

# OSHA Rule Is Curbed by Budget Office

*The agency says ethylene oxide is hazardous, but the Office of Management and Budget called OSHA's risk analysis "wholly contrived"*

The Occupational Safety and Health Administration (OSHA) was on the brink of setting strict limits on exposure to ethylene oxide, a colorless gas widely used to sterilize medical supplies and equipment. But on the eve of announcement of the final rule, the Office of Management and Budget stepped in, asserting that OSHA had grossly exaggerated the risks and underestimated the cost of the regulation. The next day, on 15 June, a final rule was issued that, according to agency staff, was stripped of a key provision.

Members of OSHA's staff, demoralized by the outcome, feel that they were second-guessed after spending the past 2 years to develop the standard. They argue that the budget office dismissed several important health studies. Public Citizen, a Washington, D.C.-based advocacy group affiliated with Ralph Nader, has petitioned the U.S. Court of Appeals to review the matter and intends to make it a test case against budget office intervention.

For the past several years, data from animal and human studies have accumulated and shown that ethylene oxide is far more hazardous than had previously been thought. The chemical is now considered a mutagen and carcinogen in animals. As for humans, there is evidence, although limited, that ethylene oxide at low levels is associated with leukemia, spontaneous abortions, and chromosomal changes, according to Philip Landrigan, a senior scientist at the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati.

Some 75,000 health care workers are potentially exposed to bursts of high concentrations of ethylene oxide. The gas is released from the protective wrappings of freshly sterilized material. Although a "long-term" limit, based on an average daily exposure over 8 hours, would reduce risk to some extent, NIOSH and others argue that it should be supplemented by a short-term limit based on a 15-minute exposure period. In 1977, NIOSH recommended a 75 parts-per-million (ppm) short-term standard, but it now advocates a limit of 5 ppm, based on the data linking the chemical to chromosomal damage, spontaneous abortions, and cancer.

But between 1977 and 1983, OSHA did little to regulate ethylene oxide more

vigorously. Then last year, a federal court ordered the agency to issue new rules. In response, OSHA's staff proposed to establish the same 5 ppm short-term limit as recommended by NIOSH. This prompted strong opposition from industry groups, such as the ethylene oxide council and the Health Industry Manufacturers Association. The agency subsequently softened the proposal to 10 ppm. But following objections from the budget office, the short-term standard was dropped entirely from the final regulation. (The final rule establishes a long-term limit of 1 ppm, which went largely unchallenged because industry and hospitals have already tightened controls in anticipation of tougher government regulations.)

In a letter to OSHA, chief of regula-

tory affairs at the budget office, Christopher DeMuth, listed several objections to OSHA's final rule that parallel many of the arguments raised by the industry groups. A budget office official said that DeMuth's criticisms were based on a review of documents in OSHA's formal regulatory docket.

After complaining that OSHA failed to comply with the Paperwork Reduction Act, DeMuth went on to assert that the short-term limit "is unsupported by any reasonable risk assessment or inference from available scientific evidence." OSHA estimated that without a short-term limit, the number of excess cancers could rise to 8 to 16 for every 10,000 workers exposed. DeMuth, however, argued that this excess cancer risk is "wholly contrived."

## OSHA Scientists Taken to Task

Last fall, Representative George Miller (D-Calif.) charged that Leonard Vance, director of the agency's office of health standards, had improperly arranged a meeting with the head of the ethylene oxide trade group. At a congressional hearing, Vance denied the charge and asserted that his subordinate, Robert Beliles, director of risk assessment, had made the appointment. Beliles denied Vance's allegation. Then the industry representative, Arlin Vorhess, who was director of corporate safety and health at Union Carbide, the principal supplier of ethylene oxide as a sterilant, wrote in a letter to the committee that he had "called Dr. Vance in my capacity as chairman of the Ethylene Oxide Industry Council . . . and asked if I could drop by" when in Washington on 16 June 1983. (Miller attempted to obtain Vance's appointment books, but this spring was told by Vance that his dogs had vomited on them and he had thrown them away.)

Beliles said in an interview from his home that to avoid further friction, he arranged a transfer to work 4 months at the Environmental Protection Agency. Upon his return in April to OSHA, he was notified by agency chief Thorne Auchter that he was removed as chairman of the ethylene oxide team and was no longer OSHA's representative to the National Toxicology Program and the editorial board of a government publication on toxicology. Vance said through OSHA spokesman John McDavitt that Beliles was not singled out. Such duties, which had been held by other scientists, were reassigned to a different branch of the agency.

Vance has also reprimanded OSHA epidemiologist Peter Infante for advocating the need for a short-term exposure limit and proposing to perform a quantitative risk assessment of the reproductive hazards of ethylene oxide. In a memo, he chided Infante for "prejudging" the issue and calling for a short-term limit. He said that the health standards staff did not have sufficient resources to conduct such a risk assessment and that OSHA had produced "sufficient" evidence to support a "protective and reasonable" standard. The risk assessment was never conducted. Last month, the Office of Management and Budget, however, criticized the agency for its failure to support adequately its final rule.—M.S.

According to a budget official who requested anonymity, OSHA's risk assessment for the short-term limit was based on the unrealistic assumption that workers would be exposed to peak levels of 10 ppm 15 minutes per day, 5 days a week, for 45 years. "Risk assessment involves realistic exposures and OSHA made no exposure estimates," said the official.

According to an OSHA report, available evidence indicates that two or more peak exposures per day "are common" and that employees could be exposed "to several hundred ppm over very short periods of time" despite a long-term limit of 1 ppm. Martin Fell, an agency analyst, argues that even if a small number of people are exposed, the chemical is sufficiently hazardous to be of concern.

DeMuth also criticized OSHA's reliance on three studies of workers, saying that all of them "have major flaws and provide no support" for the short-term limit. One study, published in the *British Medical Journal*, suggested that an increased number of spontaneous abortions were associated with pregnant women receiving single, daily 20-minute exposures on the job at concentrations of 5 to 20 ppm. DeMuth, along with the Ethylene Oxide Industry Council and the Health Industry Manufacturers Association, contended that the study is unreliable because of bias introduced in the questioning of subjects and in their selection.

OSHA rejected this complaint, citing comments from the study's lead author, Kari Hemminki of the Finnish government's Institute of Occupational Health, and Jennie Kline of Columbia University. Hemminki examined three types of sterilants—ethylene oxide, formaldehyde, and glutaraldehyde—and their possible effects on women employees. Hemminki's data were based on interviews and the discharge records of more than 1000 women in a 1979 survey of all the hospitals in Finland. Given that the employees were subjected to any one of the three chemicals, Hemminki said that selection bias could not account for the correlation between spontaneous abortions and ethylene oxide alone. Kline also downplayed any recall bias, noting that the information derived from interviews was "consistent" with the discharge records.

DeMuth also faulted two studies which indicated that short-term exposure may be associated with chromosomal effects. In one study, 14 hospital workers were exposed to an average of 19 ppm for 15 minutes from 6 to 120 times during a 6-month period. Results showed that an increased number of ge-

netic aberrations called sister chromatid exchanges were related to exposure. A study by Johnson & Johnson of its own employees produced similar results and, as a consequence, the company instituted a 10 ppm short-term exposure limit and supported OSHA's efforts to establish an identical standard.

DeMuth argued that the sister chromatid exchanges "should not be the basis of regulation" because they have not yet been linked to adverse health effects. Health scientists, such as Landrigan and OSHA director of risk assessment Robert Beliles, concede that it is unclear whether the effect can be characterized as adverse but consider these changes worrisome. Landrigan said in a paper published in the current issue of the *American Journal of Industrial Medicine* that an increasing amount of data suggests a link between chromosomal damage and human cancer and that the findings deserve "careful consideration."

OSHA officials are puzzled by the strong reaction to the agency's proposal by the White House budget office and industry groups. According to agency estimates, a two-track standard with short- and long-term limits would cost industry \$35.5 million a year, with the bulk of the expense due to compliance with the long-term standard. Said one OSHA official, "This is a cheap regulation."

Staff members speculate that the agency was an easy target because OSHA has been without a leader. OSHA chief Thorne Auchter stepped down this spring and his successor, Robert A. Rowland, was only appointed in mid-July. Although Auchter was a champion of deregulation, he did fight for standards that made their way through agency review, according to an attorney at Public Citizen.

OSHA still plans to try to salvage the short-term limit and is taking some steps to respond to the charges made by the budget office. It has sent out copies for peer review of its analysis that describes the scientific evidence to support a short-term standard. The report initially was distributed to members of OSHA's advisory board, an oversight panel comprised of scientists and non-scientists, and several groups that have a vested interest in the outcome, such as labor and industry groups. After staff complaints, top officials also sent the report to heads of government health agencies, including the National Cancer Institute and the National Institute of Environmental Health Sciences. "The siege isn't over yet," Beliles says.

—MARJORIE SUN

## House Prepares to Slash Synthetic Fuels Agency

Opposition to the Synthetic Fuels Corporation (SFC), a speck on the horizon a year ago, may soon decimate the agency's budget and strip it of authority to back new projects. In an unusual repudiation of the Democratic leadership, the House voted on 25 July by a large margin (261 to 148) to override a rule that would have blocked an anti-synfuels amendment to the Department of the Interior appropriation, scheduled for consideration on 31 July.

As a result, the House will get to vote on a budget-slashing proposal put forward by Representatives Howard Wolpe (D-Mich.), Mike Synar (D-Okla.), and Silvio Conte (R-Mass.). Their amendment would cut \$10 billion from the unspent \$13.2 billion appropriated for the SFC. The Senate has not taken any action as yet. However, because the White House has proposed cutting the SFC budget by \$9 billion (*Science*, 1 June, p. 964), the Senate is likely to go along with a reduction if the House votes for it.

The SFC was created in 1980 under the Carter Administration and given more than \$13 billion to be used in subsidizing new energy plants. The goal was to accelerate the development of a new domestic oil and gas industry that would exploit coal, oil shale, tar sands, and other indigenous resources. Special emphasis was to be placed on liquid fuels to decrease U.S. dependence on oil imported from the volatile Persian Gulf.

Proponents of the SFC said the undertaking would cost the taxpayers little or nothing because the price of oil was expected to be high enough, and the cost of synfuels low enough, that the government would not have to pay out cash to honor its price-support pledges.

This scenario began to lose credibility when demand for oil sagged in 1981 and prices fell. Recently, on 22 July, Representative Synar released a report by the General Accounting Office estimating that in 1989 the actual difference between the price of oil and promised price supports for one synfuel project (Union Oil phase II) could be \$48 per barrel.

Fiscal conservatives joined with en-