

1. HISTORY OF MONSANTO PRODUCTION AND SALES OF CHLORINATED BIPHENYLS

Monsanto entered the chlorinated biphenyls business in 1935, when it purchased the Swann Chemical Company. Production and distribution increased until the early 1970s, when, in response to reports of its presence in the environment, Monsanto restricted sales of chlorinated biphenyls. In 1977, the company ceased production and distribution of chlorinated biphenyls in cooperation with the electrical industry. Chlorinated biphenyls were banned (except for certain applications) in the U.S. in 1979.

Sales and Distribution

The chemical structure of the polychlorinated biphenyls has been known for nearly 100 years. Commercial production of these materials was initiated in 1929 by the Swann Chemical Company in response to the electrical industry's need for improved dielectric insulating fluids which would also provide increased fire resistance when used in transformers and capacitors. (See para. 2, page 2 of the Interdepartmental Task Force on PCBs report, "Polychlorinated Biphenyls and the Environment," May 1972 - Attachment 1-1.)

As the unique functional characteristics of these materials became more fully understood, additional uses were found. Their fire resistance made them an excellent choice in high pressure hydraulic applications associated with high risk of fire such as die casting and steel production. Their thermal stability and fire resistance were valuable in heat transfer systems.

Their stability, low water solubility, low vapor pressure and solvency power made them attractive in carbon-less paper systems. Their fire resistance, thermal stability and viscosity characteristics made their use desirable in hot melt adhesives and other plasticizer applications.

Chlorinated biphenyls, therefore, evolved as a unique class of chemicals which met important needs for both industry and society. In some instances, fire and building codes required the protection of life and property offered by chlorinated biphenyls. It was within this framework that Monsanto and other producers developed a growing worldwide business for these versatile products. For a retrospective discussion of the benefits of chlorinated biphenyls, see Attachment 1-2.

The following charts show the data for chlorinated biphenyls through Monsanto's voluntary phaseout program to termination of production and sales in 1977. Significant points in these charts are:

- a. Heat Transfer -- Between 1970 and 1972, a task force of Monsanto engineers worked closely with customers to replace chlorinated biphenyl fluids with materials of equivalent thermal stability but with unavoidable lower fire resistance. Phaseout was completed in 1972.
- b. Hydraulic Fluid -- Development of replacement fluids began in 1970, and sales of chlorinated biphenyl-based fluids were discontinued in 1971.

**PCB MANUFACTURING AND SALES
MONSANTO INDUSTRIAL CHEMICALS COMPANY
1957 thru 1978
(Thousands of Pounds)**

U.S. PRODUCTION (1)	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2423	2424	2425	2426	2427	2428	2429	2430	2431	2432	2433	2434	2435	2436	2437	2438	2439	2440	2441	2442	2443	2444	2445	2446	2447	2448	2449	2450	2451	2452	2453	2454	2455	2456	2457	2458	2459	2460	2461	2462	2463	2464	2465	2466	2467	2468	2469	2470	2471	2472	2473	2474	2475	2476	2477	2478	2479	2480	2481	2482	2483	2484	2485	2486	2487	2488	2489	2490	2491	2492	2493	2494	2495	2496	2497	2498	2499	2500	2501	2502	2503	2504	2505	2506	2507	2508	2509	2510	2511	2512	2513	2514	2515	2516	2517	2518	2519	2520	2521	2522	2523	2524	2525	2526	2527	2528	2529	2530	2531	2532	2533	2534	2535	2536	2537	2538	2539	2540	2541	2542	2543	2544	2545	2546	2547	2548	2549	2550	2551	2552	2553	2554	2555	2556	2557	2558	2559	2560	2561	2562	2563	2564	2565	2566	2567	2568	2569	2570	2571	2572	2573	2574	2575	2576	2577	2578	2579	2580	2581	2582	2583	2584	2585	2586	2587	2588	2589	2590	2591	2592	2593	2594	2595	2596	2597	2598	2599	2600	2601	2602	2603	2604	2605	2606	2607	2608	2609	2610	2611	2612	2613	2614	2615	2616	2617	2618	2619	2620	2621	2622	2623	2624	2625	2626	2627	2628	2629	2630	2631	2632	2633	2634	2635	2636	2637	2638	2639	2640	2641	2642	2643	2644	2645	2646	2647	2648	2649	2650	2651	2652	2653	2654	2655	2656	2657	2658	2659	2660	2661	2662	2663	2664	2665	2666	2667	2668	2669	2670	2671	2672	2673	2674	2675	2676	2677	2678	2679	2680	2681	2682	2683	2684	2685	2686	2687	2688	2689	2690	2691	2692	2693	2694	2695	2696	2697	2698	2699	2700	2701	2702	2703	2704	2705	2706	2707	2708	2709	2710	2711	2712	2713	2714	2715	2716	2717	2718	2719	2720	2721	2722	2723	2724	2725	2726	2727	2728	2729	2730	2731	2732	2733	2734	2735	2736	2737	2738	2739	2740	2741	2742	2743	2744	2745	2746	2747	2748	2749	2750	2751	2752	2753	2754	2755	2756	2757	2758	2759	2760	2761	2762	2763	2764	2765	2766	2767	2768	2769	2770	2771	2772	2773	2774	2775	2776	2777	2778	2779	2780	2781	2782	2783	2784	2785	2786	2787	2788	2789	2790	2791	2792	2793	2794	2795	2796	2797	2798	2799	2800	2801	2802	2803	2804	2805	2806	2807	2808	2809	2810	2811	2812	2813	2814	2815	2816	2817	2818	2819	2820	2821	2822	2823	2824	2825	2826	2827	2828	2829	2830	2831	2832	2833	2834	2835	2836	2837	2838	2839	2840	2841	2842	2843	2844	2845	2846	2847	2848	2849	2850	2851	2852	2853	2854	2855	2856	2857	2858	2859	2860	2861	2862	2863	2864	2865	2866	2867	2868	2869	2870	2871	2872	2873	2874	2875	2876	2877	2878	2879	2880	2881	2882	2883	2884	2885	2886	2887	2888	2889	2890	2891	2892	2893	2894	2895	2896	2897	2898	2899	2900	2901	2902	2903	2904	2905	2906	2907	2908	2909	2910	2911	2912	2913	2914	2915	2916	2917	2918	2919	2920	2921	2922	2923	2924	2925	2926	2927	2928	2929	2930	2931	2932	2933	2934	2935	2936	2937	2938	2939	2940	2941	2942	2943	2944	2945	2946	2947	2948	2949	2950	2951	2952	2953	2954	2955	2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c. Plasticizer Applications -- Sales of most chlorinated biphenyl plasticizers were terminated in 1970, with phaseout completed in 1971.

d. Miscellaneous Industrial Uses (such as vacuum pump fluids) -- Sales ended by 1971.

These voluntary restrictions resulted in a 64 percent reduction in Monsanto sales of chlorinated biphenyls from 1970 to 1972.

However, termination of sales for dielectric uses would have resulted in severe economic and social dislocation. This was recognized by the federal Interdepartmental Task Force on PCBs which concluded in 1972 that "Their continued use for transformers and capacitors in the near future is considered necessary because of the significantly increased risk of fire and explosion and the disruption of electrical service which would result from a ban on PCB use." (See para. 6, page 4, of Attachment 1-1).

Therefore, Monsanto agreed to continue supplying the products to manufacturers of electrical power distribution equipment who use chlorinated biphenyls only in sealed systems such as capacitors and transformers. In continuing to sell to such customers, however, Monsanto required assurances that the materials would be safely handled and properly disposed of.

In making this decision Monsanto believed 1) that entry of chlorinated biphenyls to the environment could

be effectively limited and controlled by users (see Attachment 1-3, Westinghouse report presented at the January 3, 1972, meeting of the National Industrial Pollution Control Council), 2) proper maintenance and decommissioning practices could limit fluid escape from transformer operations, and 3) withdrawal from production for these applications would have stopped production of equipment essential to the safe and efficient distribution and use of electrical energy. In addition, a more biodegradable lower chlorinated product (Aroclor[®] 1016) had been developed by Monsanto for use by the capacitor industry (see Attachment 1-4).

Steps Taken in Labeling and Transport Practices for Ongoing Dielectric Sales, 1972-1977

Monsanto shipped PCB fluids in both bulk carriers and in drums. Bulk shipments were made in Monsanto-owned railroad tank cars, which were used exclusively for that service, or in customer-owned tank trucks. Drum shipments were made in special reinforced drums. A multilingual warning label was affixed to each package giving a brief description of the nature of the contents and appropriate actions to be taken in the event of a spill or leak. We also supplied a label to be used on return shipments for incineration, which gave similar information.

Industry Guidelines

In June, 1970, the Board of Directors of the Power Equipment Division of the National Electrical Manufacturers Association appointed a committee to review the chlorinated

biphenyl situation as it affected electrical usage. As a result, in April, 1971, American National Standards Committee C107 was established to develop guidelines for the safe use, maintenance and disposal of askarel* and askarel-soaked materials used in electrical equipment. Monsanto participated in this committee. A final draft was completed by November, 1972, and the Standard Guideline was published in 1974 as ANSI C107.1-1974 (Attachment 1-5).

Monsanto's Withdrawal from the Chlorinated Biphenyl Business

When Monsanto decided in 1970 to restrict sales of chlorinated biphenyls, there were no satisfactory alternate materials for closed-system dielectric uses. This view was later affirmed by the EPA. At least as late as a 1975 press conference, the EPA reiterated it would not ask Monsanto to stop production because that would shut down the electrical power industry and the railroads in short order. The EPA objective was to find a way to proceed without shutting down the country. That was precisely the objective to which Monsanto had been committed since 1970.

The problems encountered in replacing chlorinated biphenyls were rooted in their unique fire resistant and dielectric characteristics and in their role in electrical and industrial applications for 45 years. The challenge facing the electrical industry was to replace chlorinated

* "Askarel" is a generic name for fire resistant dielectric fluids, including those which contained polychlorinated biphenyls, made to meet specifications set by transformers and capacitor manufacturers.

biphenyls in an orderly manner, without creating other hazards of equal or potentially greater magnitude, and at the same time avoiding serious power and transportation disruptions.

Monsanto expended considerable effort and money in major research programs aimed at developing environmentally compatible replacement fluids for the electrical industry. The level of this research was greatly reduced in 1976 when the electrical industry developed the technology to adapt other compounds to its needs. It now appears the ongoing demand for liquid-cooled transformers will be satisfied by using silicone compounds. In the capacitor industry, the trend has been toward materials such as phthalate esters.

In adopting these substitutes, the electrical industry has been forced to accept lower fire resistance. New safety devices have been required to ensure that replacement equipment will not lead to increased risk to society from fire hazards.

In our press statement of October 5, 1976, Monsanto said we would complete distribution of all inventories and withdraw from the chlorinated biphenyl dielectric business by October 31, 1977. In making the announcement, Monsanto said the company would have targeted an even earlier shutdown date had transformer and capacitor manufacturers' conversion timetables permitted. All chlorinated biphenyl production was halted by Monsanto in July, 1977, and all customer shipments were completed by September, 1977.

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At the time we stopped PCB production, Monsanto established policies which precluded licensing of chlorinated biphenyl technology and restricted sales of biphenyl to uses which would not involve halogenation.

PCBs continue to be manufactured by other firms in Germany, France, Spain, Italy and certain eastern European countries. They continue to be widely used throughout the world.

Reasons for Monsanto Phaseout

Scientific knowledge about the presence of PCBs in the environment, and about its possible significance, began to evolve during the late 1960s (see, e.g., Attachment 1-6). That evolutionary process, which is still incomplete, began with two events--one in Japan and the other in Sweden.

In 1968, about 1,000 people in Japan became ill from eating rice oil heavily contaminated with Japanese-produced PCBs as a result of an industrial accident which has come to be known as the Yusho incident. The level of PCB contamination in the rice oil was 2000 to 3000 parts per million, extremely high concentrations. Conclusions about that incident have been clouded by the unknown impact of impurities in the Japanese PCB concerned (see pages 160-167, Attachment 2-7). However, the incident sounded a cautionary signal.

In Sweden, Soren Jensen, using new analytical technology to investigate DDT residues in the environment, reported the possible presence of PCBs in fish tissue. Monsanto and others began immediately to study the Swedish work.

Before the findings could be confirmed or duplicated in the U.S., analytical methods had to be refined in order to definitively separate PCBs from other chlorinated hydrocarbons that were known to be present in the environment. New techniques were required to enable researchers to detect these chemicals in the low parts per billion ranges being reported.

The presence of PCBs in the environment in the U.S. was confirmed by 1970, but little was known about their potential impact. Because PCBs were reported in the environment and tests indicated they could accumulate in the food chain, Monsanto voluntarily decided to terminate sales of chlorinated biphenyls to open applications -- those which could result in losses to the environment. Plasticizer and carbonless paper applications fell into this category.

Because of the contamination of rice oil in Japan, food processors using Monsanto's chlorinated biphenyl heat transfer fluids were advised to change to alternative heating methods and Monsanto reemphasized the need for improved monitoring of finished food products to preclude contamination by any heat transfer fluid. The decision was made in 1971 to terminate all heat transfer fluid sales of chlorinated biphenyls, substituting other products with equivalent thermal stability.

High operating pressures cause hydraulic systems to leak. Monsanto therefore alerted users to manage wastes

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to eliminate PCB discharge to the environment. As new hydraulic fluids were developed in 1971, we terminated sales of those containing PCBs.

As described earlier, Monsanto agreed with the electrical industry and government that the benefits to society of continued chlorinated biphenyl dielectric use outweighed the low risk of uncontrolled release from these sealed applications. The key to managing the risk was sound maintenance practice and disposal control.

With particular reference to the use of PCBs in human food and animal feed processing facilities, the FDA proposed usage regulations in 1972, which were adopted in 1973, and continue in force today (21 CFR §§109.15; 110.40(b); 500.45).

Although a variety of effects of PCBs has been postulated from research of widely varying quality, there is no evidence of environmental levels of PCBs being a major human health hazard. However, it became apparent that the public perceived risks associated with continued PCB dielectric use and preferred to forego its undoubted functional benefits. Therefore, in October of 1976, we advised dielectric customers that it was our intent, consistent with their progress with substitute products, to terminate chlorinated biphenyl production and sale by October, 1977. Each of them forecast how much product would be required to effect an orderly technical transition. In 1977, we made sufficient dielectric chlorinated biphenyl to satisfy the forecast transition demand and made final

shipments in September. The small residual inventory was incinerated in our pyrolysis unit, bringing to a close our chlorinated biphenyl business.

MONS 006703

2. INFORMATION ON HEALTH EFFECTS

Chlorinated biphenyls range from liquid to solid, depending upon the degree of chlorination. On the basis of single dose animal tests commonly used to identify and label hazardous materials, they would be considered to be relatively harmless substances. Monsanto has conducted such acute toxicity and irritation tests on several chlorinated biphenyls over the years (1).

Questions have been raised in four areas of possible health effects of chlorinated biphenyls. These have been related to 1) skin (reddening, chloracne), 2) systemic effects (liver damage, respiratory effects), 3) environmental exposure, and 4) potential carcinogenicity.

A review of the literature from the 1930s and 1940s on the health effects of chlorinated biphenyls contains statements such as "Much of the literature that refers to chlorinated diphenyls is referring to the mixture of chlorinated diphenyl with chlorinated naphthalene." and "A number of the references recorded under chlorinated naphthalenes also discussed chlorinated diphenyl. It is difficult to determine the role played by the chlorinated diphenyls, as, in most instances, they were mixed with chlorinated naphthalene" (2). A parallel situation occurred during the late 1960s when reports of the detection of polychlorinated biphenyls in the environment

began to appear. There was confusion and disagreement as to whether polychlorinated biphenyls or other halogenated hydrocarbons such as DDT were being measured, since the latter had already been identified as environmental contaminants.

Skin

Sometime before 1934, Swann Chemical Co. observed dermatological symptoms in workers exposed to chlorinated biphenyls. In May, 1934, Swann Research, Inc., requested Dr. F. B. Flinn of Columbia University's College of Physicians and Surgeons to conduct an investigation "to determine whether or not the various chlorinated diphenyl compounds submitted or some impurities contained therein might be the causative agent producing the dermatitis which had developed among some of the workmen in the plant." He commented on these studies as follows:

"One is impressed with the fact that each of the Aroclors giving a positive reaction were of a fluid nature. Attempts were made to expose the animals to vapors but observations made us conclude that the only difference was that the animal would be exposed to the hot material and it was well-known that the reaction where such an exposure is given is more severe.

"One cannot but feel that any styrene compound which may be found to be present as an impurity is the cause of your trouble. I was rather surprised that more of the compounds submitted did not show or give reactions with the skin. It has been shown in some investigations that chlorine did not produce a dermatitis when metallic electrodes were used but did if the metallic electrodes were replaced by carbon electrodes. The theory was advanced that some organic chlorine compounds were produced in the latter case.

"I would suggest that you study your ventilation system in places where fumes are given off. That means be provided for the men to take a bath with soap and water if they come in contact with the type of material found to be positive. By this I mean if a leak or spillage occurs. The immediate bathing under these circumstances should be insisted on. I found that where I had gotten the material on my hands if I washed them thoroughly no trouble arose."

In his transmittal letter to Dr. J. N. Carothers of Swann Research, Inc., Anniston, Alabama, Dr. Flinn stated:

"It may interest you to know that the dermatitis which was produced by your materials in the case of rabbits cleared up in a couple of weeks, indicating that unless there are repeated exposures the effects are only of a temporary nature. As I said before, I believe that if washing facilities are present and the men are instructed to use them it will do much to supplement the increased ventilation which you have installed." (3)

In the published literature, "the first observations on the development of acnelike lesions among workers in the United States coming in contact with chloronaphthalenes and chlorodiphenyls as well as acute yellow atrophy of the liver occurring among such workers were reported in 1935" (4). Results of Swann studies were published in 1936 (5).

There is a letter report dated December 22, 1949, to Dr. R. E. Kelly (Monsanto) from Dr. L. K. Halpern of the Barnard Free Skin and Cancer Hospital (St. Louis) describing a human patch study. This consisted of applying film treated with 11.5 percent AROCLOR and gauze moistened with 100 percent AROCLOR to skin of the upper arm of 218 volunteers using the

technique developed by Dr. Louis Schwartz, Medical Director of the United States Public Health Service. Dr. Halpern reported "If the procedure recommended by the United States Public Health Service is sufficient to distinguish between chemical compounds that are innocuous when applied to the skin and other compounds that are primary irritants or sensitizers, then it would seem that Aroclor has no primary irritant effect nor is it a sensitizer of high potency." (6) Monsanto records show that this study was conducted with AROCLOR 1254.

In 1963, Monsanto received reports of subacute rabbit dermal studies it had sponsored on several chlorinated diphenyls. Salient features of these studies, conducted according to then-currently acceptable procedures, are summarized below (1).

<u>AROCLOR</u>	<u>1221</u>	<u>1242</u>	<u>1248</u>	<u>1254</u>	<u>1268</u>
No effect level*	150	50	10	10	500
LD ₅₀ **	250	75	50	75	1250
Local skin effects	none	none	none	yes	yes
Systemic injury	none	none	liver injury	liver injury	liver injury

* All dosages in mg/kg/day

** Based on 20-day dosing and 14-day observation periods

These studies showed that repeated and prolonged skin contact with the higher chlorinated biphenyls could produce skin irritation and that harmful amounts could be absorbed under such conditions. They also demonstrated that there was a safe level of exposure for each material, and that they could be handled safely if the earlier precautions to avoid excessive skin contact were observed.

Systemic Effects

On June 30, 1937, a symposium on systemic effects resulting from inhalation of chlorinated hydrocarbons was held at the Harvard School of Public Health. Dr. R. E. Kelly of Monsanto participated in the sessions at which results of investigations requested by manufacturers of chlorinated hydrocarbons were presented. Subsequently, three papers summarizing the results of those studies appeared in the scientific literature (7,8,9). With respect to chlorodiphenyls, the Harvard group concluded that "...it appears safe and it is certainly easily attained, to ventilate so that the air breathed does not contain more than 0.5 mgm. per cu.m. of any of these compounds...". In a separate unpublished report to Monsanto Company (10) Dr. C. E. Drinker of Harvard described the results of inhalation studies conducted with compound #1268, having a chlorine content of 68 percent. He concluded, "#1268, if handled with ordinary precautions as to ventilation, should be entirely harmless to workmen."

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Monsanto sponsored a study at the University of Cincinnati's Kettering Laboratory on "The Toxicity of the Vapors of AROCLOR 1242 R and AROCLOR 1254R." A report of those studies (11), presented at the 1956 meeting of the American Industrial Hygiene Association, stated that the investigation "...was undertaken because in the earlier literature dealing with the toxic effects of Aroclors, no distinction has been drawn between the toxic effects of chlorinated biphenyls and those of chlorinated naphthalenes..."

No injury was observed after prolonged intermittent exposure of several species of animals to AROCLOR 1242 at air concentrations of 1.90 to 8.63 micrograms per liter. Animals subjected to comparable exposures of AROCLOR 1254 showed signs of apparently reversible liver cell injury. The authors concluded their observations by saying "It should be noted that it was necessary to heat these Aroclors in order to increase the rate of volatilization sufficiently to attain the concentrations maintained in these experiments. To the extent that their industrial usage is carried out at ordinary temperatures, the hazard of their inhalation may well be slight or entirely absent."

These studies confirmed earlier work which indicated that no harmful effects were to be expected if these materials were used with adequate ventilation since it was necessary to heat the substances to generate sufficiently high air concentrations to injure the test animals.

Prior to 1956, the American Conference of Governmental Industrial Hygienists (ACGIH) had established a Threshold Limit Value (TLV) of 1 mg/m^3 for chlorodiphenyl. In 1956, the listing was changed to read chlorodiphenyl (42% chlorine) as 1 mg/m^3 . The 1957 list showed chlorodiphenyl (42% chlorine) as 1 mg/m^3 and an added TLV of 0.5 mg/m^3 for chlorodiphenyl (54% chlorine). The latter two values have been unchanged since then (12). Results of the Monsanto-sponsored study (11) contributed to the decision of the ACGIH to lower the TLV for the more highly chlorinated biphenyls (13).

Environmental Exposure

In response to reports of the presence of some PCBs in the environment, Monsanto, in 1969, initiated preliminary toxicity studies which led to a series of long-term tests. These tests, on the three predominant commercial polychlorinated biphenyls (AROCOR 1242, AROCOR 1254, AROCOR 1260), consisted of 2-year (lifetime) feeding to rats, 2-year feeding to dogs, 3-generation rat reproduction studies with 2 litters cast per generation, rat teratology studies and dominant lethal mutagenic studies in mice. Toxicity and reproduction studies in chickens were performed to evaluate possible untoward effects in birds such as decreases in eggshell thickness. This series of studies (1) represented the most comprehensive safety tests of the time, and was similar to the tests required for food additives, although Monsanto certainly had no intention of applying for a food additive permit.

The highest dietary level (100 ppm) in the lifetime rat feeding studies produced a weight depression at 24 months in females fed AROCLOR 1254 and liver weight increases in all groups except males fed AROCLOR 1242. As with other halogenated hydrocarbons, the important histopathologic changes were present in the livers of animals sacrificed at the end of the study. These consisted of hepatocellular (liver) alterations such as focal hypertrophy (localized enlargement), cytoplasmic lipid changes and in some animals from the 100 ppm groups, hepatomas or cholangiohepatomas (benign tumors). There was no evidence of hepatocellular carcinogenicity with any of the AROCLOR products.

In the dog 2-year studies, some slight decreases in body weight gain were noted. At the highest feeding level (100 ppm) of AROCLOR 1260, there was evidence of gastrointestinal inflammatory lesions and ulcerations.

In the rat reproduction studies, none of the AROCLOR products produced adverse effects in the 2 litters of the first generation. In the second and third generations, there was a reduction in the mating index and a decrease in the incidence of pregnancy at the 2 highest feeding levels (10 ppm and 100 ppm). The ability of females to carry pups to delivery, once conception had occurred, and to successfully nourish the young was not affected by the three AROCLOR products. No changes were produced in the reproductive tracts of either male or female rats by any of the 3 AROCLOR products.

There was no evidence of teratogenic or mutagenic changes with any of the chlorinated biphenyls at maximally tolerated dose levels in rats and mice.

In the chicken toxicity/reproduction study, AROCLOR 1260 was without effect at all test levels. AROCLOR 1242 and AROCLOR 1254 at 100 ppm in the diet decreased egg hatchability. Poor hatchability of eggs was found from hens fed 8 ppm of AROCLOR 1242. AROCLOR 1242 at 10 and 100 ppm and AROCLOR 1254 at 100 ppm were associated with reduced eggshell thickness. Chick viability was affected by both substances at a dietary level of 10 ppm.

Data developed by Monsanto and information gained from the Yusho incident in Japan were cited by the Food and Drug Administration (FDA) as a basis for establishing tolerances for chlorinated biphenyls in various foods in 1973 (14). Subsequently, the FDA proposed a reduction in those tolerances (15).

In 1976 it was reported that AROCLOR 1248 in the diet of monkeys, at or below FDA tolerance levels for chlorinated biphenyls, adversely affected reproduction (16). FDA limits on PCBs in the human diet are related to a safe level of 1 $\mu\text{g}/\text{kg}$ body weight/day (14). The studies carried out by Allen and coworkers (16) were at dosage levels of approximately 89 and 183 $\mu\text{g}/\text{kg}/\text{day}$. Their work suggested that there could be a previously unknown effect on reproduction in primates and they failed to define a no-effect level. Monsanto, therefore, undertook a detailed monkey reproduction study with carefully administered dosages at and below those previously studied.

In the Monsanto study, 32 female and 16 male rhesus monkeys, divided into 4 groups each consisting of 8 females and 4 males, were given daily dosages of 0, 5 µg/kg, 25 µg/kg or 100 µg/kg of AROCLOR 1254. The in-life portion of that study, which lasted about 14 months, has been completed.

At Monsanto's highest dosage (100 µg/kg/day), which corresponded to the low level in the Allen study, we find that AROCLOR 1254 has similar effects to those reported earlier for AROCLOR 1248. The results at the lower levels are not completely evaluated.

Potential Carcinogenicity - Animal Studies

In 1975, Dr. Renate Kimbrough reported the induction of liver carcinomas in female rats fed AROCLOR 1260 for two years (17/26). The same lot of AROCLOR 1260 was used in her study as in Monsanto's earlier test. Monsanto's study showed that AROCLOR 1260 as well as AROCLOR 1242 and AROCLOR 1254, produced liver injury, but no cancers. Therefore, an extensive reevaluation was made of the original liver slides from the Monsanto studies as well as additional liver sections from all rats in the Monsanto two-year feeding studies. These slides were examined independently by Dr. D. Gordon of Industrial BIO-TEST Laboratories, by Professor W. Richter of the University of Chicago and by Professor Parvis Pour of the Eppley Institute for Research in Cancer. In addition, Dr. Pour evaluated sections of liver from rats in Dr. Kimbrough's study.

No carcinomas were seen in the livers of rats from the Monsanto studies, and Dr. Pour did not concur with Dr. Kimbrough's diagnosis of liver cancer in rats from her study (¹⁸~~17~~) (see Attachment 2-2). The different criteria by which pathologists diagnose cancer, and the reported findings of cancer induced by polychlorinated biphenyls in various animal species, have been discussed by Dr. J. C. Calandra (¹⁹~~18~~) (Attachment 2-3).

In 1977, the National Cancer Institute reported results of a bioassay for possible carcinogenicity of AROCLOR 1254. That report stated that AROCLOR 1254 was not carcinogenic under the test conditions (²⁰~~19~~).

Human Epidemiology Studies

The toxicity testing described above has provided a foundation for understanding the potential effects of chlorinated biphenyls. However, firm conclusions cannot be drawn without human epidemiological data drawn from exposed populations.

"The view that human health risks resulting from exposure to chemicals may be determined experimentally by testing laboratory animals is one that is widely accepted in the scientific community and has been adopted by EPA. Because experimentation on human beings raises ethical questions and because epidemiological studies often provide incomplete information, toxicology studies on laboratory animals are often necessary. However, because the extrapolation from animals to man is subject to some uncertainty, corroboration

of laboratory test data with sound epidemiological information is desirable." (U.S. EPA, Support Document/Draft Voluntary Environmental Impact Statement for Polychlorinated Biphenyls, 1978). Such epidemiological data on PCBs is now becoming available.

Monsanto is aware of seven epidemiological studies done in the U.S. of persons exposed to PCBs. They include persons with occupational as well as community exposure, and the effects studied range from deviations in biological parameters, through reported symptoms and illnesses, to the occurrence of death from various causes.

Selikoff and colleagues studied 326 volunteers who were occupationally exposed to PCBs. They report the percentage of those workers with various dermatological, gastrointestinal, neurological and other symptoms, as well as the percentage with abnormal values of clinical chemistry parameters and of pulmonary function. They concluded that reported symptoms and abnormal findings in physical examinations were not related to duration of employment or level of PCBs in the blood, except for abnormal dermatological findings and abnormal levels of some indicators of liver function. Although the authors claim to have found an unusual impairment of pulmonary function in their study population, no effort was apparently made to determine whether this impairment was related to the other findings (see Attachments 2-4 and 2-5).

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In spite of a correlation of some liver function parameters with PCB exposure, the prevalence of abnormal liver function was low. The authors state, "The paucity of other abnormalities on physical examination was striking; this included a very low prevalence of abnormal liver findings." (emphasis in original).

The Center for Disease Control examined liver function and blood levels of chlorinated biphenyls in a sample of PCB workers, their families, and exposed persons in the community, in Bloomington, Indiana. This study found very mild liver dysfunction (increased levels of the enzyme GGTP) and increased blood levels of a cholesterol-like substance in persons with higher blood levels of PCBs. It is not clear if these findings have any relationship to actual illness (see Attachment 2-6).

The Michigan Department of Public Health conducted a study of 182 persons who regularly consumed sports fish, a source of PCB, and classified as "exposed", "intermediate" and "controls" according to the amount of fish consumed. A direct relationship was found between the amount of fish consumed and blood level of PCB. However, no significant difference was found between the controls and the exposed in the incidence of 19 health conditions, many of which described the symptoms reported for Yusho disease. Furthermore, in 12 of the 19 conditions, people with the condition had lower blood

PCB levels than those without the condition. The authors conclude, "As a group, the exposed participants had no health problems or medical conditions that could be correlated with PCB levels, exposure to Lake Michigan fish, or known symptoms of PCB poisoning" (see Attachment 2-7).

NIOSH has completed a study of mortality rates in workers in a transformer plant where there was exposure to PCBs, but Monsanto is unable to comment because a report of the study is not yet available.

The South Carolina State Department of Health and Environmental Control recently completed a study of 32 workers in a capacitor plant, 10 of whom were regularly exposed to PCBs. Details of the study available to Monsanto are limited to those contained in newspaper reports, but the study apparently involved a medical examination and a determination of blood PCB level. The authors state that the study "clearly shows that at present there is no evidence of physical harm resulting from working with PCBs." (See Attachment 2-8)

These four recent studies appear to constitute the most extensive epidemiological work yet done on chlorinated biphenyls. They each indicate an absence of morbidity (ill health) associated with significant exposure to PCBs.

The Mobil Corporation carried out a study of the occurrence of cases of cancer in a population exposed for varying lengths of time between 1949 and 1957. Plant medical

records were used to determine the occurrence of cancer in this group between 1958 and 1975. However, records were not available for about 20 percent of the eligible study group. The 41 men who were actually studied differed from the populations described above in that they were employed in a chemical plant which manufactured a number of different materials to which they might have been exposed during their working careers. The study found an excess of skin cancer (melanoma) based on three cases. After a preliminary report of these findings was made, the Mobil Corporation informed NIOSH that there had been "a substantial change" in the definition of the cohort, and that an analysis of the changed cohort might show quite different results. As far as Monsanto is aware, that analysis has not yet been completed.

In 1975, independent of the Mobil effort, Monsanto began to gather information for a mortality study of employees exposed to PCBs at its W. G. Krummrich plant in Sauget, Illinois. Because the plant had manufactured a number of chemicals those persons exposed to PCBs typically had a mixed exposure to other substances as they moved from job to job. Because the work histories of past employees were not computerized, it would have been necessary to identify those who had worked with PCBs by a manual search through 6,000 records. A preliminary identification was made of 50 deaths from various causes among past workers with PCB exposure, and a

review of these suggested a possible excess of lung cancer, but not of skin or pancreatic cancer. This preliminary finding was announced in 1976.

A further attempt to identify a cohort yielded 89 men who had been exposed for at least six months in the period 1945-1965, who were then followed to determine their vital status as of the end of 1977. There were no excess deaths from pancreatic cancer, but 4 lung cancer deaths were found where about 1.5 would be expected. Smoking histories were not available. The accuracy of the determination of this cohort was limited by the necessity of conducting a manual search of the records.

At the present time, computerization of the Krummrich work histories is underway, and should be completed early in 1980. At that time it will be possible to better define the exposed population, and to better determine the other substances to which the population was exposed. However, because of the mixed nature of exposures in a chemical plant, it is unlikely that the Monsanto study can ever be as specifically related to PCBs as those conducted by Dr. Selikoff, CDC, the Michigan DOH, and the South Carolina DOH.

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3. MONSANTO ACTIONS RESULTING FROM HEALTH DATA

Monsanto has been responsive to health questions about chlorinated biphenyls over the years. Those responses have been consistent with "state of the art" procedures available at the time the questions were raised. It should be noted that Monsanto's decision to leave the PCB business was based on concerns over environmental presence, not health effects.

Skin and Systemic Effects

When first reported in 1935 (1,2), the occurrence of skin and systemic effects from chloronaphthalenes and chlorodiphenyls constituted a new occupational health problem. It rapidly became of concern to federal and state occupational health personnel and to their industrial counterparts. Monsanto was among the sponsors of and a participant in the studies and the subsequent symposium held on this subject at Harvard University (3). In addition, Monsanto conducted its own studies on various polychlorinated biphenyls (4,5,6,7). Earlier, Swann Research, Inc. had conducted human patch tests on these materials (8). Results of these efforts suggested that controlling skin contact and vapor inhalation would permit safe industrial use of these substances.

In 1936, Monsanto began developing a corporate medical program. From the start, Monsanto's Medical Director ensured that chlorinated biphenyl workers at Anniston were included in this program. This consisted of periodic physical examinations, good work practices to ensure personal

cleanliness of employees, adequate ventilation of the work areas, and overall good industrial hygiene practices. The buildings at the Anniston plant were relatively open and most of the processing was done in closed equipment. Therefore, employee exposure was relatively low. However, since some customers were using chlorinated biphenyls at elevated temperatures, with a greater potential for exposure, precautionary statements for handling them were prepared for customer use as early as 1937 (9) (see Attachment 3-1, 3-2, 3-3). As additional information developed, it was incorporated into Monsanto work practices and distributed to customers by way of correspondence, technical bulletins, and other corporate publications (see Attachment 3-4). In addition, upon request, Monsanto technical and medical personnel visited customer plants to advise them on safe handling of polychlorinated biphenyls. Finally, the Monsanto-sponsored studies on AROCLOR 1242 and AROCLOR 1254 led the American Conference of Governmental Industrial Hygienists (ACGIH) to lower the Threshold Limit Value (TLV) for the higher chlorinated biphenyls in 1957 (10).

Environmental Presence

In late 1966, Soren Jensen of the Karolinska Institute in Sweden reported the detection of polychlorinated biphenyls in the environment. This was confirmed by 1970. In the interim, Monsanto's European office had entered into discussions with the Karolinska Institute in an attempt to obtain details of the findings. In early 1969, representatives

of Monsanto went from St. Louis to Sweden to meet with Jensen. He was not available, and discussions were held with his professor, Dr. Widmark. At about the same time, Monsanto decided to develop data on the chronic oral toxicity of chlorinated biphenyls. Although there was no intention of petitioning for such use, the extent of these tests was typical of those designed for the evaluation and establishment of the safety of direct and indirect food additives. This series of tests was undertaken because it represented the most comprehensive requirement of safety at that time (11). FDA was informed of the voluntary testing program in October, 1969 (12). Subsequently, as evidence of environmental presence increased, those studies were expanded in scope. Chicken studies to determine the effects of chlorinated biphenyls on avian species were completed in 1970 and 1971. Results of all these studies have been distributed to the FDA and other regulatory agencies. During this time period, Monsanto expanded the warnings on its product labels to include cautions against allowing escape to the environment (Attachment 3-5).

When, in 1976, reproductive disorders were reported in monkeys fed chlorinated biphenyls (13), Monsanto undertook a study to determine the validity of those findings. The Monsanto study is being conducted with AROCLOR 1254, a large volume material, instead of the relatively low volume AROCLOR 1248 used by the earlier investigators.

Potential Carcinogenicity

In 1975, after Dr. Kimbrough reported that AROCLOR 1260 produced liver cancer in rats (14), Monsanto undertook a

review of liver sections from its earlier studies on AROCLOR 1242, AROCLOR 1254, and AROCLOR 1260. In addition, it retained Dr. Pour of the Eppley Institute for Research in Cancer to review all liver sections from all of the AROCLOR studies, i.e., Monsanto's and Dr. Kimbrough's (15). That review showed no occurrence of liver cancers. Finally, Dr. Calandra was retained to review and comment on available literature dealing with carcinogenicity of polychlorinated biphenyls (16). Results of those evaluations have been made available to regulatory agencies.

5. COMMUNICATING WITH CUSTOMERS

Notification Procedures

Beginning in February, 1970, Monsanto notified its customers of the early reports that PCBs had been detected in the environment. Additional information was transmitted to customers as it became available, along with details of Monsanto's phaseout. The notification letters included as Attachment 5-1 indicate the priority given to terminating applications that seemed relatively likely to lead to environmental release, were food related, or used the more highly chlorinated products. We cooperated with users of hydraulic fluids and heat transfer fluids to discontinue PCB use.

Simultaneously, we introduced AROCLOR 1016, a lower chlorinated product for capacitor use, and restricted transformer fluid sales to equipment manufacturers only. In the case of both capacitor and transformer producers, we emphasized the need for control of PCBs. In 1974, Monsanto revised its dielectric literature to conform to the ANSI guideline (Attachments 5-2, 5-3, 5-4) which resulted from the industry work with ANSI referred to earlier. In 1976 the ANSI committee was reconvened to consider the need for revision of the guidelines. Completion of this task has been deferred pending issuance of EPA regulations on PCBs.

Monsanto Provided PCB Disposal Assistance to Customers

In 1969 Monsanto started testing the efficiency of PCB destruction by high temperature pyrolysis and constructed

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a 6 million pounds/year unit which was completed in May, 1971. This incinerator was designed, and was demonstrated, to destroy PCB wastes at 99.9998 percent efficiency (Attachment 5-5).

By September, 1971, this unit was in continuous operation and was destroying both waste from our production and PCBs returned by customers as they converted to non-PCB replacements. When phaseout from nonelectrical applications was complete, the incinerator was used to destroy waste PCB which collected from ongoing dielectric use.

A system was developed to properly handle customer return of wastes (Attachment 5-6). When some customers did not follow our suggested procedures, Monsanto reemphasized the need for proper packaging (Attachment 5-7). To assist in proper handling, posters were prepared and distributed to further educate those responsible for collection and handling of PCB wastes (Attachment 5-8).

In the period 1975-1976, large (approximately 80 million pounds/year) commercial facilities became available which could handle controlled PCB incineration more efficiently and economically than Monsanto's small prototype unit. These units incinerated PCBs until their operations were curtailed by the need for a specific permit under the EPA disposal regulations for PCBs, which became effective on April 18, 1978. The first permit has yet to be issued. The potential risks of accidental PCB contamination have undoubtedly increased because of the delay in EPA implementation of its incineration policy.

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Label Warnings

In 1970 Monsanto modified the labeling of PCB packages to emphasize the need to keep it from the environment (Attachment 5-9). Subsequently, labels on drums were written in seven languages (Attachment 5-10).

Assistance with Identification of PCBs

Because of the changes in composition of PCB dielectric fluids since their introduction, Monsanto worked with the IEC to document such changes. This led to ASTM standard D2283, which lists the composition of all transformer askarels used at various times since 1932 (Attachment 5-11).

Monsanto researchers worked within ASTM to develop refined technology for determination of PCBs in the environment. This resulted in approval of ASTM D3304 (Attachment 5-12) which has become standard methodology for PCB quantification. While many laboratories have the necessary equipment, proficiency in the methodology varies widely. Monsanto's Applied Sciences group regularly consults with laboratories as they gain experience in testing for PCBs. Regulations require many such tests to be performed. The testing load has been greatly increased by the policy EPA adopted in controlling PCB-contaminated oils at the 50-500 ppm level. This is causing serious delays in reporting of test results.

We recognized that after Monsanto terminated production of chlorinated biphenyls small samples of products which had previous commercial significance would be required for research and standardization of detection equipment.

Arrangements were concluded with a laboratory supply house to take custody of a limited drum quantity and to supply such samples.

Continuing Research

Monsanto is funding studies at two major universities which are directed at finding innovative approaches to reducing PCB levels in the environment.