Toxic Substances: Five-Year Struggle for Landmark Bill May Soon Be Over

After remaining five frustrating years on the congressional agenda, legislation for the control of toxic substances appears to be finally at the point of becoming law. Differences between bills passed by the House and Senate were resolved in a conference agreement on 14 September. Final congressional approval of the legislation is now imminent, and the only question that remains is whether President Ford will veto it. The smart money on Capitol Hill is saying that he won't, even though the Administration has been opposing its key provision regarding premarket screening of new chemicals.

Known as the Toxic Substances Control Act (TSCA) of 1976, this measure enjoys strong political support. The environmental and consumer groups, the volunteer health agencies (such as the Blue Cross Association, the American Cancer Society, and the National Foundation–March of Dimes), the labor unions, and even the Manufacturing Chemists Association are all supporting the bill.

Designed to screen out potentially harmful chemicals before they can be put into commercial production, the TSCA would fill a large gap in the existing array of environmental and health protection laws. Regulation of toxic substances under laws such as the Clean Air Act, the Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act has been patchy and incomplete; in the case of the water act especially, it has been agonizingly slow. By and large, such statutes contemplate regulation *after* manufacture of the substances has begun, rather than beforehand. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1972 does, like the TSCA, provide for "front-end control" over toxins but it applies only to pesticides.

Under the TSCA, chemical manufacturers would generally have to give the Environmental Protection Agency (EPA) up to 6 months' notice before beginning commercial production and marketing of a new chemical or manufacturing an existing chemical for a significant new use. Then, if the EPA administrator concludes either that the chemical may present risks to human health or the environment or that too little is known about it to permit an evaluation of its effects, he can issue an order to prohibit or limit production or use of the chemical, either indefinitely or pending adequate testing of the substance by the company that wishes to produce it.

This order, which would have to be issued 45 days before the end of the "premarket notification" period, could be challenged by the manufacturer. If challenged, the order would be voided unless the EPA administrator went to court and obtained an injunction.

The special terms under which the injunction would be issued or denied are highly unusual and, as will later be explained, are at the heart of the compromise that finally broke the 5-year House-Senate deadlock. The judge would have to issue the injunction provided the administrator can show:

1) That the substance has in fact not been tested sufficiently to permit a "reasoned evaluation" of its health and environmental effects, and

2) That, in the absence of such information, the substance "may present an unreasonable risk" to health or the environment; or that it will "enter the environment in substantial quantities"; or that there will be "substantial human exposure" to it.

The Burden of Proof

In other words, the agency would bear the burden of proof but that burden would be fairly light. To obtain an injunction it would not be necessary for EPA to prove that the substance is dangerous. It would be enough to show that—given the nature of the chemical, the lack of test data as to its effects, and the extent or circumstances of its proposed use—the substance "may present" a danger.

Once such an injunction was issued, the agency could then prescribe the tests it deemed necessary to confirm or dispel its suspicions. Should the manufacturer ultimately wish to dispute EPA's interpretation of the test results, or to contend that too much testing was being demanded, it could go back to court. But, at this point, the burden of proof would be on the manufacturer.

In sum, the TSCA appears consistent with the principle laid down last year by a National Academy of Sciences panel in its report *Decision Making for Regulating Chemicals in the Environment*. The panel held that "the burden of proof that society will obtain a benefit from a new use of a chemical should rest with those proposing such use."

The control of toxic substances has been a subject of substantial legislative concern ever since 1971, when the Council on Environmental Quality issued a report emphasizing that existing regulatory mechanisms were grossly inadequate to cope with a huge and ever-growing problem. Some 2 million recognized chemical compounds exist today, and nearly 250,000 new ones are formulated annually. Although most of the new compounds are never produced commercially, EPA estimates that about 1000 new chemicals enter the marketplace each year and subsequently find their way into the environment through use or disposal.

In 1972, and again in 1973, both the House and Senate passed toxic substances control bills, but the important differences between the bills were not resolved. The Senate bills, reflecting a clearly overriding concern for protection of the public health and environment, required premarket screening of all substances except those designated by EPA as safe. The House measures, reflecting the chemical industry's desire to escape heavy new regulatory burdens, would have permitted the agency to screen only those new substances which it had listed in advance as possibly harmful—the catch here being that any regulator would be hard put to anticipate every potentially dangerous new chemical that manufacturers might formulate and wish to produce.

That the same uncompromising attitude did not continue to hold sway this year is no doubt due in part to the growing public awareness of estimates by the National Cancer Institute and the World Health Organization that from 60 to 90 percent of all cancers are caused by environmental factors, which include the effects of toxic substances as well as the effects of things such as solar radiation and cigarette smoking. Also, the need for better control of toxic substances has been pointed up by a series of disturbing episodes that have been highlighted in the press, such as the contamination of fish in the Hudson River and the Great Lakes with PCB's. (The TSCA contains a special provision banning the manufacture of PCB's over the next 2 years.)

In any event, both the toxic substances bill passed by the Senate in March and the one passed by the House

in August embraced the principle that EPA must be given notice of most new chemicals prior to commercial production. They differed principally in that, under the Senate bill, EPA could have prohibited or restricted production of a suspect chemical simply on its own initiative, whereas, under the House measure, the agency would have had to obtain a court order to accomplish the same thing. But this difference was overcome by the conference agreement requiring EPA to go to court but making it relatively easy for it to get a court order.

Lobbyists following the legislation, whether for the chemical industry or the environmental and health groups, generally regard the agreement as a genuine compromise. Environmentalists such as Linda Billings, a lobbyist for the Sierra Club, look on the proposed TSCA as a useful beginning, even though its implementation promises to be procedurally cumbersome and perhaps inadequately staffed (the first year funding cannot exceed $12.6 million). Industry lobbyists, who some time ago became convinced that enactment of toxic substances control legislation was inevitable, by and large see the measure as one the industry can live with. Although many small chemical firms remain fearful of the legislation, apparently the only big producer known to be still opposing it is the Dow Chemical Company.

A year ago, this was not the case. In October, a group of 18 chemical industry executives, from Dow, American Cyanamid, Allied Chemical, and other com-

Vaccine Cells Found Mostly Contaminated

The bizarre problem of WI-38 cells, the principal line of human cells used for making vaccines, has been taken a further step toward resolution last week, although not toward clarification. The remaining stocks of the cells were removed last year by government authorities from the Stanford laboratory of their originator, cell biologist Leonard Hayflick (*Science*, 9 April 1976).

The present state of the cells was discussed at a conference held on 9 and 10 September at the National Institutes of Health and attended by vaccine experts from England, France, and Yugoslavia as well as the United States. Hayflick and his attorney were also present but did not speak. Indeed the past history of the cells was mentioned only in the most oblique terms, possibly because of the directive by Harry M. Meyer, director of the Bureau of Biologics, that the purpose of the conference was not to discuss the differences between Hayflick and the NIH.

The most pertinent fact to come out of the conference was the degree of contamination in Hayflick's remaining stocks. Of the 55 original ampules (containing cells grown to the 8th division, and known as 8th passage ampules) removed to the American Type Culture Collection, no less than 46 were contaminated with bacteria, principally the species known as *Micrococcus varians*. Only seven ampules were sterile. (The other two broke or exploded en route).

The seven sterile ampules should satisfy the needs of vaccine manufacturers until an alternative cell line, probably an English line known as MRC-5, has been authorized for use. WI-38 has been used to make polio and adenovirus vaccines, and has been considered for use with rubella and rabies vaccines.

International practice is to start with sterile cultures but to add antibiotics at a later stage of growth. At least one speaker at last week's conference suggested that the contaminated WI-38 cells, if cured with antibiotics, could be used for vaccine production. But another speaker pointed out that since there had clearly been a break in technique when the ampules were laid down in 1962, other contaminants such as viruses might have got in at the same time as the *Micrococcus*. J. P. Jacobs, of the English vaccine regulation authority, intends to use the MRC-5 cells, rather than take risks with cleaned-up WI-38 cells. The Bureau of Biologics has yet to announce a position.

Is it possible that vaccine makers have in the past received antibiotic-treated, not sterile and untreated, cultures of WI-38? Jacobs says there is no way of telling. Hayflick has conceded that he used to clean up with antibiotics contaminated cultures which were intended for research purposes, but that vaccine manufacturers "were never given ampules or starter cultures that knowingly came from contaminated pools, to the best of my knowledge."

Hayflick's management of the stocks of WI-38 is a matter of considerable dispute, compounded by litigation. Hayflick is at present suing the National Institutes of Health for invasion of privacy in making public the report on his activities prepared by NIH management accountant James W. Schriver and his associates. Hayflick is also about to file suit laying claim to ownership of all or some of the WI-38 stocks.

Hayflick and his attorneys have compiled a lengthy rebuttal* to the Schriver report, arguing that it is incomplete, inaccurate, and accusatory without proper cause. Schriver has responded with a counter-rebuttal, which the NIH is not yet willing to release.

One of the chief points of disagreement between Hayflick and Schriver concerns the fate of the 800 or so ampules that were originally prepared. By inference from a contract for 9th and 10th passage ampules signed between Hayflick and Merck & Co. Inc., the market value of an original 8th passage ampule is about $10,000. According to the Schriver report, some 207 ampules remain unaccounted for according to Hayflick's and other people's records. Hayflick has denied absolutely that he has any secret supply hidden away. He states in his rebuttal that the ampules in question exploded or were found to be contaminated. Schriver is understood to have searched for the ampules in both Europe and America.

A fund to help Hayflick with his legal fees has been started by a group of his friends and is being coordinated by Warren R. Stinebring, chairman of the department of microbiology at the University of Vermont.

The chief investigator of the Senate subcommittee on administrative practice has been making inquiries about the WI-38 situation and hearings may be held in conjunction with the Senate health subcommittee. Edward Kennedy is chairman of both committees.—NICHOLAS WADE

*The rebuttal, and the Schriver report, are obtainable from the Freedom of Information Coordinator, Room 307, Building 1, National Institutes of Health, Bethesda, Maryland 20014, for a fee of $11 to cover cost of reproduction.

panies, visited the White House to talk with presidential aides. The toxic substances legislation then beginning to emerge in the Senate and House was reportedly described as a threat to sales, profits, jobs, and innovation.

A few weeks later, James T. Lynn, director of the Office of Management and Budget, disclosed—in a letter to a Republican congressman who had taken issue with the Administration's support of premarket notification and screening—a major change in the Administration's position. He said that it was now felt that to require the industry to give premarket notification of new chemicals might be "overly burdensome." What the Administration now favored was for Congress to do just as the industry had long been recommending in its testimony on toxic substances bills—limit premarket notification to a list of suspect chemicals which EPA would prepare.

Since then, the Administration has clung to this position through thick and thin, even going so far as to oppose the toxic substances bill that was passed by the House with the blessings of the Manufacturing Chemists Association. But the odds now seem better than even that, in the end, President Ford will sign the toxic substances bill.

Russell E. Train, EPA administrator, certainly will be urging him not to veto it. And some of the President's shrewder political counselors are likely to be giving him similar advice, for his vetoing of a measure designed to help combat the scourge of cancer could give Jimmy Carter a potent issue. It would not be surprising if, sometime in the next few weeks, a carefully staged bill-signing ceremony takes place in the Oval Office, with the President, surrounded by environmental and industry lobbyists, declaring that a bold new step is being taken to protect the public health and the environment.

—LUTHER J. CARTER

Biological Curriculum Study Group: A $1.2-Million Misunderstanding

The Biological Sciences Curriculum Study (BSCS), one of the early school curriculum revision groups and, on several counts, the most successful, is embroiled in a financial dispute with its federal patron. At issue is a $1.2 million claim by the National Science Foundation (NSF) involving the high school biology course for which BSCS is best known. The matter is now under study by the General Accounting Office (GAO) and could end in litigation. If BSCS were ultimately required to pay the entire amount of the claim, it would probably mean the finish of the organization, at least in its present form.

The dispute centers on royalties derived from textbook sales, but the issues are complex; BSCS insists that on the main items in the claim it acted properly and with NSF approval. First raised during an NSF internal audit in 1974, the questions posed by the auditors could not be immediately resolved and now have the attention not only of BSCS, NSF, and GAO, but also the House Committee on Science and Technology, the authorizing committee for NSF. Also implicated, at least formally, is the University of Colorado, which served as BSCS's parent organization and official NSF grantee until BSCS set up as an independent, nonprofit organization in 1972.

A crucial stage in the affair was reached in March, when the Science and Technology Committee directed NSF to cut off funding to BSCS until the claim was satisfactorily dealt with. The embargo on funds was a serious blow to BSCS, since it would mean suspension of work on a Human Sciences Program (HSP)—a major, multidisciplinary science program for sixth, seventh, and eighth graders, which BSCS has been developing with NSF funds. After about 3 months of negotiation, an agreement was reached by BSCS, NSF, GAO, and the university, under which BSCS created an escrow account and pledged property, existing funds, and future royalty income sufficient to satisfy the claim in full should it ultimately be found valid. The committee then voted to lift the embargo on funding, thus permitting work on HSP to continue.

GAO, the congressional financial watchdog agency, is in the process of examining the claim. In the case of claims by government agencies against outside organizations, GAO findings are binding on the agency. If the claim (or parts of it) is found invalid by GAO, it will be dropped. If the claim is found valid, the Justice Department will presumably take court action to recover the money.

Committee attention was drawn to the matter last November by a letter in which NSF director H. Guyford Stever noted that NSF was, so to speak, turning the matter of the claim over to GAO. The embargo seems to have been triggered in March, however, by a letter written immediately before the committee's final meeting on the NSF authorization bill and directed to the committee by Representative John B. Conlan (R–Ariz.). Conlan, a conservative Republican who for the past year and a half has kept the NSF education directorate on the defensive about its curriculum development program, urged that funds for the HSP and another curriculum project about which management questions had been raised, be diverted to other uses. The committee, however, opted for the temporary embargo on funds, for it was also concerned about protecting the government's investment in HSP, which through this summer amounted to $2.3 million. Some 5½ years of development and testing on HSP will be completed this month and another 2 to 3 years and $1.6 million will be required to finish the project.

The principal claim in dispute involves $800,000 in textbook royalties. At issue is not the royalties themselves, but payments by the publishers of the three versions of the high school biology curriculum to BSCS. The difficulties arose as a result of negotiations to revise the BSCS first edition in the late 1960's. The three publishers had each paid a royalty rate of 15 percent, unusually high for a textbook. The publishers had agreed to the royalty because NSF had paid development expenses and because of their expectation—which proved to be right—that the curriculum would be a commercial success. (Nearly 4.5 million copies of the three versions have been sold to date, and an estimated half of all high school biology students use the BSCS material.)

The publishers were not, however, willing to pay the premium rate for a second edition mainly because they have lost