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SUBMISSION TO

THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF

THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

U. S. HOUSE OF REPRESENTATIVES

By

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63166

November 16, 1979

MONS 012304

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 carbonless paper systems. Their firs 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 MANUFACTU
MONSANTO INDUSTRIAL
1957 th
(Thousands

	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966
U.S. PRODUCTION	(1)	(1)	(1)	37910	36816	39883	44734	50833	60460	60640
DOMESTIC SALES	32250	29881	31310	38214	37038	39043	39132	44609	51706	59078
U.S. EXPORT SALES	(2)	(2)	(2)	(2)	(2)	(2)	3647	4006	4234	6662
DOMESTIC SALES BY CATEGORY										
Heat Transfer	0	0	0	0	0	157	562	929	1237	1706
Hydraulics/ Lubricants	1612	1549	2805	2823	4110	3915	3945	4374	4616	4258
Misc. Industrial	704	755	1009	1589	2114	1681	1536	1662	1841	1779
Transformer	12555	5710	5004	7021	6381	7984	7290	7987	9057	8010
Capacitor	17239	14069	16499	16987	18535	18362	18868	18649	23749	30804
Plasticizer Applications	(1)	3939	4573	6944	9986	9884	9181	10337	11696	13481
Petroleum Additives	0	0	0	0	0	0	0	0	0	0
DOMESTIC SALES BY PCB GRADE										
Aroclor 1221	23	16	254	169	94	140	361	896	389	528
Aroclor 1232	196	113	249	185	241	224	13	13	7	16
Aroclor 1242	18222	10444	13698	18196	19827	20884	18619	23671	31533	39667
Aroclor 1248	1779	2589	3384	2827	4823	3483	5013	5238	5605	5915
Aroclor 1254	4481	6891	6754	6986	6284	6325	6911	6280	7737	7935
Aroclor 1260	7587	5982	6619	7339	6640	6986	7826	8535	5831	5875
Aroclor 1262	31	164	369	328	361	432	414	446	558	768
Aroclor 1268	0	72	102	199	185	210	284	190	198	284
Aroclor 1016	0	0	0	0	0	0	0	0	0	0

(1) Production figures and Plasticizer Applications figures unavailable during year indicated
(2) U.S. Export Sales figures unavailable during year indicated.

MONS 012307

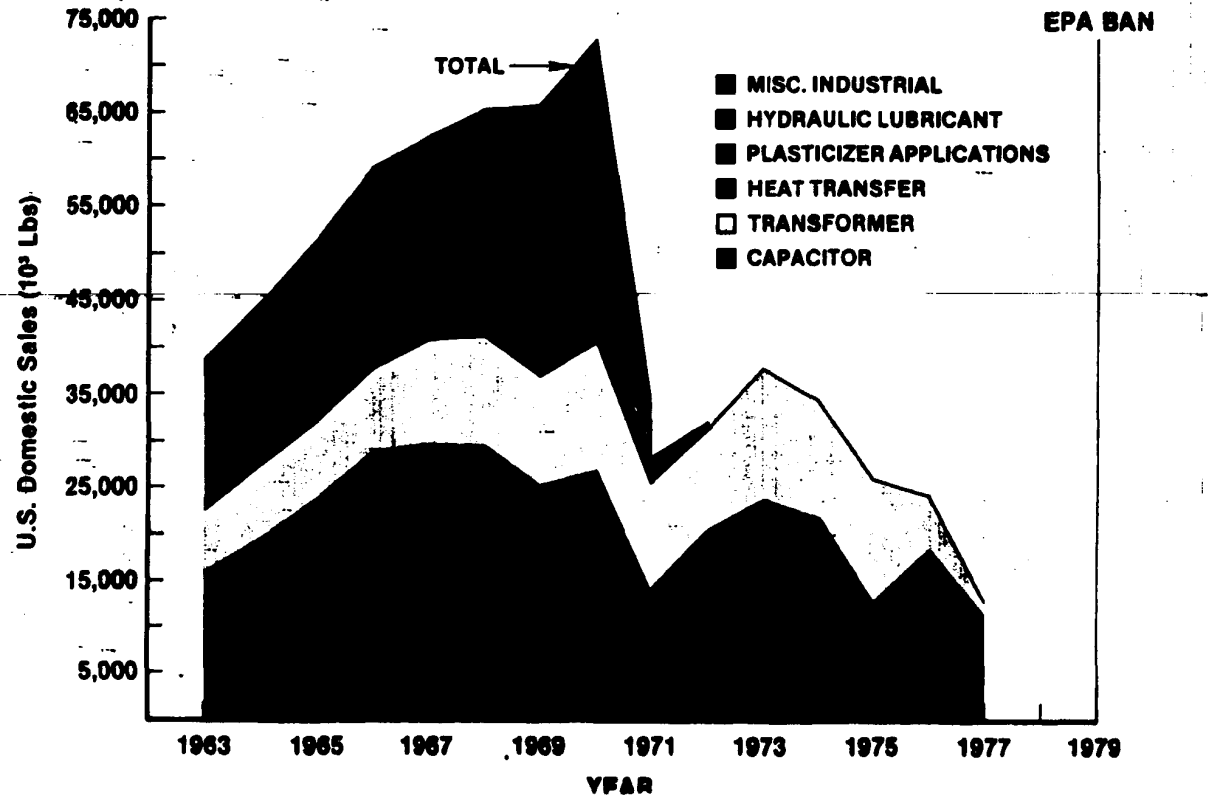
RING AND SALES
CHEMICALS COMPANY
ru 1978
of Pounds)

1967	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978
75300	62054	76300	66054	45417	38000	42178	40118	29710	29802	13330	0
63408	65116	67194	73861	34391	32242	37742	34408	25611	24329	12701	0
8124	11231	10624	13851	10848	6388	8346	5386	5712	4744	1548	0
2282	2520	3050	3958	3000	752	0	0	0	0	0	0
4643	5705	6030	7403	1552	0	0	0	0	0	0	0
1428	1283	1079	1627	1155	0	0	0	0	0	0	0
11671	11586	12105	13828	11134	11314	14176	12394	12763	6002	1617	0
29708	29580	25022	26708	14141	20176	23588	22012	12848	18327	11084	0
13381	14404	16400	19537	3250	0	0	0	0	0	0	0
0	0	1430	0	0	0	0	0	0	0	0	0
442	136	507	1476	2215	28	35	57	28	28	0	0
25	80	273	200	171	0	0	0	0	0	0	0
43005	44053	45401	46580	21981	5637	6200	6207	6436	4418	51	0
4704	4804	5080	4873	213	0	0	0	0	0	0	0
6808	8801	9822	13421	4861	6115	7976	6185	6320	1584	1508	0
6417	5252	4430	4800	1725	414	0	0	0	0	0	0
840	720	712	1023	1	0	0	0	0	0	0	0
287	200	300	300	0	0	0	0	0	0	0	0
0	0	0	0	3334	20150	23531	21955	12830	18307	11084	0

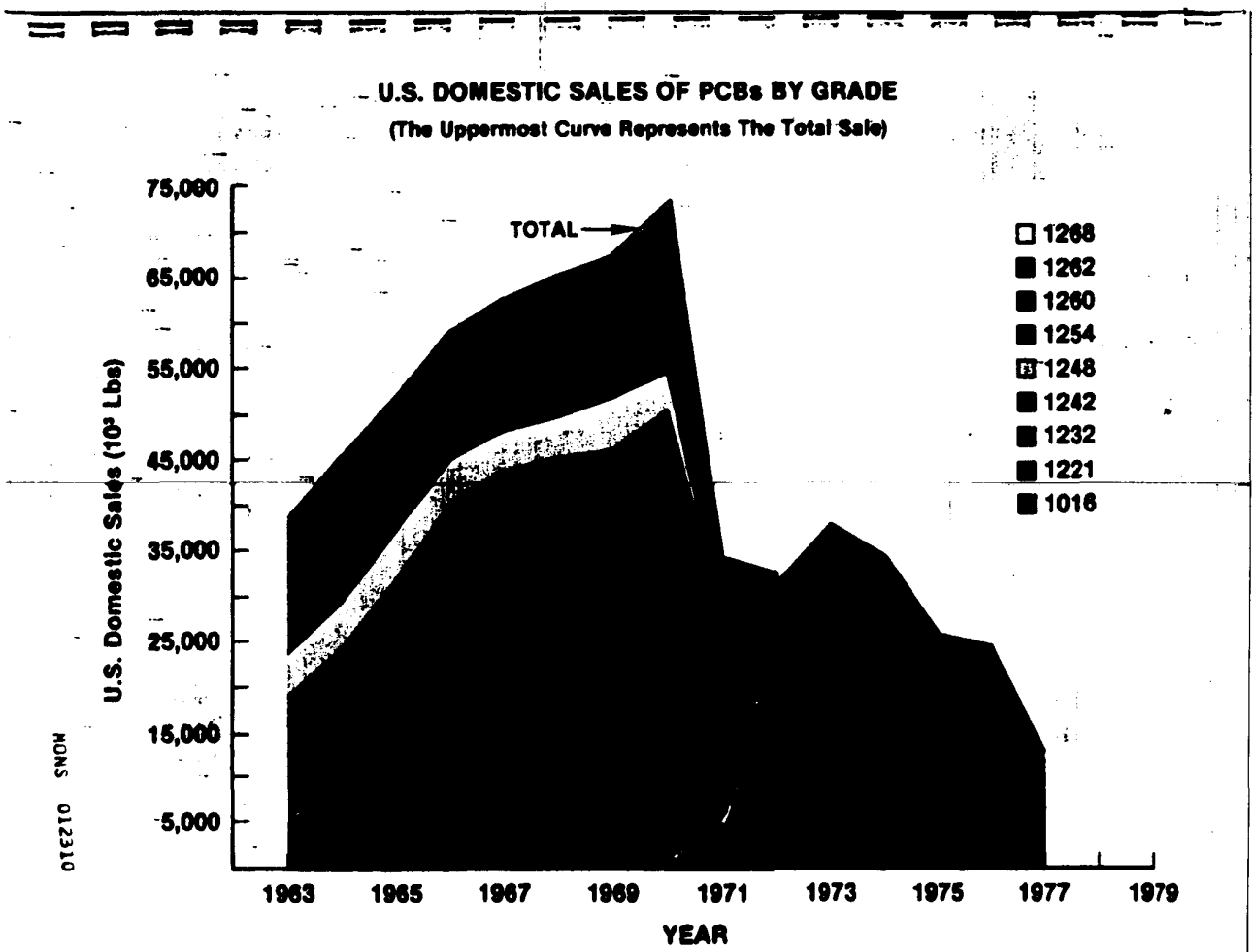
MONS 012308

U.S. DOMESTIC SALES OF PCBs BY CATEGORY

(The Uppermost Curve Represents The Total Sales.)



MDNS 012309


U.S. DOMESTIC SALES OF PCBs BY GRADE
(The Uppermost Curve Represents The Total Sale)
U.S. Domestic Sales (10^3 Lbs)
75,000
65,000
55,000
45,000
35,000
25,000
15,000
5,000
TOTAL
1268
1262
1260
1254
1248
1242
1232
1221
1016
1963
1965
1967
1969
1971
1973
1975
1977
1979
YEAR
MONS 012310

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 thie 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

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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.

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 1-7). 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, following preliminary news media reports in late 1966.

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

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.

In summary, Monsanto's decision to withdraw from the PCB business was based on concerns about environmental presence rather than health effects.

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).

AROCLOR	1221	1242	1248	1254	1268
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."

Monsanto sponsored a study at the University of Cincinnati's Kettering Laboratory on "The Toxicity of the Vapors of AROCLOR 1242 [R] and AROCLOR 1254[R]." 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 napthalenes..."

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 (AROCLOR 1242, AROCLOR 1254, AROCLOR 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 µg/kg body weight/day (14). The studies carried out by Allen and coworkers (16) were at dosage levels of approximately 89 and 183 µg/kg/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). 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. Four did not concur with Dr. Kimbrough's diagnosis of liver cancer in rats from her study (18) (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) (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).

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 detrmine whether this impairment was related to the other findings (see Attachments 2-4 and 2-5).

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 18 health conditions, many of which described the symptoms reported for Yusho disease. Furthermore, in 12 of the 18 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 Krumsrich 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.

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4. CUSTOMER RECORDS

Over the years, Monsanto developed the normal commercial records on its sales of chlorinated biphenyls. They were useful for sales and service calls, accounting, production forecasting, and, when decisions were reached to limit chlorinated biphenyls, customer lists served as the basis for our notification visits, telephone calls, letters, and publication mailings in the period 1970-1972, as we phased out all but dielectric chlorinated biphenyl sales.

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

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.

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 standardisation 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.

6. PCB DISPOSAL

During the years Monsanto made chlorinated biphenyls, the quantity of waste produced was relatively low and consisted chiefly of distillation residues, after separation of the useful product mix. Until 1971 these residues were landfilled. From 1971 to 1977 production waste was incinerated.