National Toxicology Program
Board of Scientific Counselors
Technical Reports Review Subcommittee

December 9, 2004

NIEHS, Research Triangle Park, NC

Summary Minutes

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Attendees

Members:
Mary Anna Thrall (chair)
Diane Birt
Kim Boekelheide
Michael Elwell
Thomas Gasiewicz
James Klaunig
Stephen Roberts
Richard Storer
Mary Vore
Cheryl Lyn Walker

Members Absent:
Larry Andrews
John Giesy, Jr.
Shuk-Mei Ho
Charlene McQueen
Walter Piegorsch

NIEHS Attendees:
John Bucher
Rajendra Chhabra
June Dunnick
Veronica Godfrey
James Hailey
Ronald Herbert
Georgette Hill
Michelle Hooth
Richard Irwin
C. W. Jameson
David Malarkey
Robert Maronpot
Ronald Melnick
Abraham Nyska
Gail Pearse
John Peckham
Joseph Roycroft
William Schrader
Cynthia Smith
Barbara Shane
Fernando Suarez
Molly Vallant
Kristine Witt
Mary Wolfe
Nigel Walker

Agency Attendees:
William Allaben, FDA
Mike DeNito, EPA
Julian Leahy, FDA
Mark Toraason, NIOSH

Transcriptionist:
Kay McGovern

Public Attendees:
Amy Brix, EPL Inc.
Byron Butterworth, Butterworth Consulting
Charles Capen, Ohio State University
Vincent Cogliano, WHO
Dan Deardorft, International Paper
Michael Easterling, Constella Group
Reshan Fernando, RTI
Yo-Chan Jeong, University of North Carolina at Chapel Hill
Jon Lodge, RTI
Jessica Matthews, Constella Group
Gene McConnell, ToxPath
Rodney Miller, EPL Inc.
John Schell, BBL Sciences
Chris Widrig, Airepel
Gabrielle Wilson, EPL Inc.
Michael Wyde, Dynamac

Peer Review Meeting- December 9, 2004

The meeting began at 8:30 a.m. on December 9, 2004, in the Rodbell Conference Center of the David P. Rall Building, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina.

Dr. Nigel Walker, NIEHS, described the concept of the Toxic Equivalency Factor (TEF) evaluation of dioxin-like compounds (dioxins, PCB's and furans) and the background, design, and goals of a series of NTP studies of some representative dioxin-like chemicals and mixtures of chemicals. Four reports in that series were presented at the previous peer review meeting and Dr. N. Walker summarized the design and results of those studies on 2,3,7,8-tetrachlorobenzo-*p*-dioxin (TCDD), 3,3',4,4',5-pentachlorobiphenyl (PCB 126), 2,3,4,7,8-pentachlorodibenzofuran (PeCDF), and on a mixture of those three compounds. He described development of dose-response models for various endpoints using these results. Three more reports in this series were presented at the current peer review.

3,3',4,4',5-Pentachlorobiphenyl (PCB 126) and 2,3',4,4',5-Pentachlorobiphenyl (PCB 118)

Dr. N. Walker introduced the toxicology and carcinogenesis studies of a binary mixture of PCB 126 and PCB 118 by explaining that the study was originally designed to study PCB 118 alone. However, during the course of the study, analyses revealed the presence of 0.622% of the much more potent PCB 126. The study was continued as a mixture study because humans are exposed to both PCB congeners. The proposed conclusions were:

> Under the conditions of this 2-year gavage study there was *clear evidence of carcinogenic activity* of the mixture of PCB 126 and PCB 118 in female

> Harlan Sprague-Dawley rats based on increased incidences of cholangiocarcinoma and hepatocellular neoplasms (predominantly adenomas) of the liver, and cystic keratinizing epithelioma of the lung. The marginally increased incidences of gingival squamous cell carcinoma of the oral mucosa were also considered to be related to administration of the mixture of PCB 126 and 118. Occurrences of cholangioma and hepatocholangioma of the liver may have been related to administration of the mixture of PCB 126 and PCB 118.
>
> Administration of the mixture of PCB 126 and PCB 118 caused increased incidences of nonneoplastic lesions in the liver, lung, oral mucosa, thymus, thyroid gland, adrenal cortex, pancreas, kidney, heart, lymph nodes, mesenteric artery, brain, forestomach, spleen, and nose.

Dr. Stephen Roberts, the first principal reviewer, agreed in principle with the proposed conclusions, except he felt the hepatocellular lesions should be identified only as adenomas, since one carcinoma was seen in all the groups.

Dr. Kim Boekelheide, the second principal reviewer, also agreed with the proposed conclusions.

Dr. Michael Elwell, the third principal reviewer, inquired if the transplantation studies would be added to the final version of the report. No specific answer was given to this inquiry. Dr. James Hailey said the changes recommended by the committee would be included in the final report.

Dr. Roberts moved that the conclusions be accepted as written. Dr. Boekelheide seconded the motion, which was approved unanimously with nine yes votes.

2,2',4,4',5,5'-Hexachlorobiphenyl (PCB 153)

Dr. N. Walker introduced the toxicology and carcinogenesis study of PCB 153 by noting it is the most prevalent PCB congener. He said the TEF evaluation series also included studies of PCB 126 and a mixture of PCB 126 and PCB 153 to evaluate potential interactions. He described the study design, the biochemical responses to the chemical, and the occurrence of a few cholangiomas in exposed animals. The proposed conclusions were:

> Under the conclusion of this 2-year gavage study there was *equivocal evidence of carcinogenic activity* of PCB 153 in female Harlan Sprague-Dawley rats based on the occurrences of cholangiomas of the liver.
>
> PCB 153 administration caused increased incidences of nonneoplastic lesions of the liver, thyroid gland, ovary, oviduct, and uterus in female rats.

Dr. James Klaunig, the first principal reviewer, said the conduct and interpretation of the study were proper. He inquired if cholangiofibrosis might be a possible precursor lesion to the cholangiomas.

Dr. Thomas Gasiewicz, the second principal reviewer, agreed with the proposed conclusions. He noted how cholangiolar rather than hepatocellular lesions were the predominant liver effect in this set of studies.

Dr. Cheryl Walker, the third principal reviewer, said the report was well written. She inquired if the changes in hepatic cell proliferation were significant.

Dr. N. Walker replied that the measures of cell proliferation often give skewed results but that overall no significant effects were noted. He agreed that a number of cholangiomas were seen in this series of studies and speculated that different strains of Sprague-Dawley rats might respond differently. He added that cholangiofibrosis was not a precursor lesion to cholangioma.

Dr. Klaunig moved that the conclusion be accepted as written. Dr. Gasiewicz seconded the motion, which was approved unanimously with nine yes votes.

3,3',4,4',5-Pentachlorobiphenyl (PCB 126) and 2,2',4,4',5,5'-Hexachlorobiphenyl (PCB 153)

Dr. N. Walker introduced the study on a binary mixture of PCB 126 and PCB 153 by noting that PCB 126 is the most abundant of the coplanar dioxin-like compounds and PCB 153 is the most abundant of the non-dioxin-like PCBs. Part of the study rationale was to examine for any interactive effect for the different types of PCBs. He described the study design, consisting of one group of animal that received increasing doses of both compounds in a fixed ratio, and another group that received the same amount of PCB 126 with varying amounts of PCB 153. The proposed study conclusions, based only on the first set of animal groups, were:

> Under the conditions of this 2-year gavage study there was *clear evidence of carcinogenic activity* of a constant ratio binary mixture of PCB 126 and PCB 153 in female Harlan Sprague-Dawley rats based on increased incidences of cholangiocarcinoma, hepatocholangioma, and hepatocellular neoplasms (predominantly hepatocellular adenomas) of the liver, squamous neoplasms of the lung (cystic keratinizing epithelioma and squamous cell carcinoma), and gingival squamous cell carcinoma of the oral mucosa. Increased incidences of pancreatic acinar neoplasms were also considered to be related to administration of the binary mixture of PCB 126 and PCB 153. The increased incidences of uterine squamous cell carcinoma may have been related to administration of the binary mixture of PCB 126 and PCB 153.

> Administration of the binary mixture of PCB 126 and PCB 153 caused increased incidences of nonneoplastic lesions in the liver, lung, oral mucosa, pancreas, adrenal cortex, thyroid gland, thymus, kidney, nose, forestomach, and mandibular lymph node.

Dr. Elwell, the first principal reviewer, said the study was well designed and well presented and included a number of supplemental mechanistic studies.

Dr. Richard Storer, the second principal reviewer, commented on the wealth of detail contained in the report. He inquired if a second set of conclusions would be given for the varying ratio set of mixtures and suggested that cholangiocarcinomas be added to the list of effects of the interactions between the two PCBs.

Dr. Gasiewicz, the third principal reviewer, suggested that results from the other TEF studies be included in the report for comparison.

Dr. N. Walker explained that coming to a conclusion for the PCB 126/PCB 153 varying ratio combination would require examining the result for both chemicals individually, and that drawing conclusions about potential interactions could entail policy considerations beyond the purview of these reports. He added that summarizing all the findings for the several TEF studies as cross-references in each report could make the reports unwieldy. A separate report analyzing and comparing the effects from all the studies in the TEF series will be produced once all studies are completed.

Dr. Boekelheide noted that a number of endocrine-related tumors seemed to be affected by high doses or by varying dose ratios. He suggested that the nomenclature of the binary mixture be footnoted to clarify the distinction between the constant ratio and varying ratio dose groups.

The proposed conclusions were projected on a screen. Dr. C. Walker moved and Dr. Mary Vore seconded that the panel edit the conclusions. Dr. Boekelheide suggested that the parenthetical description of hepatocellular neoplasms be changed to "predominantly adenomas." For the lung lesions, he proposed removing squamous cell carcinoma and adding "predominantly" before the cystic keratinizing epithelioma. Dr. Klaunig suggested including the term "constant ratio" before the term binary mixture to specify the groups on which conclusions are being drawn. The modified conclusions to the first paragraph follow:

> Under the conditions of this 2-year gavage study there was *clear evidence of carcinogenic activity* of a constant ratio binary mixture of PCB 126 and PCB 153 in female Harlan Sprague-Dawley rats based on increased incidences of cholangiocarcinoma, hepatocholangioma, and hepatocellular neoplasms (predominantly adenomas) of the liver, squamous neoplasms of the lung (predominantly cystic keratinizing epithelioma), and gingival squamous cell carcinoma of the oral mucosa. Increased incidences of

pancreatic acinar neoplasms were also considered to be related to administration of the constant ratio binary mixture of PCB 126 and PCB 153. The increased incidences of uterine squamous cell carcinoma may have been related to administration of the binary mixture of PCB 126 and PCB 153.

Dr. Gasiewicz moved and Dr. Elwell seconded that the conclusions be accepted as edited. The motion was approved unanimously with nine yes votes.

Anthraquinone and Impurities in NTP Test Materials

Dr. John Bucher, NIEHS, provided a background review of the NTP studies on anthraquinone, which had been presented for review and approved by the peer review committee in 1999. Thereafter, the NTP received suggestions that a mutagenic contaminant might have affected the study results. The NTP performed a number of other studies to characterize the mutagenicity of potential contaminants and metabolites and presented the results to the peer review committee in February 2004. The conclusions were again accepted, but the panel recommended the test material be called "anthracene-derived anthraquinone" in the title and the following statement be added to the abstract "The term anthraquinone used in this report refers to anthracene-derived anthraquinone". The NTP also undertook to determine more precisely the identity of the trace contaminants in the original test material and also whether the original material was in fact mutagenic.

Following the February 2004 peer review, public comments indicating confusion caused by the proposed title change were discussed by the full NTP Board of Scientific Counselors at its meeting on June 29, 2004, who recommended the issue be revisited by this Technical Report Review Subcommittee.

Dr. Roberts summarized the discussion by the NTP Board of Scientific Counselors, who saw two possible implications to the qualifier being added to the title. One is that it could serve as an alert to the reader to examine the literature more broadly; however, a second interpretation is that the technical report's findings pertain only to anthraquinone from one source. Although the subcommittee intended for the qualifier in the report's title to alert the reader, it appears some manufacturers are promoting that the findings only pertain to anthraquinone produced by this specific method.

Dr. Cynthia Smith, NIEHS, said the long-time practice for the analysis of test materials is to identify all impurities greater than 1% of the major component and to note the presence of any impurity greater than 0.1%. In the original analysis of the anthraquinone test material, the purity was assessed to be 99.9%. In subsequent recharacterizations, quantitation with authentic standards involved subfractionation with high performance liquid chromatography (HPLC) and identification by gas chromatography (GC) and HPLC/mass spectroscopy. Four impurities were identified: 9-nitroanthracene,

anthracene, phenanthrene, and anthrone. By GC, using flame ionization detection, the overall purity was 99.85% and by HPLC/UV it was 99.83%.

Dr. Klaunig asked if the samples assayed were the original test material and if any sample degradation might have occurred during the interval. Dr. Smith replied that the sample assayed was the same material used in the animal studies and it was stored frozen under argon, so degradation is unlikely. See Erratum

Dr. Richard Irwin, NIEHS, presented the results of mutagenicity tests of purified anthraquinone, anthraquinone produced by methods other than the one used to synthesize the anthraquinone used in the studies, metabolites of anthraquinone, and the original test material. Some of the data were presented in February 2004; one new finding is that the original sample used in the animal studies was negative for mutagenicity in a variety of *Salmonella* test strains, both with and without metabolic activation. Also, one sample of anthraquinone produced by the Diels-Alder synthetic process was mutagenic under some conditions. Dr. Irwin also noted that 2-hydroxyanthraquinone, a major metabolite of anthraquinone regardless of the method of manufacture, was several fold more mutagenic than 9-nitroanthracene, a minor impurity. The formation of this metabolite in the liver and its elimination in the urine is consistent with the liver and kidney effects observed in the bioassay.

Ms. Kristine Witt, NIEHS, confirmed that all the mutagenicity assays were performed under the preincubation protocol, compared with some industry-sponsored tests that used the plate incorporation assay.

Public Comments
Dr. Byron Butterworth, representing the American Forest and Paper Association, presented mutagenicity data from the plate incorporation assay on samples of anthraquinone from other sources, both commercial and purified, and suggested that the 0.1% contaminant 9-nitroanthracene could be as potent a mutagen as benzo[a]pyrene. He expressed surprise at the differences between his data and those presented by the NTP.

Dr. Bucher offered that in the paper cited by Dr. Butterworth, the mutagenicity of 9-nitroanthracene is 3 thousandths as mutagenic as benzo[a]pyrene in a second mutagenicity assay. Dr. Irwin noted that some of the samples cited by Dr. Butterworth as being nonmutagenic were only 97% pure.

The conclusions from the February 2004 meeting were displayed on an overhead screen:

Anthracene-derived Anthraquinone

> The term anthraquinone used in this report refers to anthracene-derived anthraquinone.
>
> Under the conditions of these 2-year feed studies, there was *some evidence of carcinogenic activity* of anthraquinone in male F344/N rats based on

increased incidences of renal tubule adenoma and of transitional epithelial papillomas of the kidney and urinary bladder. Hepatocellular neoplasms may have been related to exposure to anthraquinone. There was *clear evidence of carcinogenic activity* of anthraquinone in female F344/N rats based on increased incidences of renal tubule neoplasms. Increases in the incidences of urinary bladder transitional epithelial papilloma or carcinoma (combined) and of hepatocellular adenoma in female rats were also related to anthraquinone exposure. There was *clear evidence of carcinogenic activity* in male and female B6C3F_1 mice based on increased incidences of liver neoplasms. Thyroid gland follicular cell neoplasms in male and female mice may have been related to anthraquinone exposure.

Exposure to anthraquinone for 2 years caused increases in the incidences of nonneoplastic lesions of the kidney, liver, spleen, and bone marrow in male and female rats, the liver, urinary bladder, and spleen in male and female mice, and the thyroid gland and kidney in male mice.

Decreased incidences of mononuclear cell leukemia in male and female rats were attributed to exposure to anthraquinone.

Dr. C. Walker moved and Dr. Gasiewicz seconded that the conclusions adopted at the February review be accepted in that form. Dr. Klaunig offered an amendment to change the title from "anthracene-derived anthraquinone" to "anthraquinone" and discuss the role of contaminants separately. Dr. Boekelheide seconded the amendment. Drs. C. Walker and Gasiewicz then amended their original motion, to first consider just the report title.

Dr. Diane Birt noted that virtually no compound is entirely pure, and limiting chemical identifiers by source and trace contaminant could be a troubling precedent. Further, focusing on genotoxic contaminants could divert from larger issues of carcinogenicity, which need not involve mutagenicity. Dr. Elwell concurred.

Dr. Storer, who suggested the original title change, expressed a newer awareness of how the qualifier could imply the pure material may not be carcinogenic. He suggested the issue of contaminants be addressed in the abstract.

Dr. Roberts said that a title qualification would be warranted only when there is compelling evidence that the contaminant affects the study results. Dr. Vore agreed.

Dr. Gasiewicz thought that since anthraquinone derived from different sources had some different biological activities, specifying the source was important. Dr. Roberts countered that there are no other carcinogenicity results, and Dr. Birt said the data were not clear enough to attribute the carcinogenic response to the contaminants.

The motion to retain the amended title was defeated by two yes votes in favor (Drs. C. Walker and Gasiewicz) and seven no votes. Dr. Birt then moved and Dr. Elwell

seconded that "anthracene-derived" be removed from the title. The motion was approved by seven yes votes and two no votes (Drs. C. Walker and Gasiewicz).

Dr. Roberts then moved and Dr. Birt seconded that the first sentence referring to chemical identity be deleted. After discussion, the motion was approved by seven yes votes to one no vote (Dr. Gasiewicz) and one abstention (Dr. C. Walker).

Next, Dr. Gasiewicz moved that in the conclusions the term "anthracene-derived" be added at the first mention of anthraquinone. Dr. Klaunig seconded the motion. Dr. Irwin noted that commercial preparations of anthraquinone often do not specify the synthetic process. The motion was defeated with three yes votes and six no votes.

Dr. Storer introduced a motion that a sentence be added to the conclusions stating that there is biologic plausibility that a genotoxic contaminant may have contributed to the biologic activity of the test material. The motion failed for lack of a second.

Following more discussion, Dr. Bucher assured the panel that all the new data and their implications would be included in the text and in the discussion of the final report, along with the considerations of the subcommittee.

3'-Azido-3'Thymidine (AZT) Transplacental Study

Drs. Elwell and Storer did not participate in the review, discussion or vote on the draft NTP Technical Report on AZT because of a potential conflict of interest. Dr. June Dunnick, NIEHS, introduced the transplacental carcinogenicity studies of 3'-azido-3'-thymidine (AZT) by describing its use as an antiviral drug to prevent transmission of HIV, its metabolism and mutagenicity, and the design and results of the NTP studies of mice exposed transplacentally to the drug during pregnancy. The proposed conclusions were:

> Under the conditions of this study, there was *some evidence of carcinogenic activity* in F_1 Swiss CD-1 mice exposed transplacentally to AZT based on increased incidences of alveolar/bronchiolar neoplasms. There was *no evidence of carcinogenic activity* in F_1 Swiss CD-1 female mice exposed transplacentally to AZT at 50, 100, 200, or 300 mg/kg.
>
> Reproductive toxicity in the form of decreased litter size and fertility rates was observed in dams in the 200 and 300 mg AZT/kg dose groups.

Dr. C. Walker, the first principal reviewer, inquired if there was more information about the extent of potential human exposure to AZT via the transplacental route. She disagreed with the conclusions in male mice, thinking the lung neoplams merited a conclusion of *clear evidence of carcinogenic activity.*

Dr. Boekelheide, the second principal reviewer, also thought the lung tumors in males merited a conclusion of *clear evidence*.

Dr. Mary Anna Thrall, the third principal reviewer, agreed with the conclusions as written.

Dr. Dunnick responded that new data from the World Health Organization indicates approximately 40 million adults are infected now with HIV worldwide with about 60% in sub-Saharan Africa, and 2 million infected mothers giving birth each year. The number receiving AZT treatment is much smaller, and approximately 6000 children born per year in the United States are exposed to AZT prenatally.

Dr. C. Walker moved and Dr. Boekelheide seconded that the conclusion in male mice be changed to *clear evidence of carcinogenic activity*. Dr. Hailey, said the proposed conclusions are based on the NTP's judgment of the tumor response and not on mutational spectra data. The motion was passed with seven yes votes, and zero no votes.

Sodium Chlorate

Dr. Michelle Hooth, NIEHS, introduced the toxicology and carcinogenesis studies of sodium chlorate by describing its use as an oxidizing agent and bleach and its occurrence as a stable by-product in drinking water disinfected with chlorine dioxide. She next outlined the design of the drinking water studies, and the toxic and neoplastic responses in the study animals. The proposed conclusions were:

> Under the conditions of this 2-year drinking water study there was *some evidence of carcinogenic activity* of sodium chlorate in male and female F344/N rats based on increased incidences of thyroid gland neoplasms. There was *no evidence of carcinogenic activity* of sodium chlorate in male $B6C3F_1$ mice exposed to 500, 1,000, or 2,000 mg/L. There was *equivocal evidence of carcinogenic activity* of sodium chlorate in female $B6C3F_1$ mice based on marginally increased incidences of pancreatic islet neoplasms.
>
> Exposure to sodium chlorate resulted in nonneoplastic lesions in the thyroid gland of male and female rats and female mice, bone marrow of male rats and female mice, and spleen of male rats.

Dr. Birt, the first principal reviewer, thought the study was designed and reported well and she agreed with the conclusions.

Dr. Gasiewicz, the second principal reviewer, agreed with most of the conclusions, but thought the pancreatic islet neoplasms merited a conclusion of *some evidence* rather than *equivocal evidence*.

Dr. Vore, the third principal reviewer, agreed with the conclusions and inquired about the presence of chlorate in the tap water used for the control animals.

Dr. Hooth replied that chlorate was not found above the level of detection (0.11 parts per million) in any of the control water samples assayed. She explained that the pancreatic islet neoplasms were considered *equivocal evidence* because they were seen only in one sex of one species, and the decreased incidences of hyperplasia were not supportive of an effect. She noted that the NTP has never made a call of carcinogenicity in mice based on pancreatic islet neoplasms.

Public Comment
Dr. Charles Capen, representing EKA Chemical Company, spoke about the perturbation of thyroid hormone by sodium chlorate above a certain threshold as a possible link to the genesis of the observed thyroid gland neoplasms.

Dr. Birt moved and Dr. Vore seconded that the conclusions be accepted as written. The motion was carried unanimously with nine votes.

Dr. William Allaben, NCTR, asked if the concept of a threshold effect in the thyroid gland would be added to the discussion. Drs. Birt and Gasiewicz replied that this is a hypothesis that requires more testing and they did not feel the data yet support their inclusion in the discussion.

Bromodichloromethane

Dr. Ronald Melnick, NIEHS, introduced the toxicology and carcinogenesis studies of bromodichloromethane by describing its occurrence in drinking water as a byproduct of disinfection. He described a previous NTP study where bromodichloromethane given by gavage was carcinogenic at multiple sites in rats and mice. He described the design of subsequent drinking water studies and presented results on the dose response using several physiologically based pharmacokinetic models. He attributed the differences in tumor response by the two routes of administration to a variety of factors including differences in organ dosimetry, diet, and body weight. The proposed conclusions were:

> Under the conditions of this 2-year drinking water study, there was *no evidence of carcinogenic activity* of bromodichloromethane in male F344/N rats exposed to target concentrations of 175, 350, or 700 mg/L. There was *no evidence of carcinogenic activity* of bromodichloromethane in female B6C3F_1 mice exposed to target concentrations of 175, 350, or 700 mg/L.

Dr. Vore, the first principal reviewer, thought the study was well designed and she had no scientific criticism.

Dr. Klaunig, the second principal reviewer, thought the study was well designed and said the discussion about the differences in the data between the two routes of administration was good.

Dr. Birt, the third principal reviewer, agreed with the conclusions and offered some suggestions for clarifying the dose selection rationale and the in-life results.

Dr. Vore moved and Dr. Klaunig seconded that the conclusions be accepted as written. The motion was carried unanimously with nine yes votes.

Benzophenone

Dr. Rajendra Chhabra, NIEHS, introduced the toxicology and carcinogenesis studies of benzophenone by describing the design and results of the animal studies. The proposed conclusions were:

> Under the conditions of these 2-year studies, there was *some evidence of carcinogenic activity* of benzophenone in male F344/N rats based on increased incidences of renal tubule adenoma; mononuclear cell leukemia in male rats may have been related to benzophenone exposure. There was *equivocal evidence of carcinogenic activity* of benzophenone in female F344/N rats based on the marginal increased incidences of mononuclear cell leukemia and histiocytic sarcoma. There was *some evidence of carcinogenic activity* of benzophenone in male B6C3F_1 mice based on increased incidences of hepatocellular neoplasms, primarily adenoma. There was *some evidence of carcinogenic activity* of benzophenone in female B6C3F_1 mice based on increased incidences of histiocytic sarcoma; the incidences of hepatocellular adenoma in female B6C3F_1 mice may have been related to benzophenone exposure.

Dr. Storer, the first principal reviewer, thought the study was well conducted. He asked for more discussion on the interpretation of the conflicting genetic toxicology data and also if there was a link between histiocytic sarcoma and mononuclear cell leukemia.

Dr. Roberts, the second principal reviewer, agreed with the conclusions and noted that often the dose formulations were less than the target concentrations and sometimes contaminated.

Dr. Elwell, the third principal reviewer, questioned the explanations for some of the choices of *equivocal evidence* versus *some evidence*, particularly for leukemia in male rats and histiocytic sarcoma in the female rats.

Dr. Hailey replied that there are many studies in rats in which an increase was seen in mononuclear cell leukemia with no increase in histiocytic sarcoma. He added that the mononuclear cell leukemias were considered an equivocal response because the incidences in the control group as well as in the dosed groups were unusually high, but

with no difference in severity. He noted that the overall incidence of histiocytic sarcoma was only three tumors among the four dose groups and it was possible the distribution was spurious.

Dr. Storer moved, and Dr. Roberts seconded, that the conclusions be accepted as written. The motion was approved unanimously with nine yes votes.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel Program Project: Changing Social Contexts & Family Formations.

Date: December 3, 2004.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Carla T. Walls, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435–6898, *wallsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209 Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 5, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25275 Filed 11–12–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 2–3, 2004.

Time: December 2, 2004, 8:30 a.m. to 5:30 p.m.

Agenda: NICHD Director's Report presentation, Regional Research Networks, and an update on the Rehabilitation Medicine Scientist Training Program.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Time: December 3, 2004, 8:30 am. to 12 p.m.

Agenda: Other business dealing with the NABMRR Board.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Ralph M. Nitkin, PhD, Director, BSCD, National Center for Medical Rehabilitation Research, National Institute of Child Health and Human Development, NIH, 6100 Building, Room 2A03, Bethesda, MD 20892. (301) 402–4206.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nichd.nih.gov/about/ncmrr.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 5, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25276 Filed 11–12–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, R13 Application Review.

Date: November 23, 2004.

Time: 8 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Arthur L. Zachary, PhD, Office of Scientific Review, National Institutes of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12, Bethesda, MD 20892. (301) 594–2886; *zacharya@nigms.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS.)

Dated: November 5, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25277 Filed 11–12–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP) Board of Scientific Counselors Technical Reports Review Subcommittee Meeting; Review of Draft NTP Technical Reports

Pursuant to Pub. L. 92–463, notice is hereby given of the next meeting of the NTP Board of Scientific Counselors Technical Reports Review Subcommittee ("TRR Subcommittee") on December 9–10, 2004, in the Rodbell Auditorium, Rall Building at the

National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. The meeting will begin each day at 8:30 a.m. The meeting is open to the public with attendance limited only by the space available (see "Attendance, Registration, and Remote Access" below).

Agenda

The primary agenda topic is the peer review by the TRR Subcommittee of the findings and conclusions of seven draft NTP Technical Reports (TR) of rodent toxicology and carcinogenesis studies conducted by the NTP (*see* Preliminary Agenda below). There will also be a presentation on how the NTP handles contaminants in study materials and their impact on the interpretation of 2-year bioassays. In addition, at the request of the NTP Board of Scientific Counselors, the TRR Subcommittee will readdress the title of the Draft NTP Technical Report on Anthraquinone (see minutes from the NTP Board of Scientific Counselors meeting held June 29, 2004, available at *http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=720164E3-BDB7-CEBA-F338FA2626639D56*). As an introduction to the reports on the studies of polychlorinated biphenyl (PCB), a short presentation will be given on the use of Toxic Equivalency Factors (TEFs). The TEF methodology was developed as a mathematical tool that ranks the dioxin-like activity of a compound relative to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), the most potent dioxin. This methodology has been applied to the NTP studies reported in TR 531: Mixture of 3,3′,4,4′,5-Pentachlorobiphenyl (PCB 126) and 2,3′,4,4′,5-Pentachlorobiphenyl (PCB 118), TR 529: 2,2′,4,4′,5,5′-Hexachlorobiphenyl (PCB 153), and TR 530: Mixture of PCB 126 and PCB 153.

A copy of the agenda, TRR Subcommittee roster, and the draft NTP Technical Reports, as available, will be posted on the NTP Web site (*http://ntp-server.niehs.nih.gov/* under *Latest News*) and will be available upon request to the NTP Executive Secretary, Dr. Barbara S. Shane (PO Box 12233, 111 T.W. Alexander Dr., MD A3–01, Research Triangle Park, NC 27709, T: 919–541–4253; F: 919–541–0295; e-mail: *shane@niehs.nih.gov*). Following the meeting, summary minutes will be available on the TRR Subcommittee Web site (see *http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=227FC084=EB0C–7E93–9DCD6F03104F0D22*) and in hard copy upon request to the NTP Executive Secretary.

Draft Reports Available for Public Review and Comment

Approximately four weeks prior to the meeting, the draft reports will be available for public review, through the NTP Web page (*http://ntp-server.niehs.nih.gov/* under *Latest News*). Printed copies of the Draft NTP Technical Reports can be obtained, as available, from Central Data Management (NIEHS, PO Box 12233, MD EC–03, Research Triangle Park, NC 27709, T: 919–541–3419, F: 919–541–3687, e-mail: *CDM@niehs.nih.gov*).

Attendance, Registration and Remote Access

The meeting is open to the public with attendance limited only by the space available. Individuals who plan to attend are strongly encouraged to register with the NTP Executive Secretary by December 2, 2004 to ensure easy access to the NIEHS campus (contact information above) or online on the NTP Web site (*http://ntp.niehs.nih.gov* under *Latest News*). Please note that a photo ID is required to access the NIEHS campus. Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend are asked to notify the NTP Executive Secretary at least seven business days in advance of the meeting. The NTP is also making plans to videocast the TRR Subcommittee meeting through the Internet at *http://www.niehs.nih.gov/external/video.htm*. The NTP cannot guarantee the technical quality of the video casting and people wishing to use this option are encouraged to test their ability to access the video cast at the above Internet address under *Check your live video setup*.

Public Comment

Comments on any of the Draft NTP Technical Reports are welcome. Time will be provided at the meeting for oral public comment on the reports. Persons requesting time for an oral presentation on a particular report are asked to notify the NTP Executive Secretary (contact information given above) by December 2, 2004, and to provide their contact information (name, affiliation, mailing address, phone, fax, e-mail), and supporting organization (if any). Persons registering to make comments are asked to provide a written copy of their statement to the NTP Executive Secretary on or before December 2, 2004, to enable review by the TRR Subcommittee and NTP staff prior to the meeting. These statements can supplement or expand an oral presentation. Each speaker will be allotted at least 7 minutes and, if time permits, up 10 minutes for presentation of oral comments. Each organization is allowed one time slot per report being reviewed. Registration for making public comments will also be available on-site. If registering on-site to speak and reading comments from printed text, the speaker is asked to provide 25 copies of the statement for distribution to the Subcommittee and NTP staff, and to supplement the record.

Written comments without an oral presentation at the meeting are also welcome. Comments should include contact information for the submitter (name, affiliation, mailing address, phone, fax, and e-mail) and supporting organization (if any). Written comments should be received by the NTP Executive Secretary on or before December 2, 2004, to enable distribution to the Subcommittee and NTP staff for their review and consideration prior to the meeting. Written comments received in response to this notice will be posted on the NTP Web site (*http://ntp.niehs.nih.gov* under *Latest News*).

Request for Additional Information

The NTP would welcome receiving toxicology and carcinogenesis information from completed, ongoing or planned studies as well as current production data, human exposure information, and use patterns for any of the chemicals listed in this announcement. Please send this information to Central Data Management at the address given above and it will be forwarded to the appropriate NTP staff.

NTP Technical and Toxicity Report Series

The NTP conducts toxicology and carcinogenesis studies of agents of public health concern. Any scientist, organization, or member of the public may nominate a chemical for NTP testing. Details about the nomination process are available on the NTP Web site (*http://ntp.niehs.nih.gov* under *Nominations to the Testing Program*). The results of short-term rodent toxicology studies are published in the NTP Toxicity Report series. Longer-term studies, generally, rodent carcinogenicity studies, are published in the NTP Technical Report series. The NTP has a new technical report series for studies conducted in genetically modified models. PDF files of completed reports are available free-of-charge at the NTP Web site (*http://ntp-server.niehs.nih.gov/index.cfm?objectid=084801F0-F43F–7B74–0BE549908B5E5C1C*).

NTP Board of Scientific Counselors

The NTP Board of Scientific Counselors ("the Board") is a technical advisory body composed of scientists from the public and private sectors who provide primary scientific oversight and peer review to the NTP. Specifically, the Board advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and overall scientific quality. The TRR Subcommittee of the Board provides scientific peer review of the findings and conclusions of NTP Technical Reports. The Report on Carcinogens Subcommittee of the Board provides scientific peer review of nominations to the Report on Carcinogens, a Congressionally mandated listing of agents *known* or *reasonably anticipated to be human carcinogens.*

The Board's members are selected from recognized authorities knowledgeable in fields, such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. The NTP strives for equitable geographic distribution and for minority and female representation on the Board.

Dated: November 5, 2004.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

Preliminary Agenda

National Toxicology Program (NTP) Technical Reports (TR) Scheduled for Review by the NTP Board of Scientific Counselors Technical Reports Review Subcommittee

December 9–10, 2004

Rodbell Auditorium, National Institute of Environmental Health Sciences, 111 TW Alexander Drive, Research Triangle Park, NC.

1. Overview of Dioxin Toxic Equivalency Factors (TEFs).
2. TR 531: Mixture of 3,3′,4,4′,5-Pentachlorobiphenyl (PCB 126) and 2,3′,4,4′,5-Pentachlorobiphenyl (PCB 118) (CAS Nos. 57465–28–8 and 31508–00–6, respectively).
   - No longer used commercially; persistent polyhalogenated aromatic hydrocarbons present in the environment.
3. TR 529: 2,2′,4,4′,5,5′-Hexachlorobiphenyl (PCB 153) (CAS No. 35065–27–1).
   - No longer used commercially; persistent polyhalogenated aromatic hydrocarbon present in the environment.
4. TR 530: Mixture of PCB 126 and PCB 153 (CAS No: 57465–28–8 and 835065–27–1, respectively).
   - No longer used commercially; persistent polyhalogenated aromatic hydrocarbons present in the environment.
5. Discussion on Contaminants in NTP Study Materials: Impact on Interpretation of 2-year Bioassays.
   - Discussion of the Title of Draft NTP Technical Report on Anthraquinone (TR–494).
6. TR 517: Sodium Chlorate (CAS No. 7775–09–9).
   - Oxidizing agent, precursor in the synthesis of chlorine dioxide; found as byproduct in water disinfected with chlorine dioxide.
7. TR 532: Bromodichloromethane (CAS No. 75–27–4).
   - Water disinfectant by-product.
8. TR 522: 3′-Azido-3′-thymidine (AZT) (CAS No. 30516–87–1).
   - Chemotherapeutic agent for treatment of people with acquired immune deficiency syndrome (AIDS).
9. TR 533: Benzophenone (CAS No. 119–61–9).
   - Photoinitiator fragrance enhancer, ultraviolet curing agent, intermediate in the manufacture of agricultural chemicals.

[FR Doc. 04–25280 Filed 11–12–04; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

RIN 1660–ZA05

Privacy Act Systems of Records; Amendment to Existing Routine Uses

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security (DHS).

ACTION: Notice of amendment to routine uses.

SUMMARY: In compliance with the requirements of the Privacy Act of 1974, as amended, FEMA gives notice that it intends to rename its system of records notice for FEMA/REG–2, Disaster Recovery Assistance Files, to acknowledge in the nomenclature that it is now part of DHS, that it proposes to revise the existing routine uses for this system to allow information sharing with voluntary agencies actively working in the open disaster and that it proposes to add new routine uses to provide notice about routine management and oversight information sharing. In addition, to reduce the burden on the public applying for disaster assistance, FEMA has proposed to allow the registration process to be done by individuals electronically over the Internet and is therefore revising its system notice to account for electronic records.

EFFECTIVE DATE: The amended system of records will be effective December 15, 2004, unless comments are received that result in a contrary determination. The amended system of records will be applicable to major disaster or emergencies declared on or after August 13, 2004, unless comments are received that result in a contrary determination.

ADDRESSES: You may submit comments, identified by EPA DOCKET NUMBER DHS–2004–0014 and/or 1660–ZA05 by *one* of the following methods:

- EPA Federal Partner EDOCKET Web Site: *http://www.epa.gov/feddocket.* Follow instructions for submitting comments on the Web site. DHS has joined the Environmental Protection Electronic Docket System (Partner EDOCKET). DHS and its agencies (excluding the United States Coast Guard (USCG) and Transportation Security Administration (TSA)) will use the EPA Federal Partner EDOCKET system. The USCG and TSA [legacy Department of Transportation (DOT) agencies] will continue to use the DOT Docket Management System until full migration to the electronic rulemaking federal docket management system occurs in 2005.
- Federal e-Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: (202) 646–4536.
- Mail: Rules Docket Clerk, Federal Emergency Management Agency, Office of General Counsel, room 840, 500 C Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Rena Y. Kim, Privacy Act Officer, Room 840, 500 C Street, SW., Washington, DC 20472; (telephone) (202) 646–3949, or (e-mail) *Rena.Kim@dhs.gov.*

SUPPLEMENTARY INFORMATION: Prior to March 1, 2003, FEMA was an independent agency within the Federal Government. While operating as an independent agency, FEMA published notices concerning its systems of

NATIONAL TOXICOLOGY PROGRAM
BOARD OF SCIENTIFIC COUNSELORS

Technical Reports Review Subcommittee Meeting
Agenda

December 9, 2004
8:30 a.m. – 5:00 p.m.

National Institute of Environmental Health Sciences
111 TW Alexander Dr.
Research Triangle Park, NC

8:30 a.m.	Welcome		Dr. Christopher Portier, NIEHS Dr. Mary Anna Thrall, Chair
Chemical/CAS #		**Report #**	**Primary Use, Route & Species**
Toxic equivalency factors (TEFs)			
PCB mixture 3,3',4,4',5 Pentachlorobiphenyl (PCB 126) /57465-28-8, 2,3',4,4',5 Pentachlorobiphenyl (PCB118)/31508-00-6)		TR 531	No longer used commercially, persistent polyhalogenated aromatic hydrocarbons in environment; Gavage, female rats
2,2',4,4',5,5'-Hexachlorobiphenyl (PCB 153, 35065-27-1)		TR 529	No longer used commercially, persistent polyhalogenated aromatic hydrocarbons in environment; Gavage, female rats
PCB mixture (PCB 126 / PCB153)		TR 530	No longer used commercially, persistent polyhalogenated aromatic hydrocarbons in environment; Gavage, female rats
Discussion on Contaminants in NTP Study Materials: Impact on Interpretation of 2-Year Bioassays • Discussion of the Title of Draft NTP Technical Report on Anthraquinone (TR-494)			
Sodium chlorate (7775-09-9)		TR 517	Oxidizing agent, water disinfectant by-product; Drinking water, male and female rats and mice
Bromodichloromethane (75-27-4)		TR 532	Water disinfectant by-product; Drinking water, male rats and female mice
3'Azido-3'thymidine (30516-87-1)		TR 522	Chemotherapeutic agent; transplacental exposure of pups by gavage of pregnant female mice
Benzophenone (119-61-9)		TR 533	Photoinitiator, fragrance enhancer; Diet, male and female rats and mice

THE NATIONAL TOXICOLOGY PROGRAM
BOARD OF SCIENTIFIC COUNSELORS
Technical Reports Review Subcommittee Meeting
December 9, 2004

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Erratum – replacement text for minutes on NTP TR-494, page 7, paragraph 1:

Dr. Klaunig asked if the samples assayed were the original test material and if any degradation might have occurred during the interval. Further examination of the shipment information for the sample from the 2-year bioassay sent to BioReliance Corporation for genetic toxicology testing in *Salmonella* showed that it was from archived bulk material. Following completion of the bioassay, this material was stored as received at room temperature (approximately 25°C), protected from light, and without inert gas headspace. Results from purity analysis of this material upon receipt, throughout the study, and at the end of the study showed no degradation.