DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH
U.S. POST OFFICE AND COURTHOUSE
CINCINNATI, OHIO 45202

November 12, 1976

Mr. W. R. Papageorge
Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63166

Dear Mr. Papageorge:

It is a pleasure to confirm your appointment as a review consultant for our draft criteria document concerning occupational exposure to polychlorinated biphenyls. Thank you for agreeing to serve as a member of this group.

Enclosed is a copy of the draft polychlorinated biphenyl criteria document. Answers to the questions on the document and general comments on specific recommendations would be appreciated. If possible, we would like to have your comments prior to but no later than the review meeting scheduled for 9:00 a.m., Room B38, Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio on November 30, 1976. Air mail, special delivery envelopes addressed to Dr. Jerry M. Johnson, Acting Chief, Criteria Documentation Section 1 in Cincinnati are enclosed for your convenience in returning your comments and answers to the questions.

Any changes, additions, or deletions which you may recommend should be supported by data available for public inspection. Any statement based on information that is unavailable to the public cannot be included in the document. This applies to the present draft as well as any recommended changes, you should keep this in mind throughout your review. Your comments, along with those received from other consultants and reviewers, will accompany the final document to the Department of Labor for consideration along with the National Institute for Occupational Safety and Health recommendations. NIOSH recommendations will not necessarily be a consensus of all consultants and reviewers.

Draft criteria documents are provided only for your use as a NIOSH consultant. The document in its present form does not constitute an official NIOSH position. Please do not reproduce the document or distribute it to others as representing an official document or policy prior to final approval.

PCB-ARCH0746015

For your convenience in making travel arrangements, information on the location of the Taft Laboratories and local motels has been enclosed.

John Fajen is serving as criteria manager for the polychlorinated biphenyl document. If there are any questions, please contact him at 513-684-8207.

Thank you for your time and interest in the development of this document.

Sincerely yours,

Vernon E. Rose
Director, Division of
Criteria Documentation and
Standards Development

Enclosures

POLYCHLORINATED BIPHENYL EXTERNAL REVIEW QUESTIONS

1. Do you agree that the document properly identifies the critical effect(s) of PCBs on the health of the worker?

2. From your review of Chapter III, what do you identify as the critical health effect(s) of polychlorinated biphenyls (PCBs) that the standard must protect against?

3. Does the development of the recommended environmental standard in Chapter V arrive at a logical conclusion?

4. The environmental limit recommended in this document is a time-weighted average, for up to a 10-hour workday, 40 hour workweek of 0.05 mg/cu m of polychlorinated biphenyl.

   a. Do the data support this environmental limit?

   b. If observed, will this standard protect the worker from all acute and chronic adverse effects of PCB exposure?

   c. Is the recommended standard adequate protection for the pregnant worker?

   d. If you recommend a higher or lower limit, please specify and briefly discuss your recommendation.

5. Do you know of any uses of PCBs where it would not be feasible to comply with the proposed standard? If so, please supply the information.

6. The document excludes biological monitoring. Do you agree with this exclusion?

7. How would you analyse worker exposure to PCBs when the composition of the PCB is unknown?

8 The sampling procedures (Appendix I) call for collection with Florisil tubes. Is this the most satisfactory sampling method? If not, what sampling procedure do you recommend?

9. Are the instructions for calibration of equipment and the collection of samples appropriate? If not, what deficiencies should be corrected?

10. The recommended analytical method calls for analysis by gas chromatography with an electron capture detector after desorption with hexane.

   a. Is this the most satisfactory analytical method? If not, what method of analysis do you recommend?

PCB-ARCH0746017

b. Are the instructions for the analytical procedures adequate as written? If not, what deficiencies should be corrected?

11. The medical provisions require preplacement and annual medical examinations with attention directed toward neurologic and liver function and skin condition.

a. Is the annual frequency appropriate? If not what frequency do you recommend?

b. Should the requirement for medical examinations be made more specific? If so, what would you recommend?

12. The document requires that all areas where exposure to polychlorinated biphenyl occur shall be posted with a warning sign. Does the sign include all necessary information? If not, what do you recommed be added?

13. Table I-1 establishes concentration limits below which different types of respirators may be used. Are these limits appropriate?

14. Are the provisions in Section 4 for protective clothing and equipment sufficient? If not, what additions do you recommend?

15. What requirement, if any, are needed in addition to those in the document for informing the employee of the hazards associated with occupational exposure to polychlorinated biphenyls?

16. Are the work practices and control procedures outlined in Section 6 adequate, or do you recommend additional general or specific procedures? If so, please specify.

17. Records of environmental monitoring are to be maintained for at least 20 years after an individual's employment is terminated. Do you agree that these records should be maintained for this length of time? If not, what do you recommend?

18. What area of research is needed in the field of PCBs?

19. Are you aware of any publicly available information, or information which could be made public, which may have a bearing on the development of this criteria document and recommended standard but which has not been considered here? If so, please identify it and briefly indicate the area of relevance.

POLYCHLORINATED BIPHENYL EXTERNAL REVIEW QUESTIONS

1. The document inadequately documents industrial exposure related effects of PCB. It also inadequately defines clinical tests which could be used to monitor for potential adverse effects of PCB exposure among the industrial population. The document dwells at great length upon the effects observed in a population of Japanese citizens who were accidentally exposed to an acute dose of PCB in a cooking oil. No relation is established between this accidental acute oral exposure to a relatively high concentration of PCB and industrial type exposures. No relationship is established defining relative body burdens resulting from acute oral exposure versus other routes of exposure, dermal absorption and respiratory, that are more likely to occur in an industrial environment. Another study given seemingly unwarranted consideration, involved an unpublished report of an epidemiological study conducted among a group of research workers with some unknown previous exposure to PCB. No sound basis has been established to support the contention that PCBs are human carcinogens. It is suggested that efforts be extended to accurately assess the clinical health of U.S. workers exposed to PCB.

2. In studies with rodents and subhuman primates the most sensitive target organ was usually found to be the liver. In these studies the dietary level which did not produce an effect on the liver was between 1 and 10 ppm. Based upon these studies the most probable toxic effect of excessive PCB exposure would be chronic hepatic injury.

3. From the manner in which the document is put together it is impossible to tell if the recommended standard is based upon a logical scientific extrapolation of the information cited. Specifically, no attempt is made to relate the body burdens which would result from an industrial inhalation or dermal exposure to those obtained from animal experimentation or the usual data following oral administration.

   Chapter V consists of a series of data relating the toxic effects observed after many different types or routes of exposure. It then states that on the basis of all this data the environmental limit should be 0.05 mg/M^3 of PCBs in air. There is no logical support for the stated limit as based on the industrial usage this document is intended to relate. There has been no evidence shown to indicate that, as inferred on lines 4071-4072, "teratogenicity, fetotoxicity and carcinogenicity has occurred to man and to laboratory animals when they have been subjected to air-borne PCB levels below the current standard of 1.0 mg/M^3 (42% chlorine)."

4a. To be supportable a standard must be based on the application of a safety factor to experimental animal data and/or upon the utilization of previous work history exposure concentration and clinical worker monitoring data. Which of these was used in establishing this standard is not clear. Specifically, the limit of 0.05 mg/M^3 has not been supported by any data relating industrial worker exposure to clinical effects. In fact, the arrival of 0.05 mg/M^3 as a "safe" level has not been explained at all.

b. The document on line 3929 states that the current PCB standard is based on an 8-hour dermal exposure. This is not entirely correct.

PCB-ARCH0746019

The current standard does include a "skin notation" which refers to the potential contribution to the overall exposure by cutaneous route or particularly by direct skin contact. An environmental limit for air-borne material cannot totally prevent direct skin contact with material and the resulting dermal exposure. This concern has been aptly addressed by the ACGIH TLV committee on line 3925 by their reference to the fact that the current standard may not guarantee protection against dermal effects. The recommended environmental limit cannot guarantee such also since workers can still put unprotected hands in the material if they wish.

c. Inadequate information exists to properly evaluate the need for and type of protection for the pregnant worker.

d. Until better scientific evidence is brought forth supporting a necessary change in the current OSHA standard on PCBs, no justification exists for modifying the existing environment limit.

5. We recommend that the current users of PCBs, capacitor and transformer manufacturers, be consulted regarding feasibility of compliance.

6. To exclude biological monitoring in a standard for a material known to accumulate in fatty tissues would not appear advisable.

Biologic testing is an acceptable monitoring device if it is shown that a reasonable correlation exists between body burden, detrimental health effects, and degree of worker exposure. Biological monitoring may well give an indication of dermal exposure and degree of skin absorption that might not be evident through the use of air monitoring.

7. We assume that if the composition of PCBs is unknown, the sample chromatogram does not match the chromatogram of any commercial PCB standard mixture. In this case, measurement by electron capture gas chromatography is inadequate for two reasons. First, interferences may be present which may account for the differences in the chromatograms. Secondly, as pointed out in Table I of the draft, electron capture detector response varies by orders of magnitude for different PCB isomers. Hence, the analyst would not know what response factor to apply, even using the weight factor technique of Webb & McCall (see attached comments for line 5354).

Therefore, when the PCB composition is unknown, a more specific and accurate technique must be used. We recommend using GC/MS in the selected ion monitoring mode as the detector device. The parent ion and a characteristic fragment ion are monitored for each PCB homolog. This technique is much less subject to interferences and is more accurate because MS response factors are nearly constant. GC/MS detection can be used with samples collected on Florisil if sensitivity is adequate. If sensitivity is inadequate, samples should be collected on a porous polymer sorbent such as Tenax GC. Collected components are then thermally desorbed directly into the GC/MS for analysis.

8. In those cases where the sample chromatogram matches a standard PCB chromatogram, the sampling procedure is adequate. However, as mentioned in 7., we recommend sampling with Tenax GC as a more general method. Collected components can be thermally or solvent desorbed from Tenax GC. For further details, see pp 147-160 of the transcript of the Second NIOSH Solid Sorbents Roundtable in December, 1973.

PCB-ARCH0746020

9. No, several deficiencies should be corrected. See attached comments relative to lines 5252, 5253, 5258, 5273, 5291, 5292, 5303, 5310, and 5320 of the draft.

10a. We recommend collection on Tenax GC adsorbent, thermal desorption and measurement by GC/MS. See 7., 8., and attached notes.

b. See attached comments, especially the notes relevant to lines 5354, 5381, 5396, 5410, 5460, 5533, and 5590 of the draft.

11a. Annual comprehensive medical examinations are considered appropriate.

b. The medical requirements listed in the document under Section 2 are patterned after the criteria document on Tetrachloroethylene. It would seem that the medical tests for PCB exposured workers could be more specific for that particular material. Pulmanary function tests should be included as a check on capability of wearing respiratory protective devices.

Contrary to lines 202-203, medical surveillance should be made available to all workers occupationally "exposured" to PCBs who contact the material and yet not be "exposed" on the basis of the NIOSH definition given on lines 176-177.

12. There is no persuasive evidence supporting the "cancer suspect agent" labelling all PCBs, therefore such labelling is inappropriate. Warning signs should be posted in those areas in which workers are exposed above some specified limit or where potential skin contact is possible. To be functional a warning sign must inform the reader of specific effects of a material. PCBs have relatively mild irritant properties and has not been associated with acutely toxic effects. However, tissue accumulation and target organ effects may occur following prolonged exposures above the established permissible limits. A meaningful sign would warn of potential tissue PCB accumulation and indicate avoidance of skin and eye contact.

13. Considering that the concentration limits as listed in Table I-1 represent the protection factors as shown below, the limits are considered to be appropriate and consistent with the respirator decision logic used in the Standards Completion Project.

Along with the protection factor limits are listed various additional respirator types which should provide adequate protection when used in areas of respective air contaminant concentrations.

Concentrations of Polychlorinated Biphenyls	Respirator Type (Modifications to Table)
0.5 mg/M^3 or Less (10x)	3. Chemical cartridge respirator with replaceable cartridges approved for organic vapors and mists and half-mask facepiece. 4. Gas mask, chin-style or front or back mounted organic vapor and mist cannister.

PCB-ARCH0746021

Concentrations of Polychlorinated Biphenyls cont'd.	Respirator Type (Modifications to Table) cont'd.
2.5 mg/M^3 or Less (50x)	3. A gas mask with a full facepiece and front or back mounted vapor cannister with high efficiency filter.
5.0 mg/M^3 or Less (100x)	(No modification)
Greater than 5.0 mg/M^3 (100x)	(No modification)

14. Line 292: Detectable level is mentioned. Since the detectable limit of PCBs has not been addressed, this level is meaningless. It would make more sense to reduce air-borne concentrations of PCBs to below the (TWA) environmental limit or permissible exposure limit.

Lines 379 through 382 should be deleted since it seems unnecessary to have escape type devices available in all areas of "potential" exposure where the exposures might be brief at low or moderate levels. Escape type devices are generally made available in defined high risk areas containing potentially hazardous operations involving extremely toxic substances. The document does not provide data which supports PCBs as being considered extremely toxic.

Earlier comments addressed the modifications in Table I-1 on respirator types vs. concentration limits.

15. Line 405: Do hazards imply only health related hazards or environmental hazards also?

In general, Section 5 provides adequate avenues for communicating work hazards to workers.

16. The work practices and control procedures are considered adequate for the protection of workers.

17. The recommended record retention period appears to be appropriate.

18. Additional research is needed in the following areas:

a. Comparative data on the PCB body burden resulting from oral, dermal and inhalation exposures.

b. Comparative metabolism studies of an homologous series in humans, non-human primates and rodents. These studies should include both a characterization of the metabolites formed and kinetic studies to determine the rates of mobilization and excretion.

c. Clinical evaluation including liver function tests on industrial populations with previously documented PCB exposure.

d. Epidemiological studies on major populations of PCB-exposed workers.

19. Attached is a report compiled by Monsanto and distributed in November, 1975 to representatives of concerned governmental agencies, (NIOSH, OSHA, EPA, FDA, NCI, NIH) relating to histopathological evaluation of livers from rats treated with PCBs.

PCB-ARCH0746022