► Identification of substance (synonyms, labels, physical and chemical properties).

► Background and history of substance.

► Health effects (short and long-term effects and signs of exposure, with emphasis on the potential of a subject to cause cancer).

► Exposure control measures (personal protection, medical guidelines, sampling methodologies, analytical procedures, and engineering controls).

The NIOSH recommended standards for carcinogens will serve as a "trial balloon" for developing documenting procedures that can be used later for a wider variety of occupational health hazards, including mutagens and teratogens, the NIOSH working papers said. NIOSH anticipates that "full production" capability for recommended work practice standards for carcinogens will be developed during fiscal 1977.

This program will not circumvent the regulatory process, but "supports and complements it." The recommended standards will be designed "in such a way that the Occupational Safety and Health Administration could at any time make full regulatory use of them."

NIOSH said that the program also "will be designed to complement the other major documentation activities of the Institute. For example, the 'alerts' are more rapid but less comprehensive responses than these recommended standards, which are in turn more rapid but less comprehensive responses than criteria documents."

The recommended standards probably will be distributed "according to an active dissemination plan" through trade associations, unions, industry, and other sources, and will be designed "to assist employers in taking action to insure some degree of personal protection for employees from exposure to carcinogenic, mutagenic, and/or teratogenic substances."

Prototype Documents

The six substances to serve as subjects for prototype NIOSH recommended standards are as follows:

► Auramine — two manufacturers, crystal in pure form, dissolved in H_2O or CH_3CH_2OH. One human study confirms as bladder cancer. Liver cancer in rats.

► Domethyl Sulfate — one manufacturer, liquid form is inhaled causing possible bronchial and oat cell carcinoma in man (4 cases). In animals, CNS sarcomas prenatally, spreading to lungs, nasal cavities, cerebellum; also nuerocytoma and lymphosarcoma.

► Chrysene — As solid or particulate in air is inhaled. A component of coal tar and therefore a suspected carcinogen. Skin carcinomas and sarcomas in animals.

► Dieldrin — one manufacturer, no human data in IARC. Is inhaled as dust or vapor (if in solution and sprayed). Liver cancer in animals.

► N-nitroso-diethylamine — carcinogenic in all 10 species tested including monkeys (nasal, trachea, lung, esophagus, liver through ingestion, inhalation, and skin-painting). Single doses are effective prenatally in several species. Yellow volatile liquid also synthesized by bacteria in digestive tract. Many patents for various uses.

► o-Aminocazotoluene — carcinogenic in mice, rats, dogs, and hamsters. Attacking liver, gallbladder, lungs. Effective in single doses to new-born mice. Two manufacturers, a crystal used in solution as dye.

Literature Searches

A list of the 58 suspected carcinogens to undergo complete literature searches in the remainder of fiscal 1976 follows:

(1) Polycyclic Aromatic Hydrocarbons
- Benz (a) anthracene
- Benzo (a) pyrene
- Dibenzo (a,i) pyrene
- Benzo (b) fluoranthene
- Benzo (j) fluoranthene
- Benzo (e) pyrene
- *Chrysene
- Dibenz (a,h) anthracene
- Dibenzo (h,rst) pentaphene
- Dibenzo (a,h) pyrene
- Dibenzo (a,e) pyrene
- Dibenzo (a,l) pyrene
- Indeno (1,2,3-cd) pyrene

(2) Polycyclic Azaheterocyclic Compounds
- Dibenz (a,h) acridine
- Dibenz (a,j) acridine
- 7H-Dibenzo (c,g) carbazole
- Benz (c) acridine

(3) *Dieldrin

(4) *Dimethyl sulfate
- Diethyl sulfate

(5) Methyl methane sulfonate
- Ethyl methane sulfonate

(6) Urethane
- N-nitroso-n-methyl-urethane

(7) 1,3-Propane Sulton

(8) Thioacetamide

(9) N-methyl-a-nitrosoguanidine

(10) Acetamide

(11) Thiouracil

(12) *M-nitrosodiethylamine
- N-nitroso-di-n-butylamine

(13) Nitrosoethylurea
- Ethylenethiourea
- Thiourea
- Nitrosomethylurea

(14) Azo Dyes
- Amaranth
- Para-Aminoazobenzene
- *Ortho-Aminoazotoluene
- Carmoisine
- Chrysoidine
- 4-Hydroxyazobenzene
- Oil Orange SS
- Orange I
- Ponceau MX
- Ponceau BR
- Ponceau SX
- Sudan I
- Sudan II
- Sudan red 7B
- Yellow AB
- Yellow OB

(15) Other Dyes
- *Auramine
- 3,3' Dimethoxybenzidine
- 3,3' Dimethylbenzidine
- Magenta
- 4,4' methylene bis (2-methylaniline)
- 4,4' methylene dianiline

(16) Chromium and its compounds (other than Chromium VI)

*Special emphasis subjects

PLAINTIFF'S EXHIBIT
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