC), an industry group organized to combat stiff new rules proposed by the Occupational Safety and Health Administration (OSHA) to govern carcinogens, released a counterreport suggesting that the first report was little more than a figment of the collective imaginations of the government investigators. At least one of the authors of the HEW report, David P. Rall, director of the National Institute of Environmental Health Sciences (NIEHS), dismissed the rebuttal as "what might be expected of industry." Nonetheless, the AIHC report appears to demonstrate some rather serious errors in the HEW report.

Califano's motives for placing the report in the record of the hearings on the proposed OSHA regulations have been impugned by industry representatives because the report does not seem germane. It does not address conditions existing in industry now or that may exist in the future. It argues, instead, that because of conditions that have existed in industry during the past 30 years or more, the proportion of cancer in the United States attributable to occupational exposure will shortly climb from the present range of 1 to 5 percent to a much more alarming range of 20 to 40 percent. Industry thinks this is simply a scare tactic designed to buttress support for the rigid proposed guidelines. The AIHC report argues, furthermore, that the government report grossly exaggerates both the risk associated with exposure to various carcinogens and the number of workers who have been exposed to them.

The dispute can be divided into two major categories: projections about asbestos exposure and projections about exposure to other carcinogens. The government investigators used different methodologies in the two cases, and the AIHC report thus attacks them on different grounds. AIHC investigators have placed much of their emphasis on asbestos, but their most telling arguments involve other carcinogens, including arsenic, chromium, nickel, and petroleum distillates.

For carcinogens other than asbestos, the government investigators relied heavily on a 1974 study known as the National Occupational Hazard Survey (NOHS). This 2-year study was commissioned by the National Institute of Occupational Safety and Health to determine, among other things, "the extent of worker exposure to chemical and physical agents." The NOHS investigators visited a representative group, statistically selected, of business establishments and noted any exposure (without noting the degree of exposure) to any of 198 specific chemical and physical hazards. The NOHS report concluded that 38.2 million employees had nearly 4.38 billion exposures, or an average of 115 exposures per worker. The NOHS authors clearly warn that the majority of those exposures are only potential exposures or exposures to minute quantities of material, and that rapid improvements in the workplace would sharply reduce the number of exposures so that the study would become obsolete in 5 to 10 years.

Nonetheless, the government investigators took NOHS data for the number of workers exposed to carcinogens, multiplied that number by a risk ratio indicating an increased risk of tumors associated with exposure to the carcinogen, and multiplied again by the incidence for the type of tumors caused by the carcinogen. Chromium, for example, causes tumors of the respiratory tract. The NOHS data suggest that 1.5 million workers were exposed to chromium compounds during the period of the study. The normal incidence of respiratory tumors in the general population is 131 per 100,000 males over the age of 20. And studies of workers at chromate-producing plants during the 1930's indicated that those workers were five to nine times more likely to develop respiratory tumors than the population at large. Multiplying, the government investigators predicted that there will be 7,900 to 16,000 "excess" respiratory tumors in the future as a result of exposure to chromium. In a similar fashion, they computed that there would be 3,900 to 14,000 excess tumors of the respiratory tract resulting from exposure to arsenic, 350 to 1,400 excess cases of leukemia resulting from exposure to benzene, 7,300 to 16,500 excess respiratory tumors resulting from exposure to nickel compounds, and 9,100 excess lung tumors resulting from exposure to carcinogenic components of petroleum.

These estimates are clearly inflated. In each case, the investigators have taken the highest risk ratio available—ratios obtained for workers exposed to massive concentrations of the carcinogens—and multiplied that by the total number of workers who might have been exposed to the carcinogen, even though most or all of the workers have never been exposed to the concentrations upon which the risk ratios are based. In a simple analogy, one might find that the risk of the driver dying in an automobile crash is one in ten if the automobile is consistently driven at speeds in excess of 120 miles

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