CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65)

NOTICE OF INTENT TO LIST CHEMICALS
AUGUST 25, 2000

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) provides two mechanisms for administratively listing chemicals which are known to the State to cause cancer or reproductive toxicity [Health and Safety Code Section 25249.8(b)]. One mechanism by which a chemical is listed is if a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. For carcinogenicity, the United States Environmental Protection Agency (U.S. EPA), the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the United States Food and Drug Administration (FDA), and the National Institute for Occupational Safety and Health (NIOSH) have been identified as authoritative bodies for purposes of the Act. For reproductive toxicity, U.S. EPA, IARC (for transplacental carcinogenicity only), FDA, and NIOSH have been identified as authoritative bodies for purposes of the Act. The criteria for listing chemicals through the authoritative bodies mechanism are set forth in Title 22, California Code of Regulations (22 CCR), Section 12306.

Under the second mechanism for the administrative listing, a chemical is listed when a state or federal agency has formally required that the chemical be labeled or identified as causing cancer or reproductive toxicity. The criteria for listing chemicals through this mechanism are set forth in 22 CCR, Section 12902.

As the lead agency for the implementation of Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency intends to list the chemicals identified below as known to the State to cause cancer or reproductive toxicity, pursuant to the two administrative mechanisms provided in Health and Safety Code Section 25249.8(b).

In a public notice published on June 2, 2000, OEHHA announced 10 chemicals were under consideration for administrative listing based on a review of information indicating that the chemicals may meet the criteria set forth in 22 CCR, Section 12306 or Section 12902. OEHHA solicited comments and information relevant to the evaluation of these chemicals in the context of the regulatory criteria for administrative listing under Proposition 65. The public comment period began on June 2, 2000, and closed on August 1, 2000. [Except for three of the chemicals anthraquinone, AZT (3'-azido-3'-deoxythymidine), and fumonisin B1 which were granted comment period extensions until September 15, 2000.] A public forum was held on July 11, 2000 to provide an opportunity for oral comments. Written comments have been received on diuron and methyleugenol and are under review by OEHHA staff. No comments were received on five of the chemicals during the public comment period. OEHHA has determined that these five chemicals meet the criteria for administrative listing: three chemicals meet the criteria for listing under the authoritative bodies mechanism (Table A), and two chemicals meet the criteria for listing via the 'formally required to be labeled' mechanism (Table B). Documents providing the basis for the listing of these chemicals can be obtained

from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the OEHHA Home Page at www.oehha.ca.gov/.

Under the authoritative bodies mechanism, objections to the listing shall be made on the basis that there is no substantial evidence that the criteria of sufficiency of evidence of carcinogenicity or reproductive toxicity identified in 22 CCR, Section 12306 have been satisfied. Objections to listings via the second mechanism are made on the basis that the criteria and definitions in 22 CCR, Section 12902 have not been met. Any one wishing to object to the listing of chemicals in the tables below should submit written comments in triplicate, along with supporting documentation, by mail or by fax to:

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
301 Capitol Mall, 2nd Floor, Room 205
Sacramento, California 95814
Fax No.: (916) 327-1097
Telephone: (916) 445-6900

Comments may also be hand-delivered to Ms. Oshita at the Office of Environmental Health Hazard Assessment at the same address.

In order to be considered, comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by fax) by 5:00 p.m. on Monday, September 25, 2000.

Table A1. Chemicals determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12306 for listing as causing **cancer** under the authoritative bodies mechanism:

Chemical	CAS No.	Reference
Bromate ion and its water soluble salts	-----	U.S. EPA (1998)
Bromoethane	74-96-4	NTP (1989)
Isoxaflutole	141112029-0	U.S. EPA (1997)

s

Chemical	CAS No.	Toxicological Endpoints	Reference
Gemfibrozil	25812-30-0	Cancer	FDA (1998)
Zileuton	111406-87-2	Cancer Developmental toxicity Female reproductive toxicity	FDA (1996)

References:

Food and Drug Administration (FDA, 1998). Final printed labeling for the drug gemfibrozil. FDA approved 1998.

Food and Drug Administration (FDA, 1996). Final printed labeling for the drug zileuton. FDA approved 1996.

National Toxicology Program (NTP, 1989). *Toxicology and Carcinogenesis Studies of Bromoethane (Ethyl Bromide) (CAS No. 74-96-4) in F344/N Rats and B6C3F$_1$ Mice (Inhalation Studies).* NTP Technical Report Series No. 363 NTIS Publication No. 90-2818. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC.

U.S. Environmental Protection Agency (U.S. EPA, 1997). *Memorandum: Carcinogenicity Peer Review of Isoxaflutole.* Office of Prevention, Pesticides and Toxic Substances. August 6, 1997.

U.S. Environmental Protection Agency (U.S. EPA, 1998). *Health Risk Assessment/Characterization of Drinking Water Disinfection Byproduct Bromate.* Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. EPA, Washington, D.C.