

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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

**CHEMICALS UNDER CONSIDERATION FOR POSSIBLE LISTING
VIA THE AUTHORITATIVE BODIES MECHANISMS:
REQUEST FOR RELEVANT INFORMATION**

June 2, 2000

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the Act) requires the Governor to publish, and update at least annually, a list of chemicals known to the State to cause cancer or reproductive toxicity. The Act provides two mechanisms for administratively listing chemicals as 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 US Environmental Protection Agency (US EPA), the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the 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. The criteria for listing chemicals through the "authoritative bodies" mechanism are set forth in Title 22, California Code of Regulations (22 CCR) Section 12306.

The second mechanism for the administrative listing of a chemical applies if an agency of state or federal government 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 is investigating the possible listing of the chemicals identified below, based upon information in the references cited. Documentation summarizing the rationale for considering the evaluation of these chemicals for possible administrative listing is available from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the Internet at the following address:
<http://www.oehha.ca.gov/>.

OEHHA is committed to public participation and external scientific peer review in its implementation of Proposition 65, and welcomes public input on this listing process. As part of its efforts to ensure that regulatory decisions are based upon a thorough consideration of all relevant information, OEHHA is soliciting information which may be relevant to the evaluation of these chemicals in the context of the Proposition 65 administrative listing regulatory criteria (22 CCR Section 12306 or Section 12902, as appropriate).

A public forum will be held on **Tuesday, July 11, 2000** to provide an opportunity for interested parties to present oral comments and to discuss the scientific data and other information relevant to a determination as to whether these chemicals meet the criteria for listing set forth in 22 CCR Section 12306 or Section 12902. The public forum will begin at 10:00 a.m. at 1515 Clay Street, Elihu Harris State Building, Training Room G, Oakland, California and will last until all business has been conducted or until 5:00 p.m.

Written comments provided in **triplicate**, along with supporting information, may also be submitted to:

Cynthia Oshita
Office of Environmental Health Hazard Assessment
301 Capitol Mall, 2nd Floor
Sacramento, California 95814
FAX: (916) 327-1097
Telephone: (916) 445-6900

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. Tuesday, August 1, 2000.

Following the review of all comments received, OEHHA will announce its intention to proceed with the listing of those candidate chemicals that meet the regulatory criteria for administrative listing in a *Notice of Intent to List Chemicals*.

- A. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as known to cause **carcinogenicity** via the “authoritative bodies” mechanism:

Chemical	CAS No.	Reference
Anthraquinone	84-65-1	NTP (1999a) NTP (1999d)
AZT (3'-azido-3'-deoxythymidine)	30516-87-1	NTP (1999b) IARC (2000)
Bromate ion and its water soluble salts	-----	U.S. EPA (1998)
Bromoethane	74-96-4	NTP (1989)
Diuron	330-54-1	U.S. EPA (1997a)
Fumonisin B ₁	116355-83-0	NTP (1999c) NTP (1999d)
Isoxaflutole	141112-29-0	U.S. EPA (1997b)
Methyleugenol	93-15-2	NTP (1998a) NTP (1998b)

- B. Chemicals which may meet the criteria set forth in 22 CCR Section 12902 for listing as known to cause **cancer and/or reproductive toxicity** via the “formally required to be labeled or identified” mechanism:

Chemical	CAS No.	Toxicological Endpoints	References
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.

International Agency for Research on Cancer (IARC, 2000). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 76: *in press*, as reported on the IARC website at www.iarc.fr. *Some Antiviral and Antineoplastic Drugs, and Other Pharmaceutical Agents*. IARC, Lyon.

National Toxicology Program (NTP, 1989). *Toxicology and Carcinogenesis Studies of Bromoethane (Ethyl Bromide) (CAS No. 74-96-4) in F344/N Rats and B6C3F₁ 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.

National Toxicology Program (NTP, 1998a). *Toxicology and Carcinogenesis Studies of Methyleugenol (CAS No. 93-15-2) in F344/N Rats and B6C3F₁ Mice (Gavage Studies)*. Board Draft. NTP Technical Report Series No. 491 NTIS Publication No. 98-3950. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1998b). *Summary Minutes from Peer Review of Draft Technical Reports of Long-Term Toxicology and Carcinogenesis Studies by the Technical Reports Review Subcommittee on October 30, 1998*. NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1999a). *Toxicology and Carcinogenesis Studies of Anthraquinone (CAS No. 84-65-1) in F344/N Rats and B6C3F₁ Mice (Feed Studies)*. Board Draft. NTP Technical Report Series No. 494 NTIS Publication No. 99-3953. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1999b). *Toxicology and Carcinogenesis Studies of AZT (CAS No. 30516-87-1) and AZT/? -Interferon A/D in B6C3F₁ Mice (Gavage Studies)*. NTP Technical Report Series No. 469 NTIS Publication No. 96-3959. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1999c). *Toxicology and Carcinogenesis Studies of Fumonisin B₁ (CAS No. 116355-83-0) in F344/N Rats and B6C3F₁ Mice (Feed Studies)*. Board Draft. NTP Technical Report Series No. 496 NTIS Publication No. 99-3955. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1999d). *Summary Minutes from Peer Review of Draft Technical Reports of Long-Term Toxicology and Carcinogenesis Studies by the Technical Reports Review Subcommittee on May 21, 1999*. NTP, Research Triangle Park, NC.

U.S. Environmental Protection Agency (U.S. EPA, 1993). *Final Draft for the Drinking Water Criteria Document on Bromate*. Prepared for the Health and Ecological Criteria Division, Office of Science and Technology, Office of Water by Clement International Corporation. September 30, 1993.

U.S. Environmental Protection Agency (U.S. EPA, 1997a). *Memorandum: Carcinogenicity Peer Review of Diuron*. Office of Prevention, Pesticides and Toxic Substances. May 8, 1997.

U.S. Environmental Protection Agency (U.S. EPA, 1997b). *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.