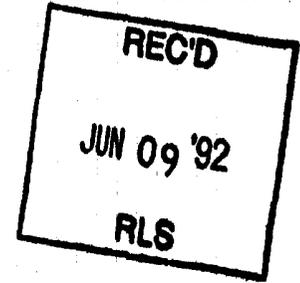


SHERWIN GARDNER
Senior Vice President
Science and Technology



202/337-9400
FAX: 202/337-4508



MEMORANDUM

TO: Technical Regulatory Affairs Committee
Technical Contacts

FR: Sherwin Gardner
Senior Vice President, Science and Technology

DT: June 3, 1992

RE: Possible Settlement of Proposition 65 "Duke II" Litigation —
AFL-CIO, et al. v. Deukmejian, et al.

The "Duke II" litigation involves a challenge by environmental and labor groups to Proposition 65's "safe harbor" regulations, which provide a temporary exemption from warning requirements for FDA-regulated products until the state establishes specific regulatory "no significant risk levels" (NSRL's) for listed carcinogens.

The lower court ruled in favor of the plaintiffs and found the regulations invalid. The case is currently on appeal. GMA, along with four other trade associations, is an intervenor in the litigation.

As you may know, plaintiffs' attorneys recently initiated settlement discussions with GMA's California counsel. GMA and the other intervenor associations are currently engaged in discussions with the other parties — the environmental and labor groups and the state.

During settlement discussions, it has become important to establish a realistic timetable for the state's completion of the task of issuing NSRL's for listed carcinogens that, to date, do not have levels associated with them — in final regulations, proposed regulations, or on the expedited risk assessment list recently published by the state. In order for the state to estimate the time it will take to complete its work, the state's scientific staff want to know how to prioritize the remaining carcinogens — in terms of the importance to industry of establishing NSRL's.

To facilitate this determination, the intervenor associations had an outside consultant consider the remaining listed carcinogens and delete chemicals that would not reasonably be expected to be present in FDA-regulated products, and chemicals for which industry does not need NSRL's for other reasons (e.g., prescription drugs). If acceptable to the memberships of the associations, these lists of "deletable" chemicals will be given to the state with the understanding that it is not important to the FDA-regulated industry that NSRL's be established for those chemicals.

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The list attached to this memo is the suggested "deletable" list for non-drug compounds.

Please examine the attached list carefully. Should you identify any chemical on it for which you would like the state to establish a NSRL, please let us know by June 16, 1992.

We will keep you informed of the progress of the settlement negotiations.

Attachment
1137L/2

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**Suggested List of Non-Drug Proposition 65 Carcinogens For Which
No Significant Risk Levels Would Not Be Requested**

<u>Compound</u>	<u>Source</u>
Betel quid with tobacco	Betel nut (not found in the U.S.)
Bitumens, extracts of steam-refined and air-refined	Class of cementitious substances of which asphalts, tars, pitches, and asphaltites are typical
Ceramic fibers (airborne particles of respirable size)	Ceramics; insulation
3,3'-Dichloro-4,4'-diaminodiphenyl ether	Industrial chemical (no known commercial applications in U.S.)
Diesel engine exhaust	Automobiles, motor vehicles, other engines
1,2-Diethylhydrazine	Rocket fuel
Erionite	Fibrous mineral (naturally occurring)
Ethyl methanesulfonate	Experimental mutagen used in research
Gasoline engine exhaust (condensates/extracts)	Engines
Glasswool fibers (airborne particles of respirable size)	Insulation
Methyl iodide	Methylation product
Mustard Gas	Nerve Gas
N-Nitrosodi-n-propylamine	Experimental mutagen/carcinogen
3-(N-Nitrosomethylamino)propionitrile	Laboratory chemical used in research only
4-(N-Nitrosomethylamino)-1- (3-pyridyl)1-butanone	Laboratory chemical used in research only

<u>Compound</u>	<u>Source</u>
Residual (heavy) fuel oils	Oils
Shale-oils	Naturally occurring; fuels
Thorium dioxide	Source material for nuclear energy
Tobacco, oral use of smokeless products	Tobacco
Tobacco smoke	Cigars, cigarettes
Tris (2-chloroethyl) phosphate	Flame retardant
Trypan blue (commercial grade)	Laboratory chemical
Unleaded gasoline (wholly vaporized)	Gasoline