



From L.L. RIPPEY

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PITTSBURGH OFFICE - 6

1987-12-31

RE: PROPOSITION 65 UPDATE

Prop 65 Warnings

Products containing chemicals which were listed February 27, 1987 by California have warning requirements which are effective February 28, 1988. These warning requirements include any that may be necessary for consumer exposures, industrial exposures as well as environmental exposures.

Recent Developments

FDA Commissioner Frank Young testified at the December 11 meeting of the Science Advisory Panel on the "substantial equivalency" of the FDA style risk assessment to that proposed by California in draft compliance guidelines. This, in combination with the diligent work of manufacturing trade associations, seems to have swayed the administration into a more reasonable position. This is expected to be reflected in emergency regulations to be enacted in January or early February at the latest.

These regulations are expected to acknowledge if only temporarily, that compliance with FDA regulations indicates that products do not pose a significant risk in terms of carcinogenesis. Such a regulation would exempt FDA-regulated products from warning requirements for carcinogens listed by California. This exemption has not been extended to apply to reproductive toxins.

The state also intends to develop a 50-chemical priority list for the purpose of conducting individual chemical risk assessments. Ultimately, they would like to develop their own "no significant risk" levels to supplant any exemption for FDA-regulated products from the requirements for carcinogens under Proposition 65.

Many comments concerning the nature of "clear and reasonable warnings" were heard at the December meeting. Manufacturers associations are asking that, in addition to direct product labeling, other forms of warnings also be accepted such as newspaper ads, in-store compendia, or even toll-free information lines. This issue also may be addressed in the anticipated regulations.



PLAINTIFF'S
EXHIBIT
AL-1697

511961 0025

California's environmental activists are expected to challenge these regulations, so any relief it offers may be short-lived. While exclusion of products complying with FDA from Prop 65 via rulemaking would be a very positive move, it still wouldn't protect manufacturers from "bounty hunter" suits. Such an exclusion would however aid in building a defense to win any citizens suit over a product complying with FDA regulations.

Alcoa's Response

Alcoa's response to Proposition 65, insofar as it covers our products, has not changed. We are endeavoring to determine the "no significant risk" dose for listed chemicals known to be in Alcoa products, then we are conducting a risk assessments to determine if various products will present "no significant risk" or if warnings should be supplied.

New chemicals for list

Dr. Bruce Ames' caveat was added to each of the 55 new chemicals proposed by the Science Advisory Panel for listing at their October 30 meeting. This caveat espouses the panel's opinion that low dose exposures to many of these chemicals pose very little, if any, risk to humans. These October 30 recommendations are expected to be officially listed by January 1, 1988. The Science Advisory Panel (SAP) at its December 11 meeting, reviewed 46 more chemicals, 39 of which were recommended to the governor for listing. The proposed agenda for the SAP's January 29 meeting has been published with a list of 51 candidate chemicals for their review. All three of these new lists in addition to the current list are attached.

Future Action

Manufacturers associations from the FDA-regulated community are still preparing lawsuits to challenge Prop 65 on constitutional grounds, but the timetable has been moved back until after California issues its emergency regulations.

LAURA L. RIPPEY

Attachments
prop65d.FDA

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Prop 65 Update
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MEMORANDUM
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J. Carter, TRE Corp., Weslock Div., 13344 So. Main St.,
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R. Kresky, Alcoa Defense Systems, 16761 Via Del Campo Court,
San Diego, CA 92127
P. Pruitt, TRE Corp., (Astech Div.), 3030 South Red Hill Av.,
Santa Ana, CA 92711

511961 0027

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

CHEMICALS KNOWN TO CAUSE CANCER OR REPRODUCTIVE TOXICITY
October 1, 1987

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. Comments should be directed to the State's lead agency for implementation of the Safe Drinking Water and Toxic Enforcement Act:

State of California
Health and Welfare Agency
1600 Ninth Street, Room 450
Sacramento, CA 95814

- Note: (1) The identification number is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing.
- (2) The date refers to the initial appearance of the chemical on the list.

CARCINOGENS

<u>Chemical</u>	<u>CAS Number</u>	<u>Date</u>
2-Acetylaminofluorene	53963	July 1, 1987
Acrylonitrile	107131	July 1, 1987
Adriamycin	23214928	July 1, 1987
AF-2:[2-(2-furyl)-3-(5-nitro-2-furyl)]acrylamide	3688537	July 1, 1987
ortho-Aminoazotoluene	97563	July 1, 1987
4-Aminobiphenyl (4-Aminodiphenyl)	92671	February 27, 1987
2 Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	712685	July 1, 1987
Amitrole	61825	July 1, 1987
ortho-Anisidine and ortho-Anisidine hydrochloride	90040	July 1, 1987
Analgesic mixtures containing phenacetin	---	February 27, 1987
Aramite	140578	July 1, 1987
Arsenic (inorganic arsenic compounds)	---	February 27, 1987
Asbestos	1332214	February 27, 1987
Auramine	492808	July 1, 1987
Azaserine	115026	July 1, 1987
Azathioprine	446866	February 27, 1987
Benz[a]anthracene	56553	July 1, 1987
Benzene	71432	February 27, 1987
Benzidine [and its salts]	92875	February 27, 1987
Benzo[b]fluoranthene	205992	July 1, 1987
Benzo[j]fluoranthene	205823	July 1, 1987
Benzo[k]fluoranthene	207089	July 1, 1987
Benzo[a]pyrene	50328	July 1, 1987
Benzotrichloride	98077	July 1, 1987
Benzyl violet 4B	1694093	July 1, 1987

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Chemicals Known to Cause Cancer
or Reproductive Toxicity
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<u>Chemical</u>	<u>CAS Number</u>	<u>Date</u>
Beryllium and beryllium compounds	---	October 1, 1987
N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornapazine)	494031	February 27, 1987
Bischloroethyl nitrosourea (BCNU)	154938	July 1, 1987
Bis(chloromethyl)ether	542881	February 27, 1987
1,4-Butanediol dimethanesulfonate (Myleran)	55981	February 27, 1987
beta-Butyrolactone	3068880	July 1, 1987
Cadmium and cadmium compounds	---	October 1, 1987
Carbon tetrachloride	56235	October 1, 1987
Certain combined chemotherapy for lymphomas	---	February 27, 1987
Chlorambucil	305033	February 27, 1987
Chloroform	67663	October 1, 1987
Chloromethyl methyl ether (technical grade)	107302	February 27, 1987
Chromium (hexavalent compounds)	---	February 27, 1987
Coke oven emissions	---	February 27, 1987
Conjugated estrogens	---	February 27, 1987
Cyclophosphamide	50180	February 27, 1987
DDT (1,1,1-Trichloro-2,2-bis(p-chlorophenyl)ethane)	50293	October 1, 1987
1,2-Dibromo-3-chloropropane (DBCP)	96128	July 1, 1987
3-3'-Dichlorobenzidine	91941	October 1, 1987
Diethylstilbestrol	56531	February 27, 1987
Epichlorohydrin	106898	October 1, 1987
Ethylene dibromide	106934	July 1, 1987
1,2-Dichloroethane (Ethylene dichloride)	107062	October 1, 1987
Ethylene oxide	75218	July 1, 1987
Hexachlorobenzene	118741	October 1, 1987
Hexachlorocyclohexane (technical grade)	---	October 1, 1987
Melphalan	148823	February 27, 1987
Methoxsalen with ultraviolet A therapy (PUVA)	298817	February 27, 1987
4,4'-Methylene bis(2-chloroaniline)	101144	July 1, 1987
Mustard Gas	505602	February 27, 1987
2-Naphthylamine	91598	February 27, 1987
Nickel refinery dust from the pyrometallurgical process	---	October 1, 1987
Nickel carbonyl	13463393	October 1, 1987
Nickel subsulfide	12035722	October 1, 1987
N-nitrosodi-n-butylamine	924163	October 1, 1987
N-nitrosodiethylamine	55185	October 1, 1987
N-nitrosodimethylamine	62759	October 1, 1987
N-nitroso-N-ethylurea	759739	October 1, 1987
N-nitroso-N-methylurea	684935	October 1, 1987
N-nitrosopyrrolidine	930552	October 1, 1987

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Chemicals Known to Cause Cancer
or Reproductive Toxicity
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<u>Chemical</u>	<u>CAS Number</u>	<u>Date</u>
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 mulespinning, metal machining, and jute processing.	---	February 27, 1987
Thorium dioxide	1314201	February 27, 1987
Treosulfan	299752	February 27, 1987
Vinyl chloride	75014	February 27, 1987

REPRODUCTIVE TOXICANTS

Aminopterin	54626	July 1, 1987
Chlorcyclizine hydrochloride	82939	July 1, 1987
1,2-Dibromo-3-chloropropane (DBCP)	96128	February 27, 1987
Diethylstilbestrol (DES)	56531	July 1, 1987
Diphenylhydantoin	630933	July 1, 1987
Ethyl alcohol in alcoholic beverages	64175	October 1, 1987
Ethylene oxide	75218	February 27, 1987
Etretinate	54350480	July 1, 1987
Isotretinoin	4759482	July 1, 1987
Lead	7439921	February 27, 1987
Methyl mercury	---	July 1, 1987
Thalidomide	50351	July 1, 1987
Valproate	99661	July 1, 1987
Warfarin	81812	July 1, 1987

511961 0030

RECOMMENDATIONS OF THE SCIENTIFIC ADVISORY PANEL
AT ITS MEETING OF OCTOBER 30, 1987. FOR LISTING
AS CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER

Carcinogens

1. Aflatoxins
2. Carrageenan (degraded) (not food grade carrageenan)
3. Chlordecone (Kepone)
4. 1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU)
5. 4-Chloro-ortho-phenylenediamine
6. para-Cresidine
7. Cupferron
8. Cycasin
9. Dacarbazine
10. Daunomycin
11. 2,4-Diaminoanisole sulfate
12. 4,4'-Diaminodiphenyl ether
13. 2,4'Diaminotoluene
14. Dibenz[a,h]acridine
15. Dibenz[a,j]acridine
16. Dibenz[a,h]anthracene
17. 7H-Dibenzo[c,g]carbazole
18. Dibenzo[a,e]pyrene
19. Dibenzo[a,h]pyrene
20. Dibenzo[a,i]pyrene
21. Dibenzo[a,l]pyrene
22. 3,3'-Dichloro-4,4'-diaminodiphenyl ether
23. Diepoxybutane
24. Di(2-ethylhexyl)phthalate
25. 1,2-Diethylhydrazine
26. Diethyl sulfate
27. Dihydrosafrole
28. 3-3'-Dimethoxybenzidine (ortho-Dianiasidine)

29. 4-Dimethylaminoazobenzene
30. trans-2-[(Dimethylamino)methylimino]-5-[2-5-nitro-2-furyl]vinyl]-1,3,4-oxadiazole
31. 3,3'-Dimethylbenzidine (ortho-Tolidine)
32. Dimethylcarbamoyl chloride
33. 1,2 Dimethylhydrazine
34. Dimethyl sulfate
35. 1,4-Dioxane
36. Direct Black 38 (technical grade)
37. Direct Blue 6 (technical grade)
38. Estradiol 17B
39. Estrone
40. Ethinylestradiol
41. Ethyleneimine
42. Ethylene thiourea
43. Ethyl methanesulfonate
44. Formaldehyde (gas)
45. Formylhydrazino)-4-(5-nitro-2-furyl)thiazole
46. Glycinaldehyde
47. Gyromitrin (acetaldehyde methylformylhydrazone)
48. Hexamethylphosphoramide
49. Hydrazine and hydrazine sulfate
50. Hydrazobenzene
51. Panfuran S
52. Polychlorinated biphenyls (containing 60 or more percent chlorine)
53. 2,3,7,8-Tetrachlorodibenzo-para-dioxin (TCDD)
54. Toxaphene (polychlorinated camphenes)
55. 2,4,6-Trichlorophenol

CAVEAT

We are asked to identify chemicals "known" to cause cancer or reproductive toxicity.

The identification of chemicals that are *potential* human carcinogens or teratogens relies largely upon results of rodent bioassays. About 1/2 of all chemicals examined for carcinogenicity, whether natural or man-made, induce tumors in rodents, and over 1/3 of all chemicals tested for teratogenicity induce birth defects. The tests are conducted at the maximum tolerated (toxic) dose, and few of these chemicals have been tested below 10% of the toxic dose and scarcely any below 1% of the toxic dose. Thus, a chemical may not be said to be "known" to cause cancer except at doses close to the toxic dose, yet pollution levels are rarely above 0.001% of the toxic dose. Neither scientific theory nor technique is capable at present of resolving the question of whether hazards exist for human exposure to chemicals at levels far below the toxic dose: expert opinion of the risk ranges from small (proportional to exposure dose) to zero.

A high percentage of the *natural* chemicals ingested by humans are likely to be rodent carcinogens or teratogens at near-toxic doses. For example, natural carcinogens are present in mushrooms, celery, parsley, basil, mustard, peanut butter, fruit juices, coffee, tea, cooked food, bread, cola drinks, and alcoholic beverages. The vast bulk (at least 99.9%) of the chemicals we are exposed to in our food and drink are natural substances, and only a tiny proportion have been examined for carcinogenicity or teratogenicity. However, Proposition 65 does not specify what level of carcinogen, other than the detectable level, poses a significant risk. This is especially important as scientists are now capable of detecting chemicals at a level of one part per billion (one person in all of China) or one part per trillion (1/16 of an inch of the distance from here to the moon). For the panel to list chemicals without setting a *de minimis* level to the listing creates a substantial likelihood that the listing will have important legal and practical consequences, and may suggest scientific conclusions, that are totally unwarranted by the scientific data underlying the listing. Thus, we believe that it is essential to set a *de minimis* level for all of the chemicals. Since scientists do not know enough to calculate risk for humans for low exposures to chemicals and in view of the above points, the panel believes a relative rule is the best *de minimis* guide to follow. The panel believes an appropriate *de minimis* level for the daily intake into humans for the carcinogen(s) under discussion is the level giving a possible hazard equivalent to that EPA now considers acceptable as a result of chlorination of drinking water. EPA allows 100 ppb of chloroform due to chlorination and assumes 2 liters daily consumption; the average U.S. tap water has been estimated at about 83 ppb. In proposing this standard we stress that we do not imply that exposure to levels above the *de minimis* level pose a significant risk. The natural carcinogens in our daily food and drink rank enormously higher as possible hazards than tap water, yet it is not at all clear that even these represent significant risks, as normally the levels are sufficiently below the toxic level. We are merely saying that a listed chemical should be ignored in terms of public health concern where the chemical is present below the *de minimis* level because that level of risk should be regarded as irrelevant.

Addendum

We recognize that this is a complex subject requiring consideration of a number of interrelated issues, including how and where possible hazard is measured, what length of exposure is assumed, and how *de minimis* is defined for both carcinogens and teratogens. We believe, therefore, that this issue should be the subject of a separate hearing by this panel or by the Health and Welfare Agency with our participation. In the interim, however, the panel is prepared to adopt the above provisional standard.

511961 0033

Chemicals reviewed by California

SAP at December 11, 1987 meeting

SAP made no decision on chemicals marked with check.

<u>CHEMICAL</u>	<u>CAS Number</u>
Indeno[1,2,3-cd]pyrene	193395
Iron dextran complex	9004664
Lead acetate	301042
✓ Lead phosphate	7446277
2-Methylaziridine (propyleneimine)	75558
4,4'-Methylenedianiline and its dihydrochloride	101779
✓ Methyl iodide	74884
Metronidazole	443481
Michler's ketone	90948
Mirex	2385855
Nitrilotriacetic acid	139139
✓ 5-Nitro-o-anisidine	99592
Nitrofen (technical grade)	1836755
Nitrogen mustard	302705
2-Nitropropane	108032
N-Nitrosodiethanolamine	1116547
p-Nitrosodiphenylamine	156105
N-Nitrosodi-n-propylamine	621647
N-Nitrosomethylvinylamine	4549400
N-Nitrosomorpholine	59892
N-Nitrosornicotine	16543558
N-Nitrosopiperidine	100754
N-Nitrososarcosine	13256229
Oxymetholone	434071
✓ Phenacetin	62442
Phenazopyridine and its hydrochloride	136403
Phenytoin and sodium salt of phenytoin	57410
Polybrominated biphenyls	
Procarbazine and its hydrochloride	366701
Progesterone	57830
1,3-Propane sultone	1120714
beta-Propiolactone	57578
Propylthiouracil	51525
✓ Reserpine	50555
Saccharin	128449
Safrole	94597
✓ Selenium sulfide	7488564
Streptozotocin	18883664
Sulfallate	95067
Thioacetamide	62555
Thiourea	62555
✓ Toluene diisocyanate	584849
ortho-Toluidine and its hydrochloride	95534
Tris(1-aziridinyl)phosphine sulfide (thiotepa)	52244
Tris(2,3-dibromopropyl)phosphate	126727
Urethane	51796

511961 0034

PROPOSED AGENDA
Safe Drinking Water and Toxic Enforcement Act of 1986
Scientific Advisory Panel

January 29, 1987
9:00 a.m.

Wyatt Pavilion
University of California, Davis

I. Staff Reports

- II. Consideration of (1) tobacco smoke and (2) tobacco, oral use of smokeless products, which have been identified by the International Agency for Research on Cancer (IARC) as having sufficient evidence of carcinogenicity in humans, as chemicals known to the State to cause cancer.
- III. Consideration of tobacco smoke as known to the State to cause reproductive toxicity.
- IV. Consideration of candidate chemicals identified as probable carcinogens by IARC as known to the State to cause cancer.

<u>Chemical</u>	<u>CAS Number</u>
Lasiocarpine	303344
Merphalan	531760
Mestranol	72333
5-Methyl chrysene	3697243
Methylazoxymethanol; methylozoxymethyl acetate	592621
4,4'-Methylene bis(2-methylaniline)	838880
Methyl methanesulfonate	66273
2-Methyl-1-nitroanthraquinone (of uncertain purity)	129157
N-Methyl-N'-Nitro-N-nitrosoguanidine	70257
Mitomycin C	50077
Monocrotaline	315220
5-(Morpholinomethyl)-3-[(5-nitro-furfurylidene)-amino]-2-oxalolidinone	139913
Nafenopin	3771195
Niridazole	61574
4-Nitrobiphenyl	92933
5-Nitroacenaphthene	602879
1-[(5-Nitrofurfurylidene)-amino]-2-imidazolidinone	555840
N-[4-(5-Nitro-2-furyl)-2-thiazolyl]acetamide	531828
Nitrogen mustard and its hydrochloride	51752
Nitrogen mustard N-oxide and its hydrochloride	302705
N-Nitroso-N-methylurethane	615532
Orange Oil SS	2646175
Phenoxybenzamine and its hydrochloride	59861
Ponceau MX	3761533
Ponceau 3R	3564098
Sterigmatocystin	10048132

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Testosterone and its esters	58220
4,4'-Thiodianiline	139651
ortho-Toluidine and its hydrochloride	636215
Trp-P-1 (Tryptophan-P-1)	62450060
Trp-P-2 (Tryptophan-P-2)	62450071
Trypan Blue (commercial grade)	72571
Uracil mustard	66751

- V. Consideration of the following chemicals identified as probable carcinogens by the Environmental Protection Agency's Carcinogen Assessment Group, as known to the State to cause cancer.

<u>Chemical</u>	<u>CAS Number</u>
Acetaldehyde	75070
Aldrin	309002
Allyl chloride	107051
1,3-Butadiene	106990
Chlordane	57749
Dichloromethane (Methylene chloride)	75092
Dieldrin	60571
2,4-Dinitrotoluene	121142
Diphenylhydrazine	122667
Bis(2-chloroethyl)ether	111444
Heptachlor	76448
Heptachlor epoxide	1024573
Hexachlorodibenzodioxin	34465468
N-nitroso-diphenylamine	86306
Tetrachloroethylene (Perchloroethylene)	127184
Trichloroethylene	79016
Unleaded gasoline vapor	---

- VI. DISCUSSION ITEM. At the next meeting, consideration of ethyl alcohol and/or alcoholic beverages as substances known to the State to cause cancer.

- VII. Public Comments

NOTE: Anyone interested in submitting comments to the Panel on any agenda item should sent those comments to: State of California, Health and Welfare Agency, 1600 Ninth Street, Room 450, Sacramento, California 95814.

NEXT MEETING: April, 1988 (tentative). Agenda: (a) ethyl alcohol/alcoholic beverages as carcinogens (b) reproductive toxins.

511961 0036