



CHEMICAL MANUFACTURERS ASSOCIATION

May 7, 1980

Mr. Richard L. Davis
Director
Health Management Services
Environmental Health Associates, Inc.
2150 Shattuck Avenue
Suite 414
Berkley, California 94704

Dear Mr. Davis:

The following summary is being presented in order that a revised or modified bid/proposal can be prepared by Environmental Health Associates, Inc., (EHA) that reflects recent action of the Vinyl Chloride Panel and Research Coordinators. Wherever possible, Panel actions are summarized according to major sections of your bid/proposal of January 15, 1980. To facilitate subsequent reference, the following sections and subsections are numbered:

1.0 Evaluation of the Current Data Base

1.1 In the light of our recent discussions it appears advisable that at the earliest possible time EHA give the Panel a written opinion on the exact current status of the data base. As you indicated, before a "Brain Case Control Study" or a "Five-Year Epidemiological Update" can be conducted, the data base must be augmented.

1.2 Panel action relevant to EHA's assessment and/or evaluation of existing data was as follows:

"We agree that Environmental Health Associates (EHA) be authorized to examine the current records, prepare a protocol for a five-year update, and conduct a reanalysis of death certificates according to the EHA letter proposal dated January 15, 1980."

2.0 "Brain Case Control Study" (BCCS)

2.1 After EHA has completed necessary assessment of the data base that pertains to the BCCS, the Panel confirmed its earlier position by voting:

EHA will be requested to prepare a protocol and a cost estimate for a "case control study" of

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cancers of the central nervous system.

- 2.2 The Panel confirmed an earlier stipulation that the protocol prepared by EHA for the BCCS will be open for bids in addition to the EHA bid.

3.0 Study Plan A

- 3.1 The Panel is in agreement on proceeding with Study Plan A described on pages 6, 7 and 9 of EHA's letter-proposal dated January 15, 1980.
- 3.2 As you reemphasized during your telephone call of May 6, 1980, the development of an accurate estimate of the probable cost to perform the five-year follow-up requires more precise information than is now available.

4.0 Study Plan B

Introductory Comment As discussed with you, the following summary of Panel action on Study Plan B is presented in an effort to assist you during the preparation of your modified bid/proposal. The preceding comment is relevant because the Panel voted to hold Study Plan B in abeyance for consideration at a future date.

- 4.1 Study Plan B should be modified by identifying the plants as follows:

Group I - Vinyl Chloride Monomer
Group II - PVC By Dispersion or Emulsion Processes
Group III - All Others

- 4.2 Under Study Plan B, EHA is to be requested to clarify the comment "...secure complete job histories for the approximate 3,300 cohort members with incomplete job histories". EHA is to characterize the deficiencies that exist in these 3,300 cohort members.

5.0 Study Plan C

Panel members expressed the opinion that there is little likelihood that Study Plan C will contribute anything new. They estimated that Study Plan C will not yield meaningful data until 10, 20 or perhaps 25 years hence.

6.0 Request for EHA's "Opinion and Position" on Mortality Study Based on Type of Plant Production

The Panel requests that EHA present its "Opinion and Position" on analyzing data in terms of those plants producing:

- (1) Vinyl Chloride Monomer
- (2) Emulsion or Dispersion Polymers (excluding latex),
- (3) All Others

The analysis(s) to treat "significant differences with respect to mortality at a cost not to exceed \$10,000".

Please contact me immediately should any item in this letter need clarification.

Sincerely,



J. T. Seawell
Staff Advisor
Vinyl Chloride

JTS:md

cc: Dr. H. C. Shah
Dr. T. R. Torkelson

TABLE I

TEST MATERIAL: Vinyl Chloride (Ethylene Derived)

Chronic Vapor Inhalation Toxicity Study - Albino Rats, Albino Mice, and Golden Hamsters

Chamber Concentration Data

Day Number	Exposure Number	Chamber Concentration (ppm)								
		TE-I		Mean	TE-II		Mean	TE-III		Mean
		Range	Range		Range	Range		Range	Range	
1	1	39	45	43	130	180	173	1820	2610	2510
4	4	45	54	51	24	162	87	1190	3600	2540
5	5	50	56	52	182	237	218	1160	3100	2202
16	12	42	63	60	54	266	156	2400	3100	2653
29	21	48	66	58	192	248	219	1090	2490	1561
39	29	42	55	43	188	216	209	1900	3010*	2455
56	48	48	114	84	172	452	298	2240	4000	2910
73	53	42	58	49	178	211	202	2380	2700	2565
80	58	45	60	54	220	364	243	2020	2760	2404
99	71	29	31	30	258	310	277	2740	3940	3185
120	86	45	46	45	168	232	199	1960	2960	2565
130	94	42	63	53	180	228	201	2680	3100	2883
150	108	35	58	49	90	288	200	1780	2920	2556
151	109	32	62	44	150	234	193	1280	2800	2349
152	110	41.5	110	58.9	170	252	198	2300	2800	2497
171	123	35	55	48	186	210	197	2320	3020	2708
186	134	47	53	49.6	184	224	209	2040	2680	2419
187	135	46.5	55.5	50.7	180	262	194	2180	3400	2550
197	141	40	55	45.1	178	216	196	2400	2700	2535
200	144	38.5	56	49	178	310	223	2340	3120	2561
201	145	37.5	55.5	48	174	212	197	2340	2740	2500
208	150	48	54.5	51.4	170	242	200	2260	3420	2627
212	152	36	64.5	48.1	154	282	194	2160	3200	2583
220	158	36.5	52.5	45	138	250	192	1440	2600	2240
221	159	44.5	55	49.2	130	138	134	2460	2620	2540
229	165	46.5	46	49.4	190	216	200	2420	2800	2583
232	166	47	71	52.3	184	228	201	2100	2820	2520
235	169	44	51	47.6	196	215	207	2440	3710	2932

TABLE I continued

TEST MATERIAL: Vinyl Chloride (Ethylene Derived)

Chronic Vapor Inhalation Toxicity Study - Albino Rats, Albino Mice and Golden Hamsters

Chamber Concentration Data

Day Number	Exposure Number	Chamber Concentration (ppm)								
		TE-I		Mean	TE-II		Mean	TE-III		T-IV** Range
		Range			Range			Range		Mean
248	178	47.5	52.5	51.2	186	222	203	2420	2700	2573
274	196	44.5	51	47.9	188	216	202	2180	2580	2377
275	197	38	56	49.5	174	242	198	2160	2640	2386
281	201	40	56	47.5	168	232	204	2360	2740	2515
304	218	45.5	50.5	48.2	202	226	218	2140	2460	2288
312	224	39	46	42.8	148	172	160	1800	2040	1920
315	225	37	52.5	44.2	146	196	174	1800	2440	2073
316	226	46	55	54	182	220	208	2080	2500	2473
318	228	46.5	52.0	49.2	170	280	192	1960	2380	2022
323	231	49.4	62	54.9	176	250	208	2160	2840	2475
332	238	56	56	56	206	208	208	2260	2380	2300
333	239	47.5	55	51.3	185	210	202	2160	2600	2556
339	243	40	60	48.9	184	234	203	2380	2960	2607
345	247	49.5	51	50	190	210	203	2140	2620	2525
351	251	35	45.5	39.5	180	246	228	2640	2900	2783
359	257	46	71	56	202	208	206	2420	2560	2487
360	248	44.5	59.5	50.7	170	216	202	2360	2840	2602

*Previously reported by IBT as 1970-2770, with a mean of 2474

**Only gross inspections were made of the TE-IV concentrations but the same problems existed with this concentration as with the others.

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TABLE II

IBT No. 663-03222

VINYL CHLORIDE RATS - SURVIVAL

T-III - 2,000 ppm

<u>Month</u>		<u>Male</u>	<u>Female</u>
5	Report	97	96
	Printout	96	95
6	Report	95	96
	Printout	96	94
7	Report	94	95
	Printout*	89 or 92	92
8	Report	90	92
	Printout	89	90
9	Report	84	85
	Printout	82	81
10	Report	76	72
	Printout	74	68
11	Report	66	48
	Printout	62	46
12	Report	42	34
	Printout	37	15(?)
13	Report	27	17
	Printout**	23	5(?)

* None of #'s or weights agree with report

** All over the lot, 5 body weights shown

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