

Monsanto

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 834-1000

March 12, 1974

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Mrs. Betty J. Billings
Hearing Clerk
Environmental Protection Agency
Room 1019-East Tower
401 "M" Street, S.W.
Washington, D. C. 20460

Re: Proposed Toxic Pollutant Effluent
Standards for Aldrin-Dieldrin, Et Al -
FWPCA (307) - Docket No. 1

Dear Mrs. Billings:

In accordance with the ORDER AND NOTICE of Judge William J. Sweeney dated February 8, 1974, enclosed are the original and three copies of the written testimony with attachments submitted on behalf of Monsanto Company in connection with the above described matter.

Yours very truly,

Phocion S. Park
Phocion S. Park
Senior Attorney

PSP/jmd

Enc.

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Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63186
Phone: (314) 894-1000

In Re: PROPOSED TOXIC POLLUTANT
EFFLUENT STANDARDS FOR ALDRIN-
DIELDRIN, ET AL - FWPCA (307) -
DOCKET NO. 1

State of Missouri)
County of St. Louis) ss:

W. B. Papageorge, being first duly sworn says:

My name is W. B. Papageorge and I am Manager, Product Acceptability for the Functional Product Groups, Monsanto Industrial Chemicals Company, an operating unit of Monsanto Company. I am a graduate of Washington University, St. Louis, Missouri with a Bachelor of Science degree in Chemical Engineering and have received a Master of Science degree in Chemical Engineering from the same institute. I am a Registered Professional Engineer in the state of Missouri.

I have been employed by Monsanto Company for approximately 22 years, during which period I have served as an engineer, maintenance superintendent, distribution superintendent, manufacturing superintendent, plant manager and manager of environmental protection. In my present position I am responsible for seeing that the quality of products produced by two business groups in Monsanto Company is properly maintained. One of the business groups within my area of responsibility is the Specialty Products Business Group which manufactures and markets polychlorinated biphenyl (PCB) products for use as dielectric fluids in transformers and capacitors. I am a member, and have served as chairman, of a committee of the National Electrical Manufacturers Association which has reviewed the environmental effects of PCBs and has recommended procedures to users of PCBs which should minimize the possibility of entry of PCBs into the environment.

a unit of Monsanto Company

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MONSANTO COMPANY'S POSITION AND RECOMMENDATIONS

As a major producer and supplier of polychlorinated biphenyls (PCBs) to the electrical industry for fire resistant dielectric fluid applications, we have reviewed and evaluated the effluent standards for these materials in proposed Part 129, Subpart I, Chapter I of Title 40, Code of Federal Regulations. Pursuant to this review, we submit the following comments and recommendations:

1. The proposed effluent standards for PCBs are unwarranted and practically and economically unattainable.
2. Actions by Monsanto and its customers, which have resulted in limiting the use of PCBs only to electrical applications in hermetically sealed units, have dramatically reduced the quantities of the more persistent PCBs introduced directly into the environment.
3. The definition of PCBs in Section 129.09a, Subpart I should be changed to read:

"Polychlorinated biphenyls (PCBs) means materials containing the biphenyl group which is chlorinated and which have been shown to persist and rapidly bioaccumulate in the aquatic environment. These chlorinated biphenyls are identified as those components having gas chromatographic retention times greater than 60, relative to p,p'-DDE-100, under the standard conditions recommended in the EPA PCB test method."

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4. The accuracy and reproducibility of results attainable between laboratories using currently available sampling and analytical techniques are questionable and further studies are recommended.
5. The proposed PCB effluent standard is based on inadequate toxicity information, on non-typical fish species and on an unusually high and artificial bioaccumulation factor. Fundamental scientifically-based data is lacking and no responsible standards can be developed at this time. We recommend that studies be conducted to obtain the relevant data and that effluent standards be established which are appropriate for the unique conditions existing at each point source.

6. We object to a limitation of 10,000 cubic feet per second being arbitrarily assigned as a maximum stream flow, without a sound technical basis demonstrating adverse effects.
7. The presence of background levels of PCBs at point sources should be considered when determining effluent levels. The following definition of "Background" should be added under Section 129.01a:

" 'Background' means amounts of toxic pollutant (1) presently found in the waterways of the United States (including the intake waters of a discharger), or (2) arising out of operations subject to this Part that occurred before the effective date of this Part, but were not discharged to the waterways of the United States before the effective date of this Part."

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8. Technology for the attainment of the proposed PCB effluent standard has not been demonstrated and is not available to the industry. Unachievement of the strict standard proposed would have the effect of a ban on the use of PCBs with serious economic and social consequences very thoroughly described in an impact statement submitted to the Agency on January 15, 1974, by the General Electric Company.

The chemical structure of polychlorinated biphenyls (PCBs) has been known for nearly 100 years. It was not until the late 1920s that a use for PCBs was found — as a dielectric fluid in transformers. The properties of PCB — inertness, fire resistance and a non-conductor of electricity — are perfectly suited to those electrical applications where high-voltage arcing could occur; possibly resulting in serious fires or damage to the equipment.

Commercial production of PCBs began in 1929. As the unique properties of the material became known, new uses were found. For example, their fire-resistant nature made them excellent choices for use in heat-transfer fluids. Their inertness gave long-lasting qualities to lubricants. Their use in surface coatings improved waterproofing characteristics.

Handling of the product at the manufacturing level has not presented problems as long as the normal industrial hygiene practices were followed and PCBs have always been considered less hazardous than many other chemicals in everyday use.

Therefore, it appeared that PCBs were a unique product which met important needs of industry.

When questions about the effect of PCBs on the environment first surfaced, Monsanto Company reviewed its product line and the applications for these products. As more data were developed concerning the effect of PCBs, Monsanto took steps to reduce the entry of PCB into the environment. The Company stopped the sale of PCBs for use in various applications, except where no acceptable alternatives were available. Today, PCBs manufactured by Monsanto Company are sold only to the electrical industry for use in closed systems as a dielectric fluid in transformers and capacitors — applications for which there exist no acceptable substitutes.

Thus the situation today is drastically different from conditions which existed only three years ago. Today about 40 million pounds per year are being carefully used in the United States by less than 50 Monsanto customers in the manufacture of sealed electrical equipment. Prior to 1971, close to 80 million pounds per year were used by thousands of customers. This lends perspective to the current debate over modest losses of PCBs to waterways.

Our manufacturing and sales reduction program was a unilateral action taken by Monsanto and was based on our evaluation of developing environmental data.

The Interdepartmental Task Force on PCBs in its report (1)* concurs that the safety benefits derived justify the continued use in dielectric applications. Recommendation 6 under Findings, Conclusions and Recommendations reads as follows:

"6. The use of PCBs should not be banned entirely. 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. Also, continued use of PCBs in transformers and capacitors presents a minimal risk of environmental contamination. The Monsanto Company, the sole domestic producer, has reported voluntarily eliminating its distribution of PCBs to all except manufacturers of electrical transformers and capacitors."

*Numbers in parentheses refer to reference list attached.

Recognizing the need for proper controls in the handling and use of PCBs, representatives of the transformer and capacitor industries, utilities and governmental agencies under the initial auspices of the National Electrical Manufacturers Association formed American National Standards Institute Committee C-107. Proposed guidelines (30) for the handling and disposal of dielectric fluids have been published. These guidelines reflect the industry's understanding of the need for proper control and have contributed significantly toward achieving this objective.

Proposals for the control of PCBs internationally were considered by the member countries of the Organization for Economic Co-operation and Development (OECD) and in February, 1973, they adopted an agreement (31) which restricts the use of PCBs to dielectric applications, non-food related heat transfer fluid applications and hydraulic fluid applications in mining equipment. This agreement is less restrictive than Monsanto's sales policy since it supports the continued use of PCBs in heat transfer and hydraulic fluids.

We have reviewed with considerable interest the effluent standards proposed for polychlorinated biphenyls in new Part 129, Subpart I, Chapter I of Title 40, Code of Federal Regulations and have objections relating to the following:

1. Definition of polychlorinated biphenyls.
2. Sampling and analytical methods.
3. Toxicity data.
4. Bioaccumulation factors.
5. Safety factors.
6. Stream flow rates.
7. Background levels of polychlorinated biphenyls.
8. Economic considerations.

DEFINITION OF POLYCHLORINATED BIPHENYLS

Commercial polychlorinated biphenyl products, of which Aroclor® products are examples, are produced by direct chlorination of biphenyl; the degree of chlorination being chosen to provide desired properties. These products are in all cases multi-component mixtures and not single entities as implied by the commonly employed acronym "PCBs".

While it is well understood and accepted that polychlorinated biphenyl isomers have a unique set of physical and chemical properties, it is apparently not understood that they bioaccumulate, dissipate and biodegrade at different rates.

This lack of understanding is reflected in the definition proposed in the EPA Toxic Pollutant Effluent Standards (Federal Register, Vol. 38, No. 247, page 35393, Section 129.09a) and we quote:

"As used in this Subpart, the term: Polychlorinated biphenyls (PCB's) means materials containing the biphenyl group which have been chlorinated to varying degrees. There are 210 possible different PCB compounds."

We object to this definition because it implies that all polychlorinated biphenyl isomers are of equal environmental concern, i.e., that they all persist and bioaccumulate in the same manner in our environment. It has been well established by academic, government, and industrial researchers that this is simply not true. Environmental monitoring programs have clearly demonstrated that, with the exception of direct high-level controllable release near points of manufacture or use, the PCBs found in our environment are the more highly chlorinated ones, i.e., those containing predominantly five or more chlorine atoms per biphenyl molecule (2 thru 13).

This is true even though the lower polychlorinated biphenyls have constituted more than 65% of all the PCBs manufactured over the years. This is strong evidence that the lower polychlorinated biphenyls degrade rapidly. It further demonstrates that even under conditions of unlimited use, and without special precautions to avoid release into our environment (which is not the case now), that the lower polychlorinated biphenyls degrade rapidly enough to prevent bioaccumulation (4, 5, 6, 27,

More recently, it has also been demonstrated in laboratory experiments that chlorinated biphenyl isomers readily undergo bacterial degradation at rates dependent upon the number of chlorines per biphenyl molecule (17, 18, 19, 20, 21 and 37). There are also good indications that ambient environmental PCB levels are decreasing at rates more rapidly than predicted (14, 15, 16).

The rapid metabolism of these chlorinated isomers and their lack of importance as contributors to the chlorinated biphenyl tissue burdens is evidenced in the results of numerous studies. Risebrough (2) reported that the chlorine composition of the PCBs detected in Atlantic Ocean zooplankton was approximately 54%. He concluded "U.S. production of Aroclor 1254 in 1970 amounted to 12 million pounds -- only one quarter

of the production of 49 million pounds of Aroclor 1242. It might be expected therefore that biphenyls with fewer chlorine atoms would predominate in planktonic samples unless these compounds were selectively degraded." Similar findings in fresh water and marine fishes were reported by Zitko (3) and Jensen, et al., (4). The disappearance of the lower chlorinated homologs in extracts of tissues from birds (5, 34) and mammals (6, 33) indicate rapid metabolism or excretion of the lower chlorinated homologs. As a result of the metabolism and/or excretion of the chlorinated biphenyls containing less than five chlorine atoms per molecule, their contribution to the effluent should not be used in measuring polychlorinated biphenyl effluent from a facility.

On the basis of these data it is unrealistic to consider all polychlorinated biphenyls equivalent in terms of persistence and bioaccumulation as does the proposed regulation. Therefore, for environmental purposes, the definition of PCBs should focus upon those which are of concern and we recommend that the following definition be substituted for that proposed in Section 129.09a, Subpart I, Title 40, Code of Federal Regulations:

"Polychlorinated biphenyls (PCBs) means materials containing the biphenyl group which is chlorinated and which have been shown to persist and rapidly bioaccumulate in the aquatic environment. These chlorinated biphenyls are identified as those components having gas chromatographic retention times greater than 60, relative to p,p-DDE = 100, under the standard conditions recommended in the EPA PCB test method."

ANALYTICAL METHODOLOGY

We have no reason to doubt that the recommended EPA PCB test method is capable of detecting parts per trillion (ppt) levels of PCBs in waste waters. However, our experience with analyzing industrial waste waters for PCBs at the parts per billion (ppb) level prompts us to be concerned about the following areas, some of which are not covered adequately in the test procedure.

1. Sampling Procedures
2. Correction for Laboratory and Reagent Background
3. Correction for Non-PCB Sample Interferences
4. Absolute Verification

5. Physical State of PCBs (Adsorbed/Dissolved)

6. Quantitation

7. Precision and Accuracy

Our concern lies in the fact that any method, especially one as complex as a PCB analytical method, which is to be used for effluent control purposes must be thoroughly evaluated and its accuracy and reproducibility proven. If this is not done, the effectiveness of any effluent limit, no matter what the level, will prove to be difficult, if not impossible to determine.

For example, we have found that if waste water streams are not sampled properly, the PCB levels found depend on the sampling procedure employed and bear no relationship to the amount of PCBs discharged. For this reason, sampling procedures used must be designed for the discharge in question and clearly stated. To our knowledge, this has not been done.

We also note that no provisions are recommended for correcting the apparent PCB level found in a sample for laboratory and reagent background. It is our experience that as one approaches the ppt level, this background can significantly affect the observed PCB level.

With regard to correction for non-PCB sample interferences, we feel that, while the procedure notes many of the possible interferences, it does not really address itself to those which are more likely to be in industrial waste water streams. For this reason, if the electron capture chromatogram does not match the PCB being manufactured or used, complete absolute verification of all components counted as PCB must be validated via an alternate technique such as gas chromatography/mass spectrometry.

We also note that the recommended EPA PCB test method does not specify a means of differentiating between dissolved and adsorbed PCBs. We believe this should be done since there is a definite difference in the toxicity and availability for bioaccumulation of dissolved and adsorbed chlorinated hydrocarbons (24, 35, 36).

While the scheme proposed for estimation (quantitation) of PCBs is logical, it suffers from the same shortcoming as do the multitude of other procedures which have been proposed. It is an empirical estimate and only a reflection of the real PCB level. Therefore, it should be determined via an alternate, more-elaborate procedure how closely the calculated PCB levels (for each of the cases) are to the real PCB levels so that they may be corrected.

Last, but not least, the precision and accuracy of any procedure proposed as a standard method should undergo a thorough inter-laboratory evaluation. If this has not already been done, it must be carried out prior to the use of the procedure for enforcement purposes. The accuracy and precision of the Monsanto PCB procedure has been subjected to a preliminary evaluation. Prior to this evaluation, we probably would have overestimated the precision and accuracy of our procedure. The exact details of the evaluation are available.

Briefly, samples were prepared by spiking distilled water with 500 ppb PCBs. Individual preparations include blanks (no PCBs), Aroclor[®] 1242, Aroclor[®] 1254 only, Aroclor[®] 1260 only, all 50-50 two-component mixtures, and a 1/3, 1/3, 1/3 preparation containing all three components. Six samples of each mixture were prepared and analyzed by two experienced analytical laboratories.

Each result, expressed in ppb of the individual Aroclor[®], was converted to percent of the total added. Analysis of variance was run on all data taken together and on each laboratory independently.

- The 95% confidence limits observed for individual results were:

Either Lab	87.5 ± 35.2%
Lab A	81.3 ± 46.4%
Lab B	93.7 ± 19.2%

- The repeatability for the individual labs, based on repeat tests of samples having identical prepared compositions was:

Lab A	± 42.0%
Lab B	± 11.6%

We feel that these results demonstrate the importance of evaluating the precision of any PCB procedure. Note that the test did not include sampling problems, used distilled water free of interferences, and was carried out at a relatively high PCB level (500 ppb; 500,000 ppt) by two experienced laboratories. It is expected that, if sampling problems were involved, and the level of PCB present was extremely low, the accuracy and precision of any PCB method would decrease considerably.

BACKGROUND FOR PROPOSED EPA EFFLUENT STANDARD.

In the establishment of the proposed effluent standard the primary basis for toxicological consideration came from the Water Quality Criteria, October, 1973, (Federal Register, Vol. 38, pages 29646 et seq., Friday, October 26, 1973). These criteria were, in turn, based on Water Quality Criteria, 1972, by the National Academy of Sciences and the National Academy of Engineering.

The Water Quality Criteria, October, 1973, have not undergone the normal review, criticism, comment and revision before final adoption. We object to the use of challengeable portions of a proposed publication in the development of critical effluent standards.

We note in Water Quality Criteria, 1972, in those sections pertaining to polychlorinated biphenyls, the frequent use of unpublished data and the disturbing use of qualifying phrases such as "...may adversely affect...", "...apparently related...", or "...the work...suggest..." In our opinion, none of the discussions present adequate data to support establishment of responsible effluent standards for PCBs.

On page 5 of Water Quality Criteria, 1972, the Committee emphasized the importance in understanding that there is a distinction between criteria and standards and that the words were not interchangeable nor or they synonyms for words such as objectives or goals. The report further states that it is necessary to establish scientifically-based recommendations for each assignable water use, implying availability of practical methods of detecting and measuring which can be applied to monitoring. Once these fundamentals are available, political, social and economical factors enter into the decision-making process to establish standards. In our opinion, these procedural steps were not followed in arriving at the proposed effluent standards for PCBs.

The maximum acceptable concentration in fresh water that would be permitted by the proposed standard is 0.002 mg/l. The rationale described in the Statement of Basis and Purpose, Toxic Pollutant Effluent Standards is based on results of a preliminary study which have suggested (not yet proven) a threshold PCB level for salmon egg mortality. We cannot accept the selection of salmon as representing organisms which are usual or may potentially be present in water systems near facilities described in Section 129.09, Code of Federal Regulations.

The cumulative sales of PCBs in the United States since 1930 has been estimated to be about 500,000 tons and that total world production was probably 1,000,000 tons (1). About one-half of the PCBs were used in applications where containment was difficult and losses into the environment were common. With this amount of material discharged into the environment, it is of considerable importance to note that extensive harm predicted by some theories has not been found and documented.

This lack of evidence indicates that all of the PCBs do not persist in the environment as a result of factors such as the biodegradation we have discussed previously. Also, the PCBs that do persist may not be available because of some factors not clearly understood at present. One characteristic which undoubtedly is of significant importance is the ability of PCBs to adsorb tenaciously to particulate matter. Under these conditions, can PCBs be rightfully considered to be environmentally active and, if so, to what degree? There exists at present a critical need for data relating to partition coefficients between water and sediments and diffusion coefficients in sediment (1, 22, 39, 40).

Although many reports have been published on the subject of polychlorinated biphenyls and living organisms, the majority of these describe the presence of PCBs in the environment. Presence should not be assumed to imply adverse effect. To our knowledge, no published report exists which conclusively relates the mortality of any wildlife species to the presence of PCBs. The only reported mortalities are those achieved in laboratory studies. Not enough is known about the fate and effect of PCBs in the natural and diverse aquatic and marine environments to properly design laboratory studies. Results from such studies are not extrapolatable to the natural situations and any conclusions derived from such studies must still be considered speculative. Fundamental scientifically-based data is lacking and, in its absence, the establishment of effluent standards for polychlorinated biphenyls cannot be made intelligently and responsibly.

In the establishment of the PCB effluent standard for freshwater systems a bioaccumulation factor of 200,000 was selected. This factor has no extrapolatable relationship to either the residues of PCB in salmon eggs or to PCB residues of fresh water forage fish. The only published report (27) of an accumulation factor of the magnitude selected was that for the hepatopancreas of the pink shrimp, Penaeus durarum. Even though an accumulation of 204,000 in the hepatopancreas has occurred a nearly complete elimination of PCB from that tissue was achieved when the shrimp were placed in water free of added PCB. The equilibrium whole body accumulation plateau indicated an approximate accumulation factor of 22,000. These results are in agreement with those reported by Stallings and Mayer (29), and with the studies of Ryther (28), Greichus et al (24) and Crump-Weisner, et al (22) showing equilibrium biomagnification factors between water and fish ranging between 1,000 and 75,000 depending on the presence and absence of sediment and the specific PCB mixture present. These data would support the selection of a factor considerably lower than the factors which were applied.

Arbitrary safety factors were applied to the tolerable chronic limit to establish the so-called "critical chronic limit" which was then used to compute the maximum allowable effluent. These safety factors were proposed to account for a multitude of variables, including non-point sources, multiple discharges and industrial growth. The safety factors proposed were identical for 7 of the 9 materials for which effluent standards were prepared. These safety factors, resulting in approximate two-fold reductions, are so small as to be of no beneficial toxicological consequence. We recommend that no safety factor be applied.

In establishing the effluent standards, an attempt was made to distinguish between types of receiving waters by classifying them as streams, lakes and impoundments, estuaries and coastal waters. We do not believe this attempt to distinguish water bodies is by any measure adequate. Water bodies are universally known to be complex systems with no two systems alike. With a complex material such as polychlorinated biphenyls, the determination of possible adverse effects in each water body becomes exceedingly difficult. The uniqueness of each water system at each point source must be considered.

A key parameter used to further describe the water body is the flow rate which was limited to the probable low rate of stream flow occurring during a seven-consecutive-day period once in ten years. We do not agree that this is realistic or appropriate. In our opinion, appropriate control is achieved using average stream flow rates.

Further, the maximum flow rate that can be used in calculating the daily discharge permitted has been arbitrarily set at 10,000 cubic feet per second. This limit is based on a nondegradation philosophy which tolerates limited diffusion and on a desire to discourage industry from locating facilities on large main inland waters and coastlines. This limitation deprives our society of the judicious use of an important great natural resource. Discharge limitations should be based on the effects a material will have on a water system, giving consideration to its size and flow rate. For PCBs, proper control will not occur by imposing maximum flow rate conditions, but by applying results from scientific studies which properly define how each water system responds to the presence of PCBs.

RESIDUAL POLYCHLORINATED BIPHENYLS

Because of their chemical and physical properties, PCBs can be found in soils and waters at point sources long after a discharge has occurred. This source of PCBs to the environment will diminish with time but its presence will distort and mask results from current control activities. To maintain control of losses, emphasis should be directed toward discharges resulting from current and future uses of PCBs.

Since this problem of background levels occurs with all materials in varying degrees, we propose the following revisions:

From Section 129.01c(b), delete the words "in intake waters for a discharger".

Add an additional definition in Section 129.01a:

" 'Background' means amounts of toxic pollutant (1) presently found in the waterways of the United States (including the intake waters of a discharger), or (2) arising out of operations subject to this Part that occurred before the effective date of this Part, but were not discharged to the waterways of the United States before the effective date of this Part."

ECONOMIC CONSIDERATIONS

At our PCB manufacturing facility, we developed and instituted an aggressive control program which we described before the Effluent Standards and Water Quality Information Advisory Committee, EPA (41). Yet, in spite of all our efforts, we cannot today meet the proposed effluent standard.

In response (42) to an inquiry from the U.S. Department of Commerce, we emphasized that technology has not been developed to the point that facilities could be designed to meet a reasonable standard. However, analytical techniques suggest a conceptual design using adsorption, settling and filtration of aqueous waste, followed by incineration of the adsorbent, probably carbon. We estimate the capital cost of such a facility, sized to handle our plant waste, at \$600,000, not including a dedicated incinerator for the disposal of the adsorbent material. Annual operating cost would approximate \$150,000.

The value of Monsanto's annual PCB production is about \$8 million, while the value of the electrical devices made therefrom is an order of magnitude larger. If Monsanto were to cease production of PCBs, the jobs of 55 employees would be eliminated directly, while those of an additional 47 employees in a supporting facility would be in jeopardy. The total payroll involved is on the order of \$1.5 million.

The impact of a PCB ban on our customers can best be described by them. However, it is apparent that capacitors or transformers made without PCBs will be less fire-resistant than present products, thus leading to an undeterminable incidence of fires, higher insurance rates, and additional protection facilities. In the case of capacitors, the replacements are likely to be larger and less efficient, thus consuming more of the resources required in their manufacture. A more complete

analysis of the consequences of a PCB ban was developed by the General Electric Company and addressed to Dr. Martha Sager, Chairman, Effluent Standards and Water Quality Advisory Committee, EPA (43). We concur with the General Electric Company's conclusions.

Our purpose in commenting on the proposed standards is to aid the Agency in the development of realistic effluent standards which will achieve the intended objectives without serious technical, social and economic disruptions. We recognize the seriousness of this endeavor and find a statement made by Mr. John R. Quarles, Jr., Deputy Administrator, Environmental Protection Agency, of considerable interest. At a recent conference, Mr. Quarles (26) stated:

"We have found it virtually impossible to devise intelligent standards which specify an appropriate degree of control over toxic pollutants irrespective of the sources of those pollutants and factors affecting the feasibility and timing of their abatement."

The difficulties which could be anticipated in establishing effluent standards were recognized by the National Academy of Science in its preparation of Water Quality Criteria, 1972. In a review which appeared in the Environmental Reporter (38) dated August 24, 1973, the following pertinent statements highlight some of the areas of concern:

"Knowledge of local environmental conditions is essential prior to application of any water quality recommendations for marine aquatic life and wildlife..."

"NAS said application of recommendations to a local situation is unique because it requires an understanding of the circulation of water and the resultant mixing and dilution of pollutants, a knowledge of biological species and determination of the most sensitive species, and an evaluation of the transport of materials through the food web."

"NAS said it is not practical to make recommendations for the relatively persistent organic pollutant based on water concentration, especially when partition coefficients are unknown."

We can appreciate Mr. Quarles' concern, particularly as it applies to PCBs. Lacking good scientific information on the fate and effects of PCBs in complex water systems each having unique characteristics, we urge extreme care be taken to avoid the promulgation of effluent standards which are unattainable and unwarranted.

W. B. Papageorge
W. B. Papageorge.

Subscribed and sworn to before me this 14th day of March 1974

Notary Public
Notary Public

My Commission expires July 18, 1975

CONFIDENTIAL

NEW YORK & LOCATION

W. B. Papageorge -- B2SK E. P. Wheeler-- A2SA

December 9, 1974

PCBs - Minutes of Meeting with
NIOSH - 11/22/74

H. S. Bergen
F. J. Fitzgerald
Robert Flint - 1740
D. B. Hosmer
Clarence Sweets

G. L. Bratsch
W. C. Engman -- 1740
G. F. Fort
R. E. Kelly
G. J. Levinskas
J. R. Savage

The meeting was held at the request of Joseph K. Wagoner, S. D. Hyg., Director, Division of Field Studies and Clinical Investigations (DFSCI), National Institute for Occupational Safety and Health (NIOSH). NIOSH reports to the Center for Disease Control (CDC) in the Department of Health, Education and Welfare (DHEW). The participants in the discussion are as shown in the attached list.

The original purpose was to explore whether Monsanto had a "suitable occupational group for study" to assess the potential chronic effects of PCBs. To be included were "PCB-exposed active and inactive workers at Monsanto in a planned retrospective cohort study." What this would involve is obtaining work histories of time spent in PCB departments, and medical records of active and still-living inactive employees.

The study would not be complete without examination of death records of those "PCB-exposed" employees who are deceased -- including those who expired while employed and those who expired after termination of employment because of retirement or for any other cause.

The proposed study was stimulated by a report from Dr. Kimbrough, Toxicologist, CDC, to NIOSH, that she had found an alarming rate of liver cancers in rats fed Aroclor 1260. Briefly, she found 15 of 180 female rats with "definite hepatic cell carcinoma" when fed Aroclor 1260 at 100 ppm in the diet for 22 months. Only one of 173 controls had the carcinoma. She then described a number of other liver tissue effects as "pre-cancerous lesions" and found these in 175 of the experimental rats and in only three of the controls.

Westinghouse Electric Corporation

FEB 6 1975

South Eastern Distribution Transformer Div.

Box 920
Highway 56 West
South Eastern Virginia 24592
(703) 575 7371

February 3, 1975

Dr. W. B. Papageorge
Manager Environmental Control
Monsanto Company
Organic Chemicals Division
800 North Linbergh Blvd.
St. Louis, Missouri 63166

Dear Dr. Papageorge:

Attached you will find a list of questions that have been asked by our employees regarding the use of Inerteen. Mr. Carry Wilburn, our Engineering Manager, felt if these questions could be answered you would be the man to answer them.

We have had, in the past, workplace meetings with our employees explaining proper use of Inerteen and telling them unless it is consumed, it presents no real danger to them.

In answering these questions, hopefully we will gain much needed knowledge on Inerteen and how to present it properly to our employees.

Thank you for your help.

Very truly yours,



Dan A. Albert
Staff Supervisor
Personnel Relations

cc: George Evisdos, Marvin Bowling

68RN 000026

1. Question: Does Inerteen have permanent effects on the human body? If so, what type of permanent damage and how long a period of time does it take for this to develop? If not, explain why, if possible.
2. Question: Several hourly employees have mentioned recently that many chemicals such as Inerteen cause sterilization after a prolonged use. Is this true?
3. Question: Since Inerteen affects birds and other animals, if there is no real effects to human beings, how do you explain it to employees in such a way that they will understand why it can kill a bird and not a human?
4. Question: If an employee spills Inerteen on his clothing and later takes the clothing home to be washed with other clothes, will this have any effect on he or his family and should he carry his clothes home to be washed?
5. Question: Employees carry Inerteen home on the soles of their shoes and complain quite a bit about the effect Inerteen has on wearing out their shoes. Is this a serious problem? Will Inerteen in the soles and leather of shoes, over a long period of time, have an effect on the feet and skin since the shoe is the only protective equipment we wear on our feet and the Inerteen penetrates through the leather.
6. Question: There is one employee in our plant who had no problem whatsoever with Inerteen years ago. After six years of using, now when he works in Inerteen (which is a part of his job) he develops a swelling on the inner bicep of his left arm, only in one location. Could this be from Inerteen or not? It goes away as soon as he gets out of the Inerteen. It is similar to the swelling after taking an injection.
7. Question: Are there hand cleaning solvent materials that we should be using when working in Inerteen to coat our skin before working in it and to wash it off after we finish working in it? Please give your recommendation. Our employees working in Inerteen are not able to use gloves since it is an assembly area. Even if they could, the Inerteen would destroy the protective glove.

Summary: If there are any questions we have not brought up that you are aware of, please include in your comments, or any other information you can give us concerning the proper use of Inerteen.

1. Xerox jilisc

GBRN 000027

Monsanto

SPECIALTY & PROCESS CHEMICALS DIVISION

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63168
Phone: (314) 884-1000

February 26, 1975

Mr. Dan A. Albert
Staff Supervisor
Personnel Relations
Westinghouse Electric Corporation
Box 290, Highway 59 West
South Boston, Virginia 24592

Dear Mr. Albert:

I have received your letter dated February 3 asking us to respond to a list of questions. Since these questions relate to human health considerations, I have asked our Medical Department to prepare the response. You should be hearing from us shortly, either from my office or from a representative of our Medical Department.

If I can be of further service please let me know.

Sincerely,



W. B. Papageorge
Manager, Product Acceptability
Specialty & Process Chemicals

WBP:pd

GBRN 000024

a unit of Monsanto Company

Monsanto

FROM (NAME & LOCATION)

W. B. Papageorge

St. Louis

B2SK

DATE

March 18, 1975

cc

C. Paton
E. P. Wheeler
D. Wood

SUBJECT

WESTINGHOUSE Inerteen

REFERENCE

TO : H. R. Ford - 1070

Attached is the original of a letter addressed to Mr. Dan A. Albert of Westinghouse, South Boston, Virginia. The contents of this letter have been reviewed with Dave Wood and it was agreed that the letter be delivered by you personally to South Boston, giving you an opportunity to discuss with the Westinghouse representatives the proper approach that must be taken in presenting this information to avoid undue concerns and misunderstandings. Will you please deliver this letter as soon as practical.

W. B. Papageorge / pd
W. B. Papageorge

/pd

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Monsanto

SPECIALTY & PROCESS CHEMICALS DIV.

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63188
Phone: (314) 884-1000

March 18, 1975

Mr. Dan A. Albert
Staff Supervisor
Personnel Relations
Westinghouse Electric Corporation
Highway 58 West
South Boston, Virginia 24592

Dear Mr. Albert:

Attached are responses to the questions listed in your letter dated February 3, 1975.

In addition to the industrial hygiene practices described in our responses to your questions, I cannot overemphasize the need to properly control the use and handling of Inerteens to prevent their escape into the environment. Also, in discussing this information with your employees, I strongly recommend that the perspective gained from over 40 years of experience in which no human harm has resulted, be emphasized. In summary, the proper handling of Inerteens should pose no environmental or human health problems, permitting society's continued use of a very valuable material.

I hope the above information is useful to you. If I can be of further service please let me know.

Sincerely,

W. B. Papageorge

W. B. Papageorge
Manager, Product Acceptability
Specialty & Process Chemicals

WBP:pd

a unit of Monsanto Company

GBRN 001641

1. Question: Does Inerteen have permanent effects on the human body? If so, what type of permanent damage and how long a period of time does it take for this to develop? If not, explain why, if possible.

The polychlorinated biphenyls in Inerteen can have permanent effects on the human body.

The length of time or period of exposure necessary to develop symptoms depends on the degree or amount of exposure. In general a single exposure for a few minutes to atmospheric concentrations that cause irritation to the eyes and/or respiratory tract would not be expected to cause either the skin eruptions or demonstrable liver injury. The problem arises from repeated and prolonged exposure to atmospheric concentrations in excess of the accepted Threshold Limit Levels or repeated and prolonged skin contact.

The polychlorinated biphenyls have not been recognized as skin "irritants" in the same sense that caustic materials or many organic chemicals are irritants. Because of their "solvent" action in removing the natural fats and oils from the skin, leaching, drying and chapping, repeated and prolonged skin contact should be avoided.

When the polychlorinated biphenyls are mixed with other chlorinated hydrocarbons, the mixture may be classified as a skin irritant.

The potential toxic effects in humans from excessive exposure to polychlorinated biphenyls include injury to the liver and chloracne. In animals, the liver effect is demonstrated by increased liver weights and injury to cellular tissue. Although chloracne is difficult to evaluate in animals, in humans, this takes the form of comedones (large blackheads with typical acute pustules) and may be an external symptom of over exposure preceding serious liver injury.

Animal data and human experience indicate that the toxic effects are similar whether exposure results from ingestion, inhalation of vapors, or absorption of the liquid material through the unbroken skin.

(See AIHA Hygienic Guide Series - "Chlorodiphenyls" attached.)

2. Question: Several hourly employees have mentioned recently that many chemicals such as Inerteen cause sterilization after prolonged use. Is this true?

There is no evidence that polychlorinated biphenyls cause "sterilization" in humans.

LSRN 001642

3. Question: Since Inerteen effects birds and other animals, if there is no real effects to human beings, how do you explain it to employees in such a way that they will understand why it can kill a bird and not a human?

There is a potential real effect to humans - including death - as discussed in the answer to Question 1.

Due to differences in metabolism of food (and food contaminants) in birds and humans (and particularly the difference in the reproduction process in birds and mammals - including humans), birds are particularly sensitive to many chlorinated hydrocarbons including polychlorinated biphenyls.

4. Question: If an employee spills Inerteen on his clothing and later takes the clothing home to be washed with other clothes, will this have any effect on he or his family and should he carry his clothes home to be washed?

There should not be any effect on an employee or his family from home laundering of work clothing. If washed with other clothing, there may be residual odor of the chlorinated hydrocarbons in the clothing.

5. Question: Employees carry Inerteen home on the soles of their shoes and complain quite a bit about the effect Inerteen has on wearing out their shoes. Is this a serious problem? Will Inerteen in the soles and leather of shoes, over a long period of time, have an effect on the feet and skin since the shoe is the only protective equipment we wear on our feet and the Inerteen penetrates through the leather.

There should not be polychlorinated biphenyl on the floor for workmen to contaminate their shoes to carry home. The plasticizer or solvent action will destroy or shorten the life of the shoes. More importantly, the wearing of contaminated shoes could lead to absorption of the liquid through the soles of the feet as through any other unbroken skin surface.

6. Question: There is one employee in our plant who had no problem whatsoever with Inerteen years ago. After six years of using, now when he works in Inerteen (which is a part of his job) he develops a swelling on the inner bicep of his left arm, only in one location. Could this be from Inerteen or not? It goes away as soon as he gets out of the Inerteen. It is similar to the swelling after taking an injection.

GBRN 001643

We do not believe there can be any association between "a swelling on the inner bicep" of the arm and exposure to polychlorinated biphenyls.

7. Question: Are there hand cleaning solvent materials that we should be using when working in Inerteen to coat our skin before working in it and to wash it off after we finish working in it? Please give your recommendation. Our employees working in Inerteen are not able to use gloves since it is an assembly area. Even if they could, the Inerteen would destroy the protective glove.

We assume the question refers to the use of "Barrier Creams" rather than a "hand cleaning solvent".

There are a number of barrier creams available to protect workers against water insoluble solvents. Probably the most effective include silicone "to provide an impenetrable shield". A problem with such creams is that they may offer a false sense of security.

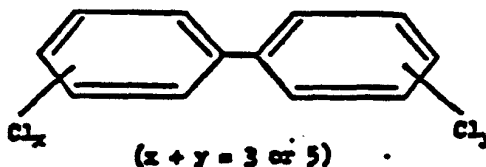
Proper use includes a discipline which requires liberal application at the beginning of a work shift and after each washing of the hands during the work day.

68RN 001044

HYGIENIC GUIDE SERIES

Chlorodiphenyls

(Containing 42% and 54% Chlorine)



Significant Physical Properties¹

The chlorodiphenyls are light straw-colored mobile (42% chlorinated) and viscous (54% chlorinated) liquids with typical chlorinated aromatic odors. These compounds are chlorinated to specific weights of chlorine. Chlorodiphenyl (42%) contains 42.0 ± 0.5 chlorine, an amount corresponding to three chlorine atoms in unassigned positions. Chlorodiphenyl (54%) contains 54.3% chlorine corresponding to five chlorine atoms in unassigned positions. Both compounds are insoluble in water, but soluble in benzene, hexane, acetone, amyl alcohol, ether and chloroform.

	Chlorodiphenyl (42%)	Chlorodiphenyl (54%)
Molecular weight:	247.53	326.45
Flash point (Cleveland O. C.):	176°-180°C (349°-336°F)	None
Distillation range:	325°-346°C	365°-390°C
Specific gravity:	1.381-1.392 (25°/15.5°C)	1.495-1.505 (65°/15.5°C)
Vapor pressure:		
0°C	0.001 mm	0.00006 mm
25°C	0.006 mm (est)	0.00054 mm (est)
150°C	4.5 mm	1.4 mm
200°C	29.0 mm	9.0 mm
At 25°C and 760 mm Hg:		
Saturated air contains	0.080 mg/liter	0.009 mg/liter
1 mg/liter =	98.3 ppm	74.9 ppm
1 ppm =	0.010 mg/liter	0.013 mg/liter

1. Hygienic Standards

A. RECOMMENDED MAXIMAL ATMOSPHERIC CONCENTRATIONS (8 hours): One milligram chlorodiphenyl (42%) per cubic meter of air and 0.5 milligrams chlorodiphenyl (54%) per cubic meter of air.² This is based on the results of

chronic animal inhalation studies.³

B. SHORT EXPOSURE TOLERANCE: Ten mg of a diphenyl of unspecified chlorine content per cubic meter of air has been reported as unbearably irritating.⁴

C. ATMOSPHERIC CONCENTRATION IMMEDIATELY HAZARDOUS TO LIFE: Not known for man. Irritation of the eyes, nose and throat at levels which have not caused acute illness preclude the likelihood of voluntary exposure to immediately hazardous concentrations.

¹The Committee wishes to acknowledge the preparation of the technical information portion of this Guide by the Industrial Hygiene and Chemical Toxicology Committee of I. M. A., and to acknowledge also the assistance of Esther S. Wheeler and Jack T. Garrett in the writing of this Guide.

GDRN 001045

II. Toxic Properties

A. INHALATION: Experiments with chlorodiphenyl (42% chlorine) were run at concentrations of 8.6 µg/liter and at 6.83 µg/liter of air. Cats, mice, rabbits and rats were unaffected by the higher level while guinea pigs showed poor growth after seventeen 7-hour/day exposures over 24 days. Eighty-four 7-hour/day exposures at the lower concentration had essentially no effect on similar species of animals.⁵

In the case of chlorodiphenyl (54% chlorine) eighty-three 7-hour/day exposures over 121 days to a concentration of 5.4 µg/liter resulted in injury to liver cells and increased liver weights in rats. At a concentration of 1.5 µg/liter for one hundred and fifty 7-hour/day exposures over 213 days, the rats showed distinct microscopic changes in the liver.⁶

The literature contains many references to the potential toxic effects of chlorinated diphenyls in man and animals. The early work included investigations of chlorinated naphthalenes, chlorinated diphenyls, chlorinated diphenyl oxide and various mixtures of these. An early report indicated serious toxic effects from chlorodiphenyl chlorinated to the extent of 65%.⁷ A later report by the principal author properly identified the earlier sample as a mixture of chlorinated diphenyl and chlorinated diphenyl benzene.⁸ However, only a few authors of subsequent papers, bulletins or textbooks have noted this correction and the original data are cited repeatedly as relating to chlorinated diphenyl alone.

B. SKIN CONTACT: Both compounds are readily absorbed through the clipped, intact skin of rabbits. The minimum lethal dose when the undiluted materials were applied to the covered clipped, intact skin of rabbits for 24 hours was approximately 1.0 gm/kg for the 42% chlorinated and 1.3 gm/kg for the 54% chlorinated.⁹

Local action on the skin is similar to that of common organic solvents where contact leads to removal of natural fats and oils with subsequent drying and cracking of the skin.

Human cases of chloracne have not been reported from the use of these two specific chlorodiphenyls. The potential undoubtedly exists because of cases which were reported from the use of chlorodiphenyls with a higher chlorine content and from mixtures with other chlorinated aromatic compounds.^{1,4,8}

C. EYE CONTACT: The liquid products and their vapors are moderately irritating to eye tissues.

D. INGESTION: The acute oral toxicities of the undiluted compounds are not great as evidenced by oral LD₅₀'s in rats of approximately 8.65 gm (7.61 to 9.78 gm) per kilogram for the 42% chlorinated and 11.9 gm (10.48 to 13.45 gm) per kilogram for the 54% chlorinated.⁹ Central atrophy of the liver appears to be the chief toxic effect.

III. Industrial Hygiene Practice

A. INDUSTRIAL USES: The chlorodiphenyls are used as dielectrics for condensers, capacitors and transformers, plasticizers in synthetic resins, in emulsion adhesives, as nonflammable hydraulic fluids and as transfer media.

B. EVALUATION OF EXPOSURES:

1. Air sampling and analysis:

a. Direct field methods: None

b. Laboratory methods:

(1) Collect in secondary butyl alcohol in fritted bubbler or two large impingers in series; concentrate sample and complete analysis by one of various methods for chlorinated hydrocarbons.⁴

(2) Sample air through combustion furnace, collect chloride ion from decomposed chlorodiphenyl in suitable alkaline solution and determine chloride ion concentration.⁹

C. HAZARDS AND THEIR RECOMMENDED CONTROL:

1. **Inhalation:** Absorption is chiefly by inhalation. Concentrations in the workroom atmosphere should be maintained below the recommended levels. Where the chlorinated diphenyls are used at room tempera-

tures, the hazard of inhalation is considered slight or absent. When these materials are subjected to elevated temperatures, the process either should be completely enclosed or other adequate mechanical exhaust ventilation must be provided to reduce concentrations to safe levels. In heat transfer media applications, the system must be designed and constructed so that it is leak-proof. Special gasket materials and pump seals are available to prevent leakage. The reservoir tank should be airtight except for a vent to the outdoors. In the event of spills or leaks of hot fluids, use chemical cartridge respirators or gas masks approved by the U. S. Bureau of Mines for protection against organic vapors. These will provide good protection up to the concentrations shown on the approval labels and the odor will give ample warning if it comes through the device.

2. **Skin contact:** Operations and handling procedures should be such as to avoid the possibility of prolonged or repeated skin contact. Contaminated clothing must be laundered before reuse.
3. **Eye contact:** Eye protection should be used where there is a possibility of liquid splashes.
4. **Ingestion:** Ingestion of these materials is not a problem in industry.
5. **Fire and explosion:** The chlorodiphenyls are fire-resistant or essentially nonflammable liquids. When exposed to flame or hot surfaces they may decompose to form CO, CO₂, HCl, phenolics and aldehydes depending on the temperature, availability of oxygen, area of the heated surface, rate of application of the liquid to the surface and other variables.

IV. Medical Information

- A. EMERGENCY TREATMENT:** Skin surfaces exposed to chlorodiphenyls should be thoroughly washed with soap and water at once. If clothing has been contaminated it should be removed promptly.
- If exposure to a high vapor concentration occurs, as in the case of spills at

elevated temperatures, the patient should be moved from exposure and kept at rest until seen by a physician. Oxygen should be administered if breathing is difficult.

Eyes contaminated with chlorodiphenyl should be irrigated with water for at least 15 minutes and the patient should be seen by a physician. Depending on the amount of inflammation and pain present, drugs like Cortisporin[®] ointment and topical Pontocaine[®] may be indicated.

- B. SPECIAL PROCEDURES:** Persons who are regularly or repeatedly exposed to chlorodiphenyls should be examined periodically to detect early evidence of skin irritation and/or liver damage. Persons with known liver disease should not be exposed to repeated contact with the chlorodiphenyls.

V. References

1. Monsanto Company, Organic Chemicals Division: *Tech. Bulletin # PL-306, Aroclor Plasticizers* (Dec. 1960).
2. American Conference of Governmental Industrial Hygienists: *Threshold Limit Values for 1964. AMA Arch. Environ. Health* 9: 545 (1964).
3. Treon, J. F., F. P. Cleveland, J. Cappel, and R. W. Atchley: *The Toxicity of the Vapors of Aroclor 1242 and Aroclor 1254. Amer. Ind. Hyg. Assoc. Quart.* 17: 204 (1956).
4. Elkins, H. B.: *The Chemistry of Industrial Toxicology*. John Wiley and Sons, Inc., New York (1959).
5. Drinker, C. K., M. F. Warren, and G. A. Bennett: *The Problem of Possible Systemic Effects from Certain Chlorinated Hydrocarbons. J. Ind. Hyg. Toxicol.* 19: 283 (1937).
6. Drinker, C. K.: *Further Observations on the Possible Systemic Toxicity of Certain of the Chlorinated Hydrocarbons. J. Ind. Hyg. Toxicol.* 21: 155 (1939).
7. Wheeler, E. P.: *Personal Communication, Monsanto Company, St. Louis, Missouri* 63166.
8. Greenburg, L., M. R. Mavers, and A. R. Smith: *The Systemic Effects Resulting from Exposure to Certain Chlorinated Hydrocarbons. J. Ind. Hyg. Toxicol.* 21: 29 (1939).

HYGIENIC GUIDES COMMITTEE

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Hygienic Guide sheets may be obtained from the AMERICAN INDUSTRIAL HYGIENE ASSOCIATION, 14125 Prevoist, Detroit 27, Michigan, at 25 cents each for two-page reprints; 30 cents each for four-page reprints. All orders for less than \$3.00 must be prepaid. Discount of 20% on orders of five or more Guides; 40% discount on orders of 100 or more Guides. Special sectional binders for the Guides may also be ordered from the Association office for \$1.25 each.

65RH 001646

April 18, 1975

Dr. George Roush, Jr.
Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63166

Dear George:

I fully appreciate that the meeting on PCB's today was not completely satisfactory and that many nagging questions remain. The enclosed is a brief summary of my personal views and I would appreciate any open and frank comments that you all may have.

Please let me know of any action that you contemplate in the way of seeking additional assistance in pathology or in contacting federal agencies. We will be pleased to be of help in any way that you may wish.

It is my feeling that we need to get together again within the next few weeks to continue our discussions.

Very truly yours,

J. C. Calandra
President

JCC:AR

cc - Dr. George Levinakas
Mr. Elmer Wheeler
Mr. William Papageorge

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1007-00

REVIEW OF PCB MEETING

. . The central issue in question is whether the PCB's are carcinogens or not. The long term studies conducted at BIO-TEST indicate that the answer is no. Drs. Ward Richter and Donovan Gordon are of this opinion which is shared by M. L. Keplinger and J. C. Calandra.

On the other hand, a study conducted by Dr. Renata Kimbrough presents evidence that in female rats of the Sherman strain, liver carcinomas were found. This is the only study in which this finding is reported in rats. BIO-TEST has no basis for refuting the findings of Kimbrough except to take exception to the design of the experiment that used only female rats and to point out that to our knowledge no one else has reported similar results in rats. It should be noted that the earlier allegation by Kimbrough that bladder cancers developed in female rats fed PCB was successfully counteracted by BIO-TEST and Monsanto personnel.

Kimura¹ worked with Kanechlor-400, a commercial brand of PCB and in a rat study of 400 days' duration concluded that "PCB's induced a benign neoplastic change, though it seemed to be still short of malignancy, and that the change appeared exclusively in the females." The author expressed concern that the benign nodules in the liver may progress to carcinomas if "specific or non-specific stimuli are introduced into the animal."

Ito² conducted a study in mice and found "hyperplastic nodules and well-differentiated hepatocellular carcinomas" at a dose level of 500 ppm of Kanechlor 500. Hepatocellular carcinomas were not induced by Kanechlor 300 and Kanechlor 400.

The evidence to date indicates that male rats are more resistant than females to the formation of nodular hyperplasia as well as hepatocellular carcinoma. Rats also are more resistant to the induction of these lesions than mice.

To return to the BIO-TEST studies on PCB, it should be noted that the liver sections which were read by the pathologists and reported in IBT No. 641-06672 and dated March 24, 1975, were not the same slides or sections as those reported on originally. The preserved livers were reprocessed by taking 4 "cuts" from different areas to obtain as large a representative sample as possible. It is not surprising that under these circumstances a different tabulation of the various primary liver lesions was found. Studies on thyroid hyperplasia and by Richter's associate, Dr. Stanley Vesselinovitch, have shown that this procedure generally results in a different qualitative and quantitative line-up of lesions that are reported by the same pathologist.

Ideally one would like to be able to reaffirm the original findings by this procedure, but this is not always possible because of the additional variables introduced. Serial sections of the liver would

eliminate some of the covariants. The important point in the most recent study of the sections is the fact that no hepatocellular carcinomas were found which is in agreement with the earlier findings. It must be emphasized that the diagnosis of "hepatoma" by Gordon and Richter connotes a benign process and must not be confused with the classical definition of the term by "human" pathologists.

Further, Dr. Squires reviewed a number of the same slides on Aroclor 1260 with Drs. Gordon, Levinskas, Kimbrough and Richter and agreed with the BIO-TEST pathologists that liver carcinomas were not present in the slides. In addition, the original slides have been in the possession of FDA since June, 1973 and to date we have not been informed of any disagreement with BIO-TEST findings.

Dr. Squires has stated in a letter to Dr. Kimbrough dated November 12, 1974, that "I define 'discrete nodules' and 'trabecular (basophilic) hyperplasia' as precancerous lesions and thus indicative of carcinogenic response." This reflects a viewpoint which is not shared by all pathologists and there is nothing that BIO-TEST can do to change this definition except for its pathologists to accept or reject the view. Drs. Richter and Gordon do not accept Dr. Squire's definition.

Workers in the field have published extensively on the pathogenesis of hepatocellular carcinoma in recent years and the concepts have undergone considerable changes since the preparation

of the final BIO-TEST report on chronic oral toxicity studies. One must note that Popper³ in his studies on Aramite in 1960 postulated that hyperplastic nodules were transformed into hepatocellular cancer; however, this concept was not generally accepted by the scientific community.

An excellent paper which describes "the highlights of some newer developments in our understanding of liver carcinogenesis" has been published by Farber.⁴ If the concepts presented in this paper as well as those of Squires, Saffiotti and others are accepted, a number of substances would have to be reclassified as liver carcinogens. Carried to extreme, we could argue that any substance that results in stimulation of liver microsomal enzymes or possesses hepatocytotoxic properties to any degree is a potential liver carcinogen.

BIO-TEST is unwilling to accept these concepts. The lesions seen in the livers of the rats in its PCB studies for Monsanto do not show vascular invasion, metastases or anaplasia - all classical features of carcinoma. We continue to view the lesions seen to be benign.

Several additional things need to be done by BIO-TEST and these include:

- (a) Re-examine the original liver slides.
- (b) Cut new sections at different levels from original paraffin blocks and read slides.
- (c) Tabulate liver findings separately in female and male rats.
- (d) If possible, develop information on the reversibility of the liver changes.

It is important to point out the following:

1. The BIO-TEST position was and remains that the PCB's were not shown to be liver carcinogens in its studies. This conclusion is the opinion of its resident pathologists as well as its independent consultant.

2. The BIO-TEST results show that a no-effect level for the development of hyperplastic nodules was found in each of its studies.

3. BIO-TEST has no means at its disposal to dispute the findings of Kimbrough that Aroclor 1260 in female Sherman rats is a liver carcinogen except on the basis of experimental design.

4. BIO-TEST is not in agreement with the classification by Squires et al. that considers hyperplastic liver nodules to be pre-cancerous.

5. BIO-TEST studies on PCB's meet the scientific standards of Toxicology and Pathology and we are prepared to assist Monsanto in any adversary situation in or out of government.

J. C. Calandra

April 18, 1975

References

- 1 Kimura, N. T. Gann 64:105 (1973).
- 2 Ito, N. J. Nat. Cancer Inst. 51:1637 (1973).
- 3 Popper, H. Cancer 13:1035 (1960).
- 4 Farber, E. Arch. Path. 98:145 (1974).

Monsanto

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63188
Phone: (314) 884-1000

July 18, 1975

Dr. J.C. Calandra
Industrial BIO-TEST Laboratories
1810 Frontage Rd.
Northbrook, Ill. 60062

re: AROCLOR 2-year Rat Feeding Studies

Dear Joe:

The attached table summarizes a comparison of the 3 revised AROCLOR reports (1242, 1254, 1250).

In 2 instances, the previous conclusion of "slightly tumorigenic" was changed to "does not appear to be carcinogenic". The latter phrase is preferable. May we request that the AROCLOR 1254 report be amended to say "does not appear to be carcinogenic".

The number of hepatomas reported for AROCLORS 1260 and 1242 have been interchanged. This appears to have arisen from confusion regarding the numbering of the animals. The original reports show tumors in animals with numbers in the 100-300 range for AROCLOR 1260 and in the 500 to 800 range for AROCLOR 1242. This leads me to conclude that the numbering scheme shown in the second set of reports is correct. With AROCLOR 1254 confusion is compounded. The original report showed tumors in animals with numbers in the units to teens, but the revised report shows animal numbers ranging from 40 to 1000. Can this be straightened out?

I was unable to reconcile the differences in the animal numbers between the first supplemental report and the original reports, I had inquired as to the changes in the numbers. As I recall, I was told that the sections had been renumbered when the new slides were made and that a key relating to the sets of numbers

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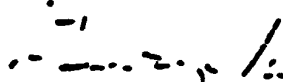
Dr. J.C. Calandra
July 18, 1975
Page - 2 -

would be supplied. This has not been done. It may not be necessary for AROCLORS 1260 and 1242, but AROCLOR 1254 remains unresolved.

Insofar as I can see, the remainder of the reports appear acceptable.

Kindest personal regards,

Sincerely,


George J. Levinskas, PhD
Mgr., Environmental Assessment
and Toxicology

/bkp

att.

cc: Dr. George Roush, Jr., M.D.

100738

-210

<u>Product</u>	<u>Supplemental Report #1 (mailed)</u>	<u>Supplemental Report #2 (JCC delivered)</u>
<u>AROCLOR 1260</u>		
conclusion	slightly tumorigenic	does not appear carcinogenic
hepatomas	3	7
range of test animal nos:		
p. 9	600 to 800	100 to 300
p. 10	1000 series	800 to 900
p. 11	70 to 100	10 to 40
p. 12	500 to 600	80 to 200
p. 13	600 to 700	200 to 300
p. 14	700 series	200 to 300
<u>AROCLOR 1254</u>		
conclusion	slightly tumorigenic	slightly tumorigenic
hepatomas	6	6
<u>AROCLOR 1242</u>		
conclusion	slightly tumorigenic	does not appear carcinogenic
hepatomas	7	3
range of test animal nos.	as in report #2 for AROCLOR 1260	as in report #1 AROCLOR 1260

August 4, 1975

Dr. George J. Levinstein, Manager
Environmental Assessment and Toxicology
Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63166

Dear George:

Re: Aroclor - 2 Year Rat Studies

In regard to the comments and questions covered in your letter dated July 18, 1975, pertaining to the above, please note the following:

1. We will amend our statement in the last paragraph on page 2 of the Aroclor 1254 report to read, "does not appear to be carcinogetic" in place of "slightly tumorigenic" as requested.

2. In regard to the animal numbers in the Aroclor 1242 and 1260 reports, they are correct in our final revised report. In the original reports, the Aroclor titles for these two materials were reversed.

3. The animal identification numbers appearing in the reports on evaluation of additional liver sections are the same as those in our original report. The animals were not renumbered.

4. We cannot find any discrepancy in animal identification numbers in the reports (original, re-evaluation, final revision) on Aroclor 1254. However, in the report on re-evaluation of additional liver sections dated March 24, 1975, there was a typographical error on page 1 which referred to Aroclor 1260 instead of 1254. Perhaps this is the basis of your confusion.

I hope that this will serve to further clarify the situation. Thank you for your assistance and cooperation.

Sincerely yours,

J. C. Calandra
President

212

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G 02138



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 17 1975

OFFICE OF ENFORCEMENT

**Monsanto Industrial Chemicals Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166**

OCT 22 1975

Gentlemen:

Recent governmental sampling data indicates the presence of Polychlorinated Biphenyls (PCBs) and comparable chemical substances in the air, in water bodies, and in fish in several areas of the country. In order to determine the nature and extent of the possible adverse effects resulting from the presence of PCB compounds in the environment, the Environmental Protection Agency (EPA), in cooperation with other federal and State agencies, is attempting to determine the sources and amounts of PCBs entering the environment. It is important that this effort be carried out without delay.

It is our understanding that your company handles PCB compounds or mixtures or comparable chemical substances in its operations. I am therefore requesting, pursuant to the authority provided by Section 308 of the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1318, and Section 114 of the Clean Air Act, as amended, 42 U.S.C. 1857c-9, that your company furnish EPA with information pertaining to your use and handling of PCBs and comparable chemical substances. In addition to a general description, which should include information as to sources, quantities, uses, and ultimate disposition, you should respond in detail to the enclosed questions. If any question is not applicable to your company or operations, please so indicate by responding "not applicable."

The information requested herein must be provided notwithstanding its possible characterization as confidential information or trade secrets. Should you so request, however, any information (other than effluent or emission data) which the Administrator of this Agency determines to constitute methods or processes entitled to protection as trade secrets will be maintained as confidential, pursuant to procedures specified in 40 CFR Part 3.

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Within 14 days of receipt of this letter, your company must provide all information concerning your current status and activities and covering the twelve month period immediately preceding receipt of this letter.

Within 30 days following receipt of this letter, your company must provide all information for all of the prior years indicated.

The information required herein should be sent directly to the address indicated below. If you have any questions you may call the person indicated below or Mr. Blake A. Miles of our office at (202)-755-4731.

We appreciate your prompt cooperation in this matter.

Sincerely yours,


Stanley W. Legro
Assistant Administrator
for Enforcement

Enclosure

Regional Contact: Mr. Earl J. Stephenson
Director, Enforcement Division
Environmental Protection Agency
1735 Baltimore
Kansas City, Missouri 64108
Telephone: (816) 374-2576

ADM 00629

POLYCHLORINATED BIPHENYL (PCB) COMPOUNDS OR MIXTURES

Within 14 days of receipt of this letter, your company must provide all information concerning your current status and activities and covering the twelve month period immediately preceding receipt of this letter.

Within 30 days following receipt of this letter, your company must provide all information for all of the prior years indicated.

FOR PURPOSES OF THIS LETTER, THE PHRASE "PCB COMPOUND OR MIXTURE" INCLUDES ALL CHEMICAL SUBSTANCES KNOWN OR BELIEVED BY YOU TO BE PCB COMPOUNDS OR MIXTURES OR OF A SIMILAR CHEMICAL NATURE, IRRESPECTIVE OF TRADE NAME, AND SPECIFICALLY INCLUDING CHLORINATED TERPHENYLS. *differe*

1. For each PCB compound or mixture produced or imported by your company, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

- a. The total amount of each PCB compound or mixture produced or imported. ✓
- b. The name and address of each of your company's facilities which handle PCB compounds or mixtures (including production facilities and wholesale and retail outlets), and the amount of each PCB compound or mixture distributed through each facility. *Sawyer + WMS. (perm)*
- c. The name and address of each customer of each PCB compound or mixture, the amount of each PCB compound or mixture obtained by each customer from each facility, and each customer's delivery point(s) for the receipt of each PCB compound or mixture. *Can do SLS. add*

2. For each PCB compound or mixture incorporated by your company into its products, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

- a. A description of each product.
- b. For each product the total amount incorporated of each PCB compound or mixture.

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2. (continued)

c. For each product the name and address of each source from which your company obtained each PCB compound or mixture, and the amount of each PCB compound or mixture obtained from each source.

d. The name and address of each of your company's facilities which handle such products (including production facilities and wholesale and retail outlets), and the amount of each product distributed through each facility.

e. The name and address of each customer of each product, and the amount of each product obtained by each customer from each facility. For consumer products list only the total production of each product at each facility and the total number of customers. Do not provide the name and address of each customer of consumer products.

3. For each PCB compound or mixture used by your company in its operations other than for incorporation into its products, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

a. A description of each use.

b. For each use the total amount of each PCB compound or mixture.

c. For each use the name and address of each source from which your company obtained each PCB compound or mixture, and the amount of each PCB compound or mixture obtained from each source.

4. For each PCB compound or mixture reclaimed by your company, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

a. A description of each method of reclamation.

b. For each method of reclamation, the total amount of each PCB compound or mixture reclaimed.

c. The total amount of each PCB compound or mixture reclaimed.

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--d. The name and address of each source from which your company obtained PCB compounds or mixtures, and the amount of each PCB compound or mixture obtained from each source.

e. For each method of reclamation, the location of every reclamation site, the name and address of each party involved in the reclamation of each PCB compound or mixture, and the amount of each PCB compound or mixture reclaimed by each party.

5. For each PCB compound or mixture disposed of by your company (with or without the involvement of other parties), for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

a. A description of each method of disposal.

b. For each method of disposal the total amount of each PCB compound or mixture disposed.

c. The total amount of each PCB compound or mixture disposed.

d. The name and address of each source from which your company obtained PCB compounds or mixtures, and the amount of each PCB compound or mixture obtained from each source.

e. For each method of disposal, the location of every disposal site, the name and address of each party involved in the disposal of each PCB compound or mixture, and the amount of each PCB compound or mixture disposed of by each party.

6. The composition by chemical name and percent by weight of each PCB compound or mixture produced, imported, sold, reclaimed, used, and/or disposed of by your company since January 1, 1971.

7. The results of any and all sampling and analysis performed by your company, its agents or contractors since January 1, 1971, concerning the following:

a. Concentrations of PCB compounds or mixtures in the effluent of any discharges by the company (into waters of the United States or Publicly Owned Treatment Works) or in the emissions of the company into the air.

*Koenig
Recd*

Difficult

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b. The flow and/or composition of any discharges or emissions by the company (into waters of the United States or Publicly Owned Treatment Works, or into the air) which contain PCB compounds or mixtures.

c. Concentrations of PCB compounds or mixtures in receiving waters (both upstream and downstream) of any discharges by the company which contain PCB compounds or mixtures and concentrations of PCB compounds or mixtures in the air in the area of the company.

8. The methods by which PCB compounds or mixtures are transported to, by, and/or from your company, including:

a. A description of each method of transportation, and the form in which PCB compounds or mixtures are transported by each method. Where different methods of transportation are used at different facilities specify which transportation method is used at each facility.

b. The names and addresses of all known transporters of PCB compounds or mixtures.

9. All occasions (including spills) of which you are aware on which PCB compounds or mixtures have or may have been introduced into the environment. In particular, describe such occasions insofar as they involved PCB compounds or mixtures in their liquid state, as incorporated into closed systems, or as incorporated into open systems. For each occasion, indicate name and address of party involved; dates, time, and location of the discharge or spill; and the amounts involved.

10. A description of any adverse health or environmental effects which you know or believe to have resulted from the introduction of PCB compounds or mixtures into the environment. Indicate any specific occasions including dates, times, locations, amounts, and parties involved for which such effects are known.

11. Any and all other information which you possess concerning:

a. The production, importation, reclamation, use, distribution, and disposal of PCB compounds or mixtures.

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b. The discharge of PCB compounds or mixtures into the environment.

In addition to the above, EPA would appreciate receiving any other information which you possess concerning the distribution and discharge of PCB compounds or mixtures by sources other than your company, including your company's customers and sources.

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Monsanto

FROM / NAME & LOCATION: David Wood-St. Louis-B25D

DATE: October 30, 1975 cc: f-EPA

SUBJECT: EPA

REFERENCE: COMMENTS ON EPA LETTER REC'D 10-17

TO: W. B. PapaGeorge
B25K

1. Bill, this seems to be a new version.
2. Page 1. Cl. Terphenyls specifically mentioned.
3. a) Production records answer 1(a).
b) Remember we warehoused PCBs for short period 1974 ahead labor contract renewal.
c) Question 1c raises a problem that has been at back of my mind. #2 report is supposed to show "ship to" address, but if this is case, why do 3rd party W/GZ shipments appear under "bill to" locations.
4. Q2 a) No problem
b) No problem
c) No problem
d) No problem
e) Policy - Hanley level?
5. Q3-No problem except 71/72
6. Q4-No reclamation.
7. Q5-a) No problem
b) Difficult. Can split Dielec/ET/Hydraulic
; But some returns mixtures of oil/PCB, etc.
c) Can do.
d) Difficult
e) Difficult
8. Q6 - Available
9. Q7 - a) Guess we have
b) Guess we have
c) Guess we have
10. Q8 - a) Bulk Rail
Bulk R - 3 accounts
Drum - Specify drum construction
b) E. M. Potter

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11. Q9 - Should answer from our activity?

12. Q10 - None? Rusho? Clarence years ago - Dangerous Question.

13. Q11 - a) Might get HUB again?

b) Should write this one very carefully - can make some positive points in this section.

David Wood

/deb

ADM 006289