

CLEARY, GOTTLIB, STEEN & HAMILTON
1752 N STREET, N.W.
WASHINGTON, D. C. 20036
(202) 728-2700

December 2, 1988

MEMORANDUM FOR AIHC

NOVEMBER MONTHLY REPORT

1. EPA

a. Changing of the Guard. Lee Thomas has resigned as EPA Administrator effective January 20. Various proposals are floating to revise the organizational structure of EPA, including cabinet status. Vaun Newill, EPA Assistant Administrator for Research and Development has also resigned.

b. NESHAPs. EPA has filed papers in Natural Resources Defense Council v. Thomas asking that the U.S. Court of Appeals for the D.C. Circuit allow the Agency to postpone a decision in "the Benzene Rulemaking" implementing the Vinyl Chloride decision until August 31, 1989. NRDC has not objected. Eight specific substances proposed to be listed under Section 112 of the Clean Air Act will be directly affected by the determination.

c. National Contingency Plan. On November 17, EPA released proposed changes to the Superfund National Contingency Plan (NCP). Key issues addressed include scope of removal actions, ARARs (applicable, relevant and appropriate requirements), and selection of remedy. The proposed NCP states: "Overall protection of human health and the environment and compliance with [ARARs] (or invoking a waiver) are threshold criteria that must be satisfied in order for an alternative to be eligible for selection. Long-term effectiveness and permanence, reduction of toxicity, mobility, or volume, short-term effectiveness, implementability, and cost are the primary balancing factors used to weigh major trade-offs between alternative hazardous waste management strategies." State and community acceptance are described as "modifying considerations" that are formally taken into account after public comment is received on a proposed remedial plan.

AP00053659

The proposed NCP provides that remedial action selected at Superfund sites should reduce contaminant exposure levels so that the excess risk of an individual contracting cancer due to lifetime exposures to carcinogens is no higher than to a range between 10^{-4} to 10^{-7} . Reportedly, OMB has sought to reduce the range of risks used to determine contamination allowed to remain at Superfund sites from 10^{-4} to 10^{-7} to 10^{-4} to 10^{-6} , with 10^{-5} as the point of departure. Dingell has criticized OMB's involvement.

d. SAB. The Science Advisory Board has criticized a document by EPA's Carcinogen Assessment Group (CAG) on lead carcinogenicity as incomplete and inconsistent with Agency Guidelines on cancer risk. At issue is a tentative designation by CAG of lead as a "B2" (probable human carcinogen).

SAB has recommended revisions to EPA's radionuclide NESMAP methodology to include a quantitative analysis of modeling uncertainties.

SAB has commented on EPA's recently proposed Guidelines for Male and Female Reproductive Risk Assessment. SAB recommends that the Male and Female Guidelines be combined and that there be more thorough discussion of weight-of-the-evidence, including the relative significance of various end-points. The Guidelines also note the relevance of maternal toxicity in assessing effects observed. The comment on the importance of mechanistic data seems pertinent to EPA's pending update of the cancer guidelines: "The 'probable positive' category should not include agents for which there is convincing evidence that the mechanism(s) by which an agent causes adverse reproductive effects in one or more mammalian species are not applicable to humans."

e. Cancer Guidelines. EPA will conduct a public workshop relating to changes in the Cancer Risk Assessment Guidelines in January and hopes to complete revision to the Guidelines in 1989.

f. Exposure Guidelines. EPA will soon propose new Exposure Assessment Guidelines; currently the Guidelines are under review by the Risk Assessment Council.

g. EPA Reports. EPA has published a layman's report on its activities on environmental issues (air, water, land, toxic chemicals, indoor air pollution), entitled "Environmental Progress and Challenges: EPA's Update." Another EPA study, "Indoor Air Quality in Public Buildings," asserts that indoor air pollutants such as VOCs can be 100 times greater in new buildings than surrounding outdoor levels and may contribute to

the "sick building" syndrome. OMB has now cleared a home survey to estimate the relationship between cancer and indoor air pollution.

h. Global Warming. An EPA report entitled "The Potential Effects of Global Climate Change in the United States" addresses global warming and greenhouse effects, including scenarios based on five to nine degree (Fahrenheit) hikes in U.S. temperatures.

i. Non-Attainment Policy. It is reported that EPA will soon issue an advance notice of proposed rulemaking proposing extremely stringent revisions to the Implementation Plan for Southern California in an effort to force Congress to act on clean air legislation.

j. CAIR Rule. EPA has promulgated a comprehensive assessment information rule seeking toxicity data on chemicals under TSCA. The original proposal requested information on 47 chemicals and environmentalists have alleged that OMB forced the reduction in the number of chemicals.

k. Methylene Chloride. EPA has issued data call-ins requiring manufacturers of pesticide products containing methylene chloride to provide additional health and safety data or face cancellation of their products.

l. Human Subject Studies. EPA and 14 other agencies have issued a joint proposed rule, "Federal Policy for the Protection of Human Subjects," 53 Fed. Reg. 45661 (Nov. 10, 1988). Provisions are included relating to documentation of "informed consent" by subjects.

m. Acute Toxicity Tests. Animal rights activists have criticized a new EPA policy that will reduce by 1/5 the number of animals used in acute toxicity tests as an insufficient reduction in animal wastage.

2. OSHA/NIOSH

a. Hazard Communication. The D.C. Circuit has upheld OSHA's citation of General Carbon under the Hazard Communication Standard for failing to put warning labels on copper and graphite brushes that emit those substances at 1% of the Permissible Exposure Level. The Court rejected the company's argument that the brushes were "articles" and did not pose significant risk to workers. St. Mary's Carbon Co., General Carbon v. OSHRC (No. 87-1805, Nov. 8, 1988). The court noted that the current definition of article does not require that exposure levels be so high as to pose actual risk for the labeling requirements to apply. The court sustained OSHA's

view that all hazards included in the MSDS must be listed on the label, but did not rule on issues relating to the appropriateness of the label since they had not been raised below.

OSHA will hold hearings on December 6 in connection with its pending rulemaking to revise the generic Hazard Communication Standard. Key issues include the "articles" exemption and the issue of de minimis; whether all hazards listed in the MSDS must be included on the label; and the treatment of mixtures.

b. Grain Dust Standard. The U.S. Court of Appeals for the Fifth Circuit has upheld OSHA's grain dust standard setting a 1/8 inch action level but remanded to the Agency an issue relating to the economic feasibility of applying the grain handling standard to grain elevator operators. National Grain and Feed Association v. OSHA (Nos. 87-2960 and 88-4256, Oct. 27, 1988).

c. Proposed Fine. OSHA proposes to fine John Morrell & Co. \$4.33 million for failing to prevent cumulative trauma disorder among employees at its meat packing plant. The fine would be the largest ever assessed against a single employer.

d. Benzene Workers. Shell Oil reports that its workers have no higher rates of leukemia, abnormal blood counts or chromosome aberrations than the national average. The information was developed through the company's medical surveillance program.

e. NIOSH Interest In Reproductive Risks. A NIOSH official, Janet Haartz, told the NTP that 15% of NIOSH resources are devoted to the study of reproductive hazards.

f. BLS Survey. A Bureau of Labor Statistics survey issued on November 15 reports 400,000 more workplace injuries and illnesses in 1987 than in 1986. The increase may be attributable to increased reporting, according to the BLS Commissioner.

3. EEOC

a. Fetal Protection Decision. The EEOC has ruled that there is reasonable cause to believe that the Children's Hospital of Birmingham violated sex discrimination laws by requiring a pregnant x-ray technologist to take maternity leave. The hospital had based its removal of the employee on the belief that there is no safe level of radiation exposure to the developing fetus. EEOC disagreed with the hospital's scientific conclusion.

4. ATSDR

a. Available Documents. The Agency for Toxic Substances and Disease Registry has published a "Proposed Decision Guide for Identification of Chemical Specific Data Needs Relevant to Toxicological Profiles." A final document, "Policies and Procedures for Establishing a National Registry of Persons Exposed to Hazardous Substances," is also available. Clement Associates has a contract to do tox profiles.

5. ITC.

a. Priority List. The Interagency Testing Committee has added six chemicals to the priority list for consideration by EPA as part of the process of identifying chemicals for testing under TSCA. The ITC recommended butyraldehyde without the usual 12-month time frame for EPA's response.

6. DEPARTMENT OF HEALTH AND HUMAN SERVICES

a. NTP. The National Toxicology Program recommended toxicology tests for 13 chemicals on November 15. NTP has also published its peer review panel evaluation schedule for toxicology and carcinogenesis studies. 53 Fed. Reg. 46942 (Nov. 21, 1988).

7. CONGRESS

a. Air Toxics. Dingell has introduced an EPA-drafted bill to control hazardous air pollutants prior to termination of the last session of Congress.

b. High Risk Occupational Disease Notification. In a recent speech, the chief counsel for the Senate Subcommittee on Labor, James Brudney, predicted that Congress would consider a work-related disease and notification bill next year. Brudney claimed that such legislation would not duplicate OSHA hazard communication and was needed because cancer cases could be prevented if workers were notified and sought earlier medical attention.

8. IN THE STATES.

a. Proposition 65 - New Regulations. New regulations have been issued by the State of California on October 27 implementing Proposition 65. Environmentalists have criticized the regulations as affording insufficient protection from pesticide contamination of groundwater.

b. Proposition 65 - Reproductive Hazards. The California Science Advisory Panel issued Draft Interim Guidelines for identifying developmental and reproductive hazards under Proposition 65. The November 15 Guidelines state that in evaluating sufficiency of data, a weight-of-the-evidence approach should be utilized to evaluate the body of information available for a given chemical. Maternal toxicity should be addressed on a case-by-case basis. "The types of developmental effects should be examined carefully and not discounted as being secondary to maternal toxicity, especially when exposures are near the levels considered to be maternally toxic. In some situations, where human exposures are near the levels considered to be the maternally toxic dose, substances that show developmental effects at doses associated with maternal toxicity should be considered for listing."

The Panel recommended that the list of reproductive toxins be expanded to include ethylene glycol monoethyl ether, ethylene glycol monomethyl ether, hexachlorobenzene, iodine-131, and mechlorethamine. The Panel meets again on December 16.

c. Proposition 65 - Preemption. The Environmental Defense Fund has written Assistant Secretary of Health and Human Services, Robert Helms, the official responsible for implementing President Reagan's Executive Order on Federalism, that federal preemption of Proposition 65 may be counter to that order.

d. Proposition 65 - Litigation. On the litigation front, the California Lieutenant Governor has filed a notice of intent to sue eight major oil companies for alleged violation of Proposition 65 based on claimed leaks of benzene from underground storage tanks.

Also on the litigation front, tobacco companies have settled a court case brought by the Attorney General and agreed to begin labeling individual packages of tobacco products to comply with the warning requirements of Proposition 65. The companies had attempted to comply by establishing a toll free number. The companies have stated that they plan to label in all 50 states rather than attempt to limit labels to California.

Litigation by the environmentalists continues over the propriety of regulations exempting food, drugs and cosmetics from Proposition 65 due to FDA regulation.

e. California Controls On Benzene Emissions From Gasoline. California has proposed regulations limiting the benzene content of gasoline for motor vehicles in the state.

f. Cal/OSHA. On November 8, California voters passed Proposition 97, reinstating state enforcement of occupational safety and health regulation.

g. Toxic Hazards in Michigan. A Michigan Public Interest Group asserts that high cancer rates in certain Michigan counties are attributable to exposure to toxic substances from waste sites and in the workplace.

h. Massachusetts Study. The Massachusetts Department of Health has issued a study showing low awareness of reproductive hazards among 198 employers surveyed (chemical and electronic firms). The authors claim that only 40% of firms who used suspected reproductive hazards expressed awareness of health risks. The authors conclude that there is need for additional information on such risks as well as guidance in formulating non-discriminatory policies.

6. SCIENCE NOTES

a. Modeling of Dioxin Risks. Michael Gough of Resources for the Future has published a paper entitled "Science Policy Choices and the Estimation of Cancer Risk Associated with Exposure to TCDD," vol. 8, Risk Analysis, No. 3 (1988). Gough reviews EPA's risk assessment for TCDD and discusses the implications of EPA's departure from a no-threshold model.

b. Risk Communication. In the same issue of Risk Analysis, Carlyn Konheim discusses "Risk Communication in the Real World." She argues that site-specific risk assessments do not answer the public's real concerns about the safety of a project. What is needed is a risk-benefit analysis, an explanation of comparative risk, and answers to practical questions, not merely a prediction of upper bound risks.

c. Travis Book. Curtis Travis of Oak Ridge has published a new book, Carcinogenic Risk Assessment (ed. Plenum, N.Y., 1988).

d. Alarm From Epidemiology Studies. In the current issue of "Science," Alvan Feinstein of the Yale School of Medicine, writes that epidemiology studies often exaggerate cancer risks of daily life.

e. Epidemiology Primer. Otto Wong has published an article "Using Epidemiology to Determine Causation in Disease" in Natural Resources and the Environment (Vol. 3, 1988). The article reviews classic criteria for determining whether or not a causal association exists in layman's terms.

f. Reproductive Hazards Study. The Semiconductor Industry is about to award a contract to address possible elevated instances of miscarriages related to semiconductor manufacturing.

Sara D. Schotland