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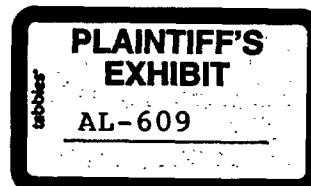
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California Proposition 65
Safe Drinking Water and Toxic Enforcement Act of 1986

Nov. 4, 1986, Proposition 65 was approved by a majority of California voters, ostensibly to protect them from hazardous chemicals, but it has far reaching implications outside that state. Thus far there are a total of 83 chemicals listed by the State of California as being carcinogens or reproductive toxicants (Attachment 1). Warning requirements for the first 29 listed chemicals have an effective date of 27 February 1988. Most observers believe that the complete list of IARC (International Agency for Research on Cancer) carcinogens will eventually be on California's list. In general terms, Prop 65 prohibits the discharge of carcinogens and reproductive toxins into the environment it also requires that "clear and reasonable" warnings be given before exposing people to carcinogens or reproductive toxins. The warnings which are mandated will probably have standard verbiage. Proposed language for warnings is in Attachment 2. Anyone doing business in the state of California will have to consider the possibility that their process, product, or service might be considered as a source of exposure under this Act. A detailed discussion of each section of this law is in Attachment 3.

All exposures are addressed by this law, consumer product exposures, occupational exposures and environmental exposures. Any exposures which don't fit into the consumer or occupational category are deemed to be environmental exposures. The Act doesn't clearly define "exposure" and initially this was feared to be the same as "significant amount" which is defined as any detectable amount. Draft interpretative guidelines (not legally binding) which have been issued by the California Health and Welfare Agency (HWA), the lead agency for this law, discuss a risk model for determining "significant risk". The determination that a specific application of a chemical does not pose a "significant risk" can be used to exempt that application from the warning requirements as well as the discharge prohibitions. In order to take advantage of the exemption for lack of "significant risk", businesses may very well have to show that the risk from all sources including their application poses no significant risk. Exemptions to these provisions can also be based on effective dates. Discharge prohibitions are effective 20 months after the listing of a chemical. Warning requirements are in effect 12 months after the listing of a chemical.

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Exemptions can also be granted when discharges conform with all other applicable regulations, permits and orders. There is a similar exemption for warning requirements when existing Federal law governing warnings preempts other laws. Thomas Warriner, Undersecretary of California HWA has stated that he is taking cognizance of applicable Federal regulations and has not yet identified any standards which clearly meet this requirement. This statement was made in regard to the warning requirement and it is unclear whether HWA will take a similar position on exemptions to the discharge prohibition.

While California's HWA is the lead agency, it not the agency responsible for enforcing this law. Any violation of this act is subject to civil penalties of up to \$2500 per day and actions may be brought by officials in the state of California as well as by private parties, who have the added incentive of monetary gain if the outcome of their suit supports their claim. If you use a risk model to determine that your application is exempt, you will still have to defend your position in the case of a suit.

There are four approaches people have taken to this regulation:

1. Exemption petitions have been filed with the state of California by trade associations representing the full spectrum of products covered by the FDA including food packaging. None of petitioners are optimistic.
2. Those same trade associations have also filed petitions with the FDA asking that agency for preemption of the California rule under the supremacy clause of the U.S. Constitution. To date there has been one letter from FDA Commissioner Young to Governor Deukmejian with no response. It is the belief of the various trade associations seeking exemptions that the FDA is reluctant to take a strong stand because of the prevailing climate of "federalism" in this administration. They believe that FDA would feel freer to act if there was support from the Department of Health and Human Services and from the Office of Management and Budget. In order to let these agencies know the nation wide impact it was suggested that interested parties contact their congressmen and make their positions known.
3. A Court challenge of this rule by a coalition of adversely affected entities based on any number of constitutional issues from due process, and supremacy to the commerce clause is possible. The Council on Labeling Uniformity is a coalition of trade associations covered by the FDA regulations. If they fail in their attempt to get FDA preemption they will consider this route.

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4. Obtain a "safe use determination" from HWA. In the draft interpretive guidelines HWA has proposed safe use determinations in order to provide guidance on the application of Prop 65. HWA will make a safe use determination for a particular application (processing fee - \$500) but any determination that they make is strictly advisory and not legally binding.

5. Implementation of compliance strategies is complicated by uncertainties created by HWA's frequent policy changes, their vague interpretive language and the total lack of specific regulations. Many people who think that California's rule making process is sufficiently slow to prevent any rules from being finalized before the February 27 effective date for the warning provisions. The principle author of Prop. 65, David Roe who represents the Environmental Defense Fund, proudly pointed out the "self implementing" nature of this law; it will go into effect and be enforced whether or not there are regulations.

There are several ongoing Alcoa FDA programs which should put us in good stead in making favorable risk assessments for our FDA sensitive products. These include a program to get continuing commodity guarantees from materials suppliers that residual vinyl chloride monomer level in their products is less than 5 ppb. and programs to remove IARC classified carcinogens from the metal rolling areas of plants where metal goes into FDA sensitive products.

The Environmental Defense Fund (EDF) who campaigned for this law in California is not promoting this type of rule in other states however there are several other states currently considering similar laws.

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ATTACHMENT 1

CHEMICALS LISTED UNDER PROPOSITION 65 AS KNOWN
TO CAUSE CANCER OR REPRODUCTIVE TOXICITY

CARCINOGENS

<u>Chemical</u>	<u>CAS Number</u>	<u>Date of Listing</u>
2-Acetylaminofluorene	53963	7/1/87
Acrylonitrile	107131	7/1/87
Adriamycin	23214928	7/1/87
AF-2; [2-(2-furyl)-3-(5-nitro-2-furyl)] acrylamide	3688537	7/1/87
ortho-Aminoazotoluene	97563	7/1/87
4-Aminobiphenyl (4-Aminodiphenyl)	92671	2/27/87
2 Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	712685	7/1/87
Amitrole	61825	7/1/87
ortho-Anisidine and ortho-Anisidine hydrochloride	90040	7/1/87
Analgesic mixtures containing phenacetin	---	2/27/87
Aramite	140578	7/1/87
Arsenic (inorganic arsenic compounds)	---	2/27/87
Asbestos	1332214	2/27/87
Auramine	492808	7/1/87
Azaserine	115026	7/1/87
Azathioprine	446866	2/27/87
Benz[a]anthracene	56553	7/1/87
Benzene	71432	2/27/87
Benzidine [and its salts]	92875	2/27/87
Benzo[b]fluoranthene	205992	7/1/87
Benzo[j]fluoranthene	205823	7/1/87
Benzo[k]fluoranthene	207089	7/1/87
Benzo[a]pyrene	50328	7/1/87
Benzotrichloride	98077	7/1/87
Benzyl violet 4B	1694093	7/1/87
N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornapazine)	494031	2/27/87
Bischloroethyl nitrosourea (BCNU)	154938	7/1/87
Bis(chloromethyl) ether	542881	2/27/87
1,4-Butanediol dimethanesulfonate (Myleran)	55981	2/27/87
beta-Butyrolactone	3068880	7/1/87
Certain combined chemotherapy for lymphomas	---	2/27/87
Chloroambucil	305033	2/27/87
Chloromethyl methyl ether (technical grade)	107302	2/27/87

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<u>Chemical</u>	<u>CAS Number</u>	<u>Date of Listing</u>
Chromium and certain chromium compounds	---	2/27/87
Coke oven emissions	---	2/27/87
Conjugated estrogens	---	2/27/87
Cyclophosphamide	50180	2/27/87
1,2-Dibromo-3-chloro-propane (DBCP)	96128	7/1/87
Diethylstilbestrol	56531	2/27/87
Ethylene dibromide	106934	7/1/87
Ethylene oxide	75218	7/1/87
Melphalan	148823	2/27/87
Methoxsalen with ultra-violet A therapy (PUVA)	298817	2/27/87
4,4'-Methylene bis (2-chloroaniline)	101144	7/1/87
Mustard Gas	505602	2/27/87
2-Naphthylamine	91598	2/27/87
Soots tars and lubricant base oils and derived products, specifically vacuum distillates, acid treated oils, aromatic oils, mildly solvent-refined oils, mildly hydrotreated oils, used engine oils, and mineral oils, when used in occupations such as mule-spinning, metal machinery, and jute processing.	---	2/27/87
Thorium dioxide	1314201	2/27/87
Treosulfan	299752	2/27/87
Vinyl chloride	75014	2/27/87

REPRODUCTIVE TOXICANTS

Aminopterin	54626	7/1/87
Chlorocyclizine hydrochloride	82939	7/1/87
1,2-Dibromo-3-chloropropane (DBCP)	96128	2/27/87
Diethylstilbestrol (DES)	56531	7/1/87
Diphenylhydantoin	630933	7/1/87
Ethylene oxide	75218	2/27/87
Etretinate	54350480	7/1/87
Isotretinoin	4759482	7/1/87
Lead	7439921	2/27/87
Methyl mercury	7439976	7/1/87
Thalidomide	50351	7/1/87
Valproate	99661	7/1/87
Warfarin	81812	7/1/87

Chemicals Added by the Science Advisory Panel
August 28, 1987

Name	CAS Number
Carcinogens	
Beryllium and beryllium compounds (by injection)	-----
Cadium and cadmium compounds	-----
Carbon tetrachloride	56235
Chloroform	67663
DDT	50293
3,3' - Dichlorobenzidine	91941
1,2 - Dichloroethane (Ethylene dichloride) (not by inhalation)	107062
Epichlorhydrin	106898
Hexachlorobenzene	118741
Crude hexachlorocyclohexane isomers	-----
Nickel refinery dust	-----
Nickel subsulfide	-----
Nickel carbonyl	-----
Dibutyl nitrosamine	924163
Diethyl nitrosamine	55185
Dimethyl nitrosamine	62759
N-nitroso-N-ethylurea	759739
N-nitroso-N-methylurea	684935
N-nitrosopyrrolidine	-----
Reproductive Toxicant	
Ethyl Alcohol	64175

Note: The above list is tentative pending a review of the transcript and the release of the official list.

SCIENTIFIC ADVISORY PANEL
Safe Drinking Water and Toxic Enforcement Act of 1986
Chemicals Known to the State to Cause Cancer or Reproductive Toxicity

PROPOSED CRITERIA

The Safe Drinking Water and Toxic Enforcement Act of 1986 states, "A chemical is known to the state to cause cancer or reproductive toxicity if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity...." (Health and Safety Code Section 25249.8(b)).

The Scientific Advisory Panel, the state's qualified experts for the Safe Drinking Water and Toxic Enforcement Act of 1986, will consider a chemical known to the state to cause cancer or reproductive toxicity if exposure to that chemical has been shown through scientifically valid testing according to generally accepted principles to have any of the following results.

CHEMICALS THAT CAUSE CANCER

1. Sufficient evidence of cancer in people.
2. Limited or suggestive evidence of cancer in people, supported by sufficient evidence from studies on experimental animals, such that a cancer risk to people may be reasonably anticipated.
3. Sufficient evidence of cancer in experimental animals, such that a cancer risk to people may be reasonably anticipated.

CHEMICALS THAT CAUSE REPRODUCTIVE TOXICITY

1. Sufficient evidence of adverse reproductive effects in people.
2. Limited or suggestive evidence of adverse reproductive effects in people, supported by sufficient evidence from studies on experimental animals, such that effects in people may be reasonably anticipated.
3. Sufficient evidence of adverse reproductive effects in experimental animals, such that effects in people may be reasonably anticipated.

Adverse reproductive effects include, but are not limited to, the toxicologic endpoints listed below.

<u>Female</u>	<u>Male</u>	<u>Conceptus</u>
menstrual disorders	impotence	embryo/fetus toxicity
infertility	semen quality changes	birth defects
spontaneous abortion	genetic damage	neurodevelopmental abnormalities
genetic damage	adverse effects on	transplacental carcinogenesis*
adverse effects on	gonadal function	genetic damage
gonadal function		stillbirth
adverse effects on		functional/developmental changes
conception		
maternal complications		

* Chemicals that cause transplacental carcinogenesis are to be listed as both reproductive toxicants and carcinogens.

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ATTACHMENT 2

- A. For consumer products that contain a chemical known to the state to cause cancer:

"WARNING: This product contains a chemical known to the State of California to cause cancer."

- B. For consumer products that contain a chemical known to the state to cause reproductive toxicity:

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

- C. For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health & Safety Code Section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

- D. For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

- E. For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Beer, Wine, and other alcoholic beverages are known to the State of California to cause birth defects.

- (5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

- (c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "occupational exposure" is an exposure, in

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the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

- A. A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make likely that the warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.
- B. A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.
- C. A material safety data sheet (MSDS) that includes a statement concerning the carcinogenicity or reproductive toxicity of a chemical delivered, displayed or otherwise made available to individuals prior to the exposure for which the warning is given under circumstances which make it likely to be read.

(2) For purposes of subparagraph (1)(A) of this subdivision, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of subparagraph (1)(B) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

- A. For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

- B. For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause

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(4) Where a MSDS is used to supply a warning, it must satisfy the provisions of subdivision (a) of this section, and be written in terms which are likely to be understood by the individuals exposed.

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "environmental exposure" is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

- A. A warning that appears on a sign in the affected area. The term "sign" means a presentation of written, printed or graphic matter. The term "affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning.
- B. A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.
- C. A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of paragraph (1)(A) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer or birth defects:

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- A. For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

- B. For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

Attachment 3

California Proposition 65
Chapter 6.6

Section 25249.5 Is a prohibition against knowingly discharging chemicals known by the state of California to cause cancer or reproductive toxicity into drinking water. Draft interpretive guidelines define environmental exposure as exposure to a person which occurs as a result of contact with an environmental medium (ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or any man-made or natural substance). At one point California had intended using the drinking water action levels and maximum contaminant levels in setting allowable discharge limits (measured in the effluent stream) and exposure levels. This approach has been dropped and California is now proposing to use the risk assessment approach (discussed further in section .10).

Section 25249.6 Requires that "clear and reasonable" warnings be given before persons are "knowingly and intentionally" exposed to carcinogens and reproductive toxins. Warnings under this act are not necessarily provided separately to each exposed individual. The obligation to warn under this section is on the producer or packager rather than on the retail seller.

Section 25249.7 Violations of the discharge and warning provisions are liable for civil penalties not to exceed \$2500 per day for each violation. This also covers "threatening to violate" which is defined as creating conditions which pose a substantial probability that a violation will occur. Actions can be brought by the Attorney General, any district attorney or by a city attorney (cities with pop. > 750,000 or with consent of the district attorney). Actions may also be brought by any person in the public interest within 60 days after giving notice and if there is no public action against the violation. This is known as the "bounty hunter" provision because the private person bringing the suit will be awarded 25% of the penalties recovered from the action. The ultimate decisions will be made by juries rather than by scientific experts.

Section 25249.8 The initial list of 29 chemicals published by the Governor of California was the result of some compromise by interested parties. Additional chemicals can be added to the list upon recommendation of California's Science Advisory Panel. It is anticipated that it is only a matter of time before all of the chemicals listed by the International Agency for Research on Cancer (IARC) are included among the chemicals on California's list.

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Section 25249.9 Discharge prohibitions are effective 20 months following listing of a chemical by California. Discharge prohibitions do not apply to releases which:

- will not cause any "significant amount" of the chemical to enter drinking water. Significant amount is defined as detectable amount except an amount which would meet the exemptions in 25249.10 (c) if an individual were exposed to such an amount in drinking water.
- discharge conforms with all other laws and with every applicable regulation, permit, requirement, and order.

The burden of showing that discharges meet these criteria is on the defendant.

Section 25249.10 Warning requirements do not apply to chemicals "known by the state of California to cause cancer when:

- exposure takes place less than 12 month after listing of the chemical
- federal law governing warning preempts California's authority
- exposure to a chemical doesn't pose "significant risk", for carcinogens this means that an assumed lifetime exposure at the level in question. Although this is not written into the Act, most people are assuming that this will be the one-in-a-million risk model. EDF would like a "no significant risk" determination to be applicable only to situations that meet the 1/10⁶ model and are unavoidable.
- exposure to a chemical doesn't cause "significant risk", of reproductive toxicity (no observable effect at one thousand times the level in question)

Just as with the discharge prohibitions, it is up to the defendant in enforcement proceeding brought under the warning provisions of this act to show that the exposure meets one of the above criteria.

Both draft interpretive guidelines have discussed exemptions for "naturally occurring" chemicals. "Naturally occurring" chemicals are expected to be defined in the proposed regulations as chemicals whose presence is not a result of any past or present human activity. Also any increase in the amount of a naturally occurring chemical in food which could have been avoided by proper processing, storage or handling is not naturally occurring.

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Section 25249.12 The lead agency responsible for implementation is the California Health and Welfare Agency. This is the agency which will eventually adopt regulations, standards and permits for the implementation of this Act. There have been two sets of non-binding interpretative guidelines to date but each has differed greatly from the other and it is not certain how much of either will be converted into regulations. There is hope that regulations will provide some relief from the standard by defining de minimis levels, exposures, risk assessment methods and detectable levels.

Section 25249.13 This rule does not effect any legal obligations required in common law or in other statutes or regulations.

The Act contains a provision that requires any amendments to further the purposes of the Act.