Perspectives
on current developments

Regulating Cancer—Fast, Fast, Fast Relief!

The Occupational Safety and Health Administration completed its three-year task of writing a generic carcinogen policy on January 22, 1980. If this final rule takes effect, it is sure to fulfill its purpose of speeding the rate at which OSHA regulates suspected carcinogens, because it forecloses debate on many of the scientific uncertainties that have burdened proceedings so far.

In the nine years of its existence, OSHA has concluded only seven rulemakings on carcinogens—typically taking three to five years from the announcement of a proceeding to the end of judicial review. Other agencies have faced similar delays. Several years ago OSHA, the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, and the Food Safety and Quality Service of the Department of Agriculture joined forces (under the auspices of the Interagency Regulatory Liaison Group) to work out a common perspective on the troublesome issues involved in assessing cancer risk. The IRLG's draft report, which is the product of that interagency effort, forms the basis for the scientific judgments in both OSHA's final rule and in EPA's October 10 proposal on airborne carcinogens. The two policies differ significantly in a number of ways, however, particularly in the conclusiveness accorded to those scientific judgments across the board.

These policies, especially OSHA's, will affect the nature of federal health and safety regulation and the levels of costs (in the billions of dollars) that such regulation imposes on the economy. Not surprisingly, OSHA's rule is being challenged in the courts (by the American Petroleum Institute and the AFL-CIO, among others) and its effective date of April 22 may well be delayed. EPA's rule, when it is promulgated, is apt to meet a similar reception.

OSHA's final policy seeks to expedite rulemaking by restricting the grounds for agency decision—and thus, if the policy is upheld by the courts, the grounds of judicial review. The plan has three key elements: (1) strict time limits for the various steps in a rulemaking, with an overall limit of six months from proposal to final rule; (2) classification of suspect carcinogens into two categories, with specific compliance standards (outlined in the "model generic standard") to follow automatically for each category; and (3) the treating of certain scientific questions as "resolved" and hence not subject to challenge in a rulemaking proceeding (or subject to challenge only on the basis of narrowly specified types of evidence).

Suspected carcinogens will be classified as Category I or Category II based on scientific evidence alone. A Category I listing results when there is positive epidemiological evidence in humans, or positive results from a single long-term animal test confirmed by a "concordance" with other evidence. Concordance may be supplied by "short-term" tests of mutagenic action, such as in mammalian cell cultures or bacteria, or by other "suggestive" animal evidence. (The concordance requirement is intended to reduce the possibility of a "false positive" result from a single animal test without the expense and delay of further long-term animal tests.) A Category II listing results for those chemicals where an animal test is only "suggestive" or where concordance is lacking. The aim is to encourage the development of data that would elevate the chemical to Category I.

Significantly, the only basis for listing a substance in either category is the strength of the scientific evidence. Risk assessment considerations (such as the number of potentially exposed workers) are permitted, however, in setting priorities *within* each category. Thus, in theory, OSHA should not find itself chasing after very weak carcinogens or those affecting

small numbers of workers, at the expense of substances that are more dangerous.

The listing of a chemical in Category I automatically triggers the requirement that worker exposure be reduced to zero if "suitable substitutes" exist, or otherwise to the "lowest feasible level." This requirement may not be challenged in any rulemaking. A Category II listing requires exposure reduction also, but to a level to be determined on a case-by-case basis. In both cases, compliance must be achieved by means of engineering and work practice controls (not personal protective devices) and at no cost to the employee.

The obvious question about this, of course, is: what is the "lowest feasible level"? Although OSHA is emphatic in most parts of its *Federal Register* notice that this is solely a question of technical feasibility, the text contains sufficient discussion of economics to produce some ambiguity. It is stated, for example, that a regulation will be "designed so as to be achievable from an economic perspective" and that OSHA intends "to take into account technological and economic considerations in determining feasibility." What this will mean—whether it implies a broadening of OSHA's previous practice of equating economic feasibility with the narrow criterion of a company's or industry's financial viability—remains to be seen.

Of central importance are the scientific judgments that OSHA is attempting to predetermine for all later proceedings. These judgments, which generally follow the recommendations of the IRLG policy statement, are not compelled by solid scientific evidence, but are *elected* in the face of scientific uncertainty:

- It is assumed that there is no safe ("zero-effect") level of exposure to carcinogens. Hence worker exposure must be reduced to zero whenever "feasible," even in the face of rising marginal costs and falling marginal returns.
- Negative human epidemiological evidence is not considered at all unless it concerns workers exposed to the substance in question for at least twenty years and observed for at least thirty years from the start of exposure. Such evidence is unlikely to be available for most substances and impossible for new ones.
- When both positive and negative animal tests exist, the negative evidence is disregarded entirely if it is in a different species from the positive evidence, even though this lowers the confidence one can place in making interspecies extrapolations (for example, from rats to man). When positive and negative results exist within the same species, preferential weight is given to the positive result. (Whether a given result can be repeated is not a trivial question. Just now, for example, there is a very serious conflict concerning the chemical ethylene dichloride: one animal study was solidly positive in both rats and mice, a larger study was decisively negative in the same two species, and in both cases the investigators were well-established experts. Since this substance is a high-volume industrial solvent to which many workers are exposed, whether it is regulated as a Category I carcinogen is a matter of some interest.)
- No distinction is recognized between substances that initiate cancer and those that merely "promote" existing cancers. A high frequency of tumors often exists spontaneously in inbred strains, so that many instances of positive response may result from promotion rather than initiation. Little is known about the mechanism(s) of promotion, especially about dose-response. The arguments that are used against the existence of "safe doses" for initiating carcinogens may not be applicable to promotion. However, OSHA here assumes that they are, thus foreclosing what would ordinarily be a prime area of reasonable dispute.
- No distinction is recognized between benign and malignant tumors. This highly consequential decision, which in some cases will change a result from statistically negative to positive, can only be challenged by showing (in at least two long-term tests in each of two mammalian species) that the benign tumors are of a type that *never* progresses to malignancy. Practically speaking, this is impossible.
- OSHA recognizes no such thing as an "overdose." The agency closes off this frequent source of previous regulatory delay with a thrilling theoretical leap: a statistically significant increase in tumor frequency at *any* dose, including one so high that it severely depresses the test animals' weight and/or shortens their lives, is taken to be acceptable evidence. Such evidence may not be challenged except by showing that the true carcinogen is a metabolite of the administered substance (a chemically altered derivative produced by body chemistry)

In Brief-

Of Spice and Men. Fans of the carcinogen-of-the-week sweepstakes may enjoy guessing the identity of a food additive reported last year to cause cancer in mice (*Nutrition and Cancer*, vol. 1, no. 3). Researchers at the University of Kentucky painted moderate doses of this additive on the skins of weanling mice for three months and observed the mice until they died. Their finding: a highly significant increase in malignant tumors at sites distal to the site of administration (77 percent for the experimental animals versus 11 percent for the controls). The substance also turned out to be a direct-acting mutagen (that is, mutagenic in the Ames test without metabolic activation), and hence especially dangerous. By OSHA's new criteria, it is a Category I carcinogen (see page 4). The additive is found in ice cream, baked goods, candy, prepared meats, pickles, soups, and condiments. It has long been officially classified as "Generally Recognized As Safe," a listing that must now be considered in jeopardy.

What is it? Piper nigrum—ordinary black table pepper.

Credits and Debits on the Regulatory Front. On March 14, relying on the heretofore unused Credit Control Act of 1969, President Carter authorized the Federal Reserve System to restrain the growth of consumer credit and money market mutual funds. The Fed's approach is to make that growth less attractive by requiring consumer lenders and the money market funds to maintain special noninterest-bearing deposits with the Federal Reserve equal to 15 percent of increases in certain types of credit or in fund assets above the "base amounts" outstanding on March 14. Among the institutions subject to the new regulation are those commercial banks, mutual savings banks, savings and loan associations, finance companies, credit unions, retailers, and credit card companies that had $2 million or more in covered credit on March 14, as well as all money market funds—a very large net, indeed. It was announced that these institutions must, by certain dates, file "base amount" reports with the Federal Reserve, provide monthly reports on covered credit or assets outstanding (giving daily averages, if possible, or figures for particular dates acceptable to Fed), and adjust their noninterest-bearing deposits accordingly.

As announced on March 14, the program seemed complex enough. Then came the refinements, adjustments, and embellishments on the original text. On March 26, one Federal Reserve governor spoke of possible changes in the consumer credit controls—such as monthly adjustments of the credit ceiling to take account of seasonal surges in demand (for example, Christmas and summer) and prohibition of higher monthly charges on revolving credit accounts and credit cards where borrowers have not added to their balances. On March 28, the Fed modified its rules on money market funds—exempting, for example, (1) funds having assets below $100 million, (2) personal trusts, pension, retirement, and other tax-exempt accounts invested in money market funds, and (3) the tax-exempt assets of funds that invest at least 80 percent of their assets in short-term tax-exempt obligations. It also put the reporting and deposit requirements for money market funds on a weekly basis.

More "fine-tuning" is sure to come. The conflict between this ambitious new venture and the fashionable goal of deregulation has not yet been widely noted.

Deregulating State Regulation. On March 3, the Supreme Court, in *California Liquor Dealers* v. *Midcal Aluminum*, held that California's wine pricing regulations "plainly" violated the Sherman Act and were not protected by the Twenty-first Amendment (see *Regulation*, November/December 1979, page 14). Given this decision, the seventh in the last five years to examine the scope of the "state action" exemption from the antitrust laws, it is now clear that passive state regulation, even if couched in mandatory language, will not create antitrust immunity.

The decision greatly narrows the kind of "state action" that can be argued to immunize private conduct from antitrust attack, and seems to encourage arguments that the antitrust laws preempt anticompetitive state laws, at least where the state is not directly and actively involved in supervising the regulated activities. Whether conduct in compliance with state law will be subject to treble damage attacks is still unclear, although the Court has hinted in other decisions that equitable concerns might bar damage awards in such situations. That issue will undoubtedly be before the Court soon.

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that is never produced at low doses—an exceedingly rigorous requirement, indeed. Significantly, the presence of a high dose may *not* be questioned on the simple ground that an overdose-related debilitated state of health might itself raise tumor incidence, though this would ordinarily seem a good possibility.

All in all, OSHA's cancer policy, if upheld by the courts, can be expected to speed the agency's carcinogen regulation proceedings. But it will do so only by declining to undertake many of those inquiries that render such case-by-case proceedings preferable to a meat-ax statutory approach. It is no easy matter to determine the point on the spectrum between wholesale categorical prohibition and highly particularized consideration that is most desirable. Clearly, however, OSHA's approach

produces a substantial loss of regulatory flexibility and precision.

The Environmental Protection Agency's proposal on airborne carcinogens, dated October 10, leaves much more room for the exercise of judgment on a case-by-case basis. Under EPA's proposal, the agency would list a substance as presenting a "significant carcinogenic risk to the public" on the basic of a consideration of available epidemiological and risk-assessment evidence. Upon making such a determination, it would in most cases immediately impose a generic standard consisting of "low-cost and readily implemented" procedures designed to control "fugitive" emissions (leaks and spills). Thereafter, the agency, giving priority to substances presenting the greatest human hazard, would determine the "best available technology" for limiting exposure and would impose a standard mandating that technology.

In choosing "best available technology," EPA would specifically review environmental, energy, and economic considerations (including in the latter effects on plant closures, employment, and end-product prices). Controls beyond "best available technology" would depend on "the Administrator's judgment" that the remaining risk is "unreasonable." Thus, EPA is quite explicit about its intention to consider costs and risk-assessment factors. OSHA, by contrast, will consider risk assessment only in establishing priorities, and is at best unclear about its intention to consider costs.

Another difference is that EPA does not foreclose discussion of scientific issues from future rulemakings (with the single exception that it will not consider the possibility of "zero-risk" exposure). Instead, EPA will determine human carcinogenicity based upon the "weight and quality of the evidence" presented—with a rebuttable presumption in favor of the scientific judgments recommended by the final IRLG report.

Both agencies are trying to grapple with a difficult conceptual problem. Carcinogens are not like other toxic hazards: they can take decades to act; they act erratically (not everyone exposed to the same risk develops cancer) so that evidence of carcinogenicity is largely statistical; and because the elemental cancer-causing event is single-cell rather than systemic, it is virtually impossible to determine zero-effect thresholds with certainty. Thus, in carcinogen regulation, reasonably conclusive proof is difficult to obtain quickly, and is in any case a matter of how much risk is tolerable.

This may well justify a case-by-case judgment that a regulatory ban is in order, even where the scientific evidence is much less than conclusive. The problem with OSHA's new policy is that it combines this caution with the abandonment of the case-by-case approach—and will thereby produce a ban of some substances that even a supercautious evaluation of all the particularized variables would permit. One wonders whether the result sought to be achieved by the wholesale excision of these genuine scientific issues from case-by-case proceedings could not more rationally be achieved by imposing some discipline on the administrative and judicial procedures that now produce the absurdity of three-to-five year regulatory delays. To reduce delay by presuming guilt is simple, but costly.

The 1981 Budget and Regulatory Reform

In these times of concern about excessive government spending—and of equivalent concern about excessive regulation—the President's fiscal 1981 budget contains a real surprise. Proposed expenditures for regulatory agencies, whether measured in current or constant (1970) dollars, are expected to show their largest percentage increase since 1978. Moreover, continuing an eight-year trend, the greatest growth is slated for the largest categories of regulatory activity—the economy-wide programs of social regulation. Interestingly, however, the rise in the number of regulators is expected to be modest.

The summary figures shown here are drawn from an analysis of regulatory agency budgets and personnel by the Center for the Study of American Business at Washington University in St. Louis. The center's analysis covers fifty-seven regulatory agencies.

According to the President's new budget, proposed 1981 expenditures for these fifty-seven agencies amount to $6.9 billion, an increase of $910 million (or 15 percent) over 1980. This compares with an average annual

increase of $550 million (or 13 percent) for the 1976–80 period. When expressed in constant (1970) dollars, proposed expenditures are expected to rise by $180 million (or 5.8 percent) in 1981, moderately above the average annual increase of $160 million (or 5.6 percent) for 1976–80.

Staffing figures, as noted, show a somewhat different picture. While there continue to be more regulators each year, the annual rate of increase has tapered off to 2 percent in the 1979–81 period. This could be explained by the absence of major new regulatory programs in the last few years. Another possibility, suggested by the Center for the Study of American Business, is that programs that put a greater share of the compliance burden on the private sector are replacing or outgrowing those that emphasize direct federal monitoring or enforcement.

GROWTH OF FIFTY-SEVEN FEDERAL REGULATORY AGENCIES
Selected Fiscal Years, 1971–81

Area	1971	1977	1978	1979	1980 (est.)	1981 (est.)
Social Regulation	EXPENDITURES ($ billions)					
Consumer safety and health	$ .6	1.8	2.3	2.5	2.6	2.9
Job safety and other working conditions	$ .1	.5	.5	.6	.7	.8
Energy and the environment	$ .1	1.0	1.3	1.5	1.7	2.2
	$ .8	3.3	4.1	4.6	5.0	5.9
Economic Regulation						
Finance and banking	$ .1	.2	.3	.3	.3	.3
Other industry-specific	$ .2	.3	.3	.3	.4	.4
General business	$ .1	.2	.2	.3	.3	.3
	$ .4	.7	.8	.9	1.0	1.0
TOTAL	$1.2	4.0	4.9	5.5	6.0	6.9
TOTAL IN 1970 DOLLARS*	$1.2	2.6	3.0	3.0	3.1	3.2
PERMANENT FULL-TIME POSITIONS (thousands)						
Social Regulation	10.8	58.4	61.9	63.6	65.4	66.2
Economic Regulation	18.3	23.6	24.3	23.9	24.5	24.6
TOTAL	29.1	82.0	86.2	87.5	89.9	90.8

*Adjusted by GNP deflator (actual and, for 1980–81, estimated in 1981 budget).
Source: Center for the Study of American Business, Washington University.

Finally, analysis of 1977–81 staffing and expenditure patterns, by regulatory category, gives support to the theory that what has been occurring is a shift in the type of regulation rather than a crest in the wave of regulation. Total personnel grew from 82,000 in 1977 to nearly 91,000 in 1981, with the great bulk of that growth occurring in two categories, Energy and the Environment and Job Safety and Other Working Conditions. In the same period, budgeted expenditures grew by $2.9 billion, with the three categories of social regulation contributing $2.6 billion of that growth and rising by a total of 73 percent.

With regulatory agency budgets and personnel headed for new highs, fifty-five members of the House of Representatives have called for a 17.5 percent across-the-board cut in the budgets of major regulatory agencies. Their purpose is to force regulators "to concentrate on only those activities that are of highest priority and provide the greatest social payoffs." This is of course optimistic. Expenditure reduction will not necessarily winnow out only the less efficient regulation, and is not the quick and easy close oversight that Congress seems to be seeking. Nevertheless, the relationship between agency expenditures and the total volume of regulation is close enough that the 1981 budget figures warrant attention.

Managing Wastes Wastefully?

The Environmental Protection Agency is making progress towards implementing what may be its most comprehensive regulatory program yet—the control of hazardous wastes under the Resource Conservation and Recovery Act of 1976 (RCRA). Final regulations applicable to businesses that generate and transport such wastes were issued on February 26, and the final standards on disposal sites are expected in late April.

RCRA seeks to prevent roadside dumping and other unsafe disposal methods by imposing a system of hands-on government regulation. The new regulations call for EPA to track hazardous wastes "from cradle to grave," relying heavily on a manifest system of recordkeeping. Under the system, all generators, transporters, and disposers of wastes must obtain EPA identification numbers. Generators are responsible for determining whether their waste falls under EPA specifications for hazardous wastes. If so, they may ship it only via transporters who have EPA identification numbers and only to dis-

posal sites that have EPA permits. Each shipment must be accompanied by a manifest naming the generator, the transporter, and the disposal site (all identified by their EPA numbers), and describing the waste and its characteristics. When the waste reaches the disposal site, a copy of the manifest must be mailed back to the generator. If a manifest is not returned within thirty-five days, the generator must file an Exception Report with the EPA. Generators must also file annual reports summarizing all waste shipments during the year. With this documentation to work with, the agency will attempt the gargantuan task of tracking, from an estimated 750,000 sources to an estimated 32,000 disposal sites, an estimated 57 million tons of hazardous wastes each year.

The agency's preliminary estimate was that the February and April regulations, combined, would cost over $600 million a year in added compliance costs. (A revised estimate coming in April is expected to be much higher.) Of this total, $120 million results from the proposed requirement (mandated by RCRA) that disposal site operators have liability insurance for damages caused by waste-handling activity.

Unfortunately, RCRA leaves unanswered many questions concerning private liability for improper waste disposal. These questions have come to the fore in recent federal and state enforcement suits and in damage suits brought under state tort laws. Typical of these are the suits stemming from the leakage of hazardous wastes from the Love Canal in Niagara Falls, New York.

The Love Canal property was purchased by Hooker Chemical Company in 1942 and used for burial of chemical wastes for ten years. Then, in 1953, the company sold the property to the Board of Education of the City of Niagara Falls for $1. The deed explicitly stated that the property had been used for the dumping of chemical wastes that might be hazardous; it also contained a clause transferring to the school board all liability for future damages resulting from the wastes and required that similar clauses be included in all future deeds. In 1978, residents of homes built after 1953 on property adjoining the canal began noticing odors in their basements. When investigations showed that chemicals from the canal had leached out into the surrounding ground, the residents were evacuated.

That much is certain; the rest is unclear. Whether Hooker used adequate disposal methods, whether post-1953 excavation of the canal site (permitted by the school board) contributed significantly to the leakage, and whether the leakage had any negative health effects are issues that will be contested in court. EPA's suit seeks to compel Hooker to pay $45 million in clean-up costs and civil fines, and more than fifty private suits seek damages totalling several hundred million dollars.

The central legal issue posed by such suits is whether a hazardous substance—like some child who never reaches adulthood and can never be disowned—remains forever the legal responsibility of its generator. In traditional tort law, when a house with an unsafe condition—say, a crumbling bay window overhanging the sidewalk—was sold, liability for subsequent injury passed to the buyer, at least if the condition had been specifically brought to the buyer's attention. But modern courts have displayed some tendency to alter this rule, and the current state of the law in many jurisdictions is uncertain. Is an absolute rule of continuing liability applicable to "inherently dangerous" waste? Or to premises upon which such wastes have been stored? Or is the normal rule of exclusive responsibility by the new owner altered only when the seller *knows* that the new owner does not have the resources to eliminate or suppress the hazard. Or when he *should have known?* Or does he have a positive duty to ensure that the new owner has—and intends to use—adequate resources for that purpose?

Another important legal issue involves the need to establish negligence on the part of the defendant. Negligence (or malicious intent) is generally required for tort actions, but the common law (and some statutes) has imposed so-called strict liability for certain "inherently dangerous" items or activities. If, for example, you choose to do some blasting with dynamite, you are likely to be liable for any damage you may cause, no matter how diligent you have been in taking known necessary precautions. Are all hazardous wastes subject to a similar rule? Or some of them?

Apart from the legal issues, there are some highly practical difficulties associated with such litigation. The cost of proving damages can be substantial, involving expensive epidemiological studies beyond the means of individual

plaintiffs and beyond the venturesomeness of contingent-fee attorneys. And the ultimate practical difficulty (by no means peculiar to this type of litigation) is the inability to find the prospective defendant or, if he is found, the inability to collect against him because he is insolvent. The last problem may be partially solved by RCRA's liability insurance requirement for disposal site operators—but only partially, because the proposed rules leave open the possibility that coverage will end when an operator goes out of business and because RCRA itself provides no answer to the problem of current "orphan" sites for which responsible parties cannot be found.

Congress has begun to consider these problems, and two Senate subcommittees are currently marking up one proposal, the Environmental Emergency Response Act of 1980 introduced by Senator John C. Culver (Democrat, Iowa). While it is too early to know what will emerge, it seems clear that the final bill will provide for a "superfund" to be used in cleaning up orphan sites and will take some action toward resolving the liability situation. It has been proposed, for instance, to make generators "jointly and severally" liable with disposers for waste-related damages (thereby settling the issue of whether liability could be assigned —it could not); to declare waste-handling an "ultra-hazardous activity" (thereby subjecting generators, transporters, and disposal site operators to a standard of strict liability); and to set guidelines by which EPA would make preliminary determinations of causation (thereby relieving plaintiffs of at least some of the costs of necessary epidemiological studies). In addition, current proposals would create a federal right of action for hazardous waste victims, thus ensuring uniformity of protection and enabling suit to be brought in the federal courts. Among the matters most certain to be controversial is the issue of who is to pay for the superfund. One House proposal would take the simple approach of levying a 5¢ a barrel tax on domestically refined oil—a sure sign that the issue is still up in the air.

In observing the progress of the RCRA regulations and of proposals for additional legislation, one has the disturbing impression of impending overkill. It is unquestionably true that the disposal of hazardous chemicals poses a social threat that cannot entirely be met by the deterrent and compensatory effect of normal, ex post facto, private-law court remedies. But it is a broad leap from that judgment to the conclusion that all hazardous wastes must be subjected to a regime of cradle-to-grave manifests and mandatory insurance—a regime that seems designed to achieve the blissful but utterly unrealistic goal of eliminating, at whatever cost, all risk associated with this particular activity. There is a certain anti-industrial, "greening-of-America" passion behind the demand for 100 percent insulation from this particular hazard of the nonmonastic life, even though we all probably run a much greater risk of being struck by an uninsured motorist every day. Some hazardous wastes—such as spent nuclear fuel, which is handled under separate statutes—have such potential for mass destruction that they undoubtedly require hands-on regulation, fully as intensive as a cradle-to-grave manifest system. Similar treatment may be justified for disposal sites at which huge quantities of moderately hazardous waste are accumulated. But beyond these cases, it seems that some sensible distinctions in the degree of regulation can be made; and at the opposite extreme it is possible to conceive of some hazardous wastes—which have no potential for mass destruction and whose causality in producing injury is easy to establish—that require not much more than a clarification of the laws governing private liability and a statutory requirement of disposal in a particular fashion. It is instructive to note that clarification of private liability *alone* might have sufficed to avoid the Love Canal disaster. That episode probably would not have developed as it did if the tort responsibilities of both Hooker and the school board had been clear at the outset.

The seriousness of the new-found congressional and executive branch belief in cost-benefit analysis and regulatory reform meets its most demanding test not in attacking ancient and outmoded prescriptions, but in resisting imprudent response to loud-voiced current concerns. In the 1970s, the lack of such resistance produced some notorious excesses in product safety, occupational safety, and consumer protection regulation. The very real problem of improving protection against hazardous waste provides one of the first tests of regulatory prudence in the 1980s.