



Testing

**NTP DRAFT FISCAL 1982 ANNUAL PLAN LISTS
CHEMICALS SLATED FOR GENETIC, CANCER TESTS**

A total of 19 two-year carcinogenesis bioassays will be started and another 27 completed under the National Toxicology Program in fiscal 1982, according to a draft of the program's annual plan.

In addition, 300 substances will be tested in *Salmonella* for mutagenic activity, 72 will be tested for heritable genetic effects in *Drosophila*, and 75 will be tested for cytogenetic effects in Chinese hamster ovary cells, the draft plan noted.

Lists of the chemicals to be tested during fiscal 1982 are published in the Full Text section of this issue.

The draft plan, a copy of which was obtained by BNA, outlines NTP plans for the fiscal year beginning in October 1981. Funding levels outlined in the plan are contingent on final approval without change of President Reagan's fiscal 1982 budget request.

According to the draft, the fiscal 1982 funding level of \$74.8 million, up from \$68.4 million in fiscal 1981, will allow the program to stabilize the number of chemicals placed on test, especially long-term bioassay. It also will allow the program to devote a greater proportion of resources and attention to test methods development and research, according to the draft.

Carcinogenicity Testing Program

In the carcinogenesis testing program, the draft said all 19 chemicals beginning bioassays in fiscal 1982 will be tested using broadened protocols with various special studies integrated into the experimental design.

The program also will begin three long-term studies not formally a part of the bioassay program. These studies will examine the cause of increased risk of buccal and pharyngeal cancer experienced by newsprint pressroom workers, the effects of fluoride on the fibrogenicity and carcinogenicity of chrysotile asbestos, and the effect of aging in susceptibility to known carcinogens.

The program also will complete evaluation of test data received on the mouse lung adenoma test to help determine the feasibility of using this short-term bioassay in carcinogenicity testing of chemicals, the draft said.

Program Goals Listed

Although fiscal 1982 is the program's fourth year, it will be its first year in permanent status. During fiscal 1981, the program also took over responsibility for the National Cancer Institute's carcinogenesis bioassay program.

Under the broad objective of providing the necessary scientific information for prevention of human disease related to chemical exposure, the program has four principal goals:

- ▶ To broaden the toxicological characterization of chemicals that are tested;
- ▶ To increase the rate of chemical testing as funding permits;
- ▶ To develop protocols appropriate for regulatory needs; and
- ▶ To communicate program plans and results to govern-

ment agencies, the medical and scientific community, and the public.

Carcinogens**SECOND ANNUAL MAGUIRE REPORT TO LIST
88 SUBSTANCES, UP FROM 25 IN FIRST REPORT**

A total of 88 chemical substances or processes are to be listed in the Second Annual Report on Carcinogens, scheduled for release by the Department of Health and Human Services in about two months.

The report, originally slated for release in December 1981, is prepared by the National Toxicology Program. Known as the "Maguire Amendment Report," the annual document was mandated by a 1978 amendment to the Public Health Service Act. That amendment requires the department to publish annually a report listing all substances known or reasonably anticipated to cause cancer and to which a significant number of persons in the United States are exposed (Current Report, Feb. 15, 1980, p. 1717).

The first annual report, released Aug. 6, 1980, listed 25 chemicals and processes (Aug. 8, 1980, p. 559).

According to an HHS spokesperson, the second annual report is undergoing review and should be ready for release in about two months. A synopsis of the report, however, was included in the NTP annual plan for fiscal 1982, obtained in draft form by BNA (See related article on this page).

Substances are entered on the report because the International Agency for Research on Cancer has determined that there is "sufficient evidence of carcinogenicity in experimental animals" to classify them as animal carcinogens, because they are regulated by the United States government as carcinogens, because they have been found to cause cancer in bioassays conducted by the National Cancer Institute or NTP, or because they were suggested for inclusion by the U.S. agencies that cooperated in preparing the report according to the NTP draft annual plan.

Among the 88 substances or processes in the report are naturally occurring substances, additives to foods or cosmetics, pesticides, pharmaceuticals, and a large number of substances that are associated with industrial production or are byproducts of manufacture, NTP said.

Substances Listed

Among the substances listed in the second annual report, but not listed in the first report, are acrylonitrile, carbon tetrachloride, chloroform, a number of dibenzopyrenes, formaldehyde, lindane, mirex, a number of nitrosamines, polychlorinated biphenyls, saccharin, TCDD, and toxaphene.

The 88 substances on the list are:

2-Acetylaminofluorene
Acrylonitrile
Aflatoxins
4-Aminobiphenyl
Amitrole
Aramite
Arsenic and compounds
Asbestos
Auramine, manufacture of
Benz(a)anthracene

Benzene
 Benzidine
 Benzo(b)fluoranthene and benzo(j)fluoranthene
 Benzo(a)pyrene
 Beryllium and compounds
 N,N-Bis(2-chloroethyl)-2-naphthylamine
 Bis(chloromethyl) ether and chloromethyl methyl ether
 Cadmium and certain compounds
 Carbon tetrachloride
 Chlorambucil
 Chloroform
 Chromium and compounds
 Coke oven emissions
 p-Cresidine
 Cycasin
 Cyclophosphamide
 2,4-Diaminotoluene
 Dibenz(a,h)acridine
 Dibenz(a,j)acridine
 Dibenz(a,h)anthracene
 7H-Dibenzo(c,g)carbazole
 Dibenzo(a,h)pyrene
 Dibenzo(a,i)pyrene
 1,2-Dibromo-3-chloropropane
 1,2-Dibromoethane
 Dichlorobenzidine
 1,2-Dichloroethane
 Diethylstilbestrol
 4-Dimethylaminoazobenzene
 Dimethyl carbamoyl chloride
 Dimethyl sulfate
 1,4-Dioxane
 Formaldehyde
 Hematite underground mining
 Hydrazobenzene
 Indeno(1,2,3-cd)pyrene
 Iron dextran
 Isopropyl alcohol manufacture using strong acid process
 Kepone
 Lead acetate and lead phosphate
 Lindane and other hexachlorocyclohexane isomers
 Melphalan
 Mirex
 Mustard gas
 2-Naphthylamine
 Nickel refining and certain compounds
 N-Nitrosodi-N-butylamine
 N-Nitrosodiethanolamine
 N-Nitrosodiethylamine
 N-Nitrosodimethylamine
 N-Nitrosodi-N-propylamine
 N-Nitroso-N-ethylurea
 N-Nitroso-N-methylurea
 N-Nitrosomethyl vinylamine
 N-Nitrosomorpholine
 N-Nitrosomornicotine
 N-Nitrosopiperidine
 N-Nitrosopyrrolidine
 N-Nitrososarcosine
 Oxymethalone
 Phenacetin
 Phenazopyridine hydrochloride
 Phenytoin
 Polychlorinated biphenyls
 Procarbazine and procarbazine hydrochloride
 β -Propiolactone
 Reserpine

Saccharin
 Saffrole
 Soots, tars, and oils
 Streptozotocin
 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)
 Thorium dioxide
 o-Toluidine hydrochloride
 Toxaphene
 Tris(axiridinyl)-phosphine sulfide
 Tris(2,3-dibromopropyl)phosphate
 Vinyl chloride

Testing

PHENYLENEDIAMINE COMMENT PERIOD EXTENDED; SPECIAL INDUSTRY PANEL FORMED

Industry groups seeking extra time to comment on an Environmental Protection Agency advance notice of proposed rulemaking on phenylenediamine testing were granted partial relief as the agency extended the timetable an additional 30 days to April 8 (47 FR 10597).

In written comments on the advance notice, the Chemical Manufacturers Association and the Cosmetic, Toiletry, and Fragrance Association asked that EPA extend the comment period 60 days beyond the original March 9 deadline.

CMA said the additional time was needed for a newly formed phenylenediamine special program panel to conduct a survey of chemical uses, manufacturers' production volume, and human and environmental exposures to the chemicals.

The special panel, which is under the auspices of CMA, was formed after the agency in January issued the advance notice indicating it may require testing on 13 phenylenediamines and monitoring of 34 other members of that chemical category (Current Report, Jan. 15, p. 1084). EPA is considering action on the chemicals under the Toxic Substances Control Act on recommendation of the Interagency Testing Committee.

Chemical Manufacturers Association

The special phenylenediamine manufacturers panel "plans to discuss its proposed survey form with EPA staff before it is finalized and to consult with the staff as the survey proceeds," according to CMA's comments.

The panel also will form a toxicology task group to analyze the toxicological issues raised by the agency's advance notice, the industry group said. The group will review all available scientific literature on the chemicals and evaluate the agency's suggested testing.

The phenylenediamine panel is one of a number of chemical manufacturer's groups which have organized the makers of one chemical or chemical category, often under the umbrella of a wider-ranging industry association such as CMA. In a few cases, the groups have offered to conduct voluntary testing in lieu of the agency issuing a formal test rule under Section 4 of TSCA.

Other Comments

The International Isocyanate Institute Inc. and Eastman Kodak Co. commented on individual members of the phenylenediamines category under consideration for either testing or monitoring by the agency.

The institute called on the agency not to regulate 1,3-diamine-4-methylbenzene, 2,6-diamine-4-methylbenzene, and diaminetoluene, claiming that exposure to the chemicals is low.