BEFORE THE UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

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Hearing for the Closed and Controlled

Waste Process Rule

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Room 3906
Waterside Mall
401 M Street, S.W.
Washington, D.C.

Monday, July 26, 1982

The meeting convened at 9:07 a.m., Richard J. Guimond presiding.

EPA PANEL

Richard J. Guimond

Alan Carpien

John Smith

William Gunter

David Redford

Laura Campbell

Denise Keehner

Amy Moll

I N D E X

P R O C E E D I N G S

MR. GUIMOND: Welcome to our hearing this morning. My name is Richard Guimond. I'm Chief of the Chemical Regulation Branch in the Office of Toxic Substances. I'll be the chairman of this hearing panel.

The other members of the panel and myself would like to give you a welcome to the hearing. As you know, EPA proposed a rule to control the release of PCBs enclosed in control waste processes. This action was taken in response to a decision from the U.S. Court of Appeals for the District of Columbia Circuit.

Our goal for the hearing is to learn more about PCBs manufactured in low concentrations, the impact that the proposed exclusion from the statutory ban may have, learn about the analytical methods for monitoring PCBs and processes affected by the rule, learn any problems associated with this.

Among the issues in which the agency has requested comment are the appropriateness of the exclusion, the need to specify criteria for determining the absence of PCBs, the appropriateness of using limits of quantification versus limits of detection, and the suitability of allowing manufacturers to use best theoretical analysis in lieu of actual monitoring.

As most of you are aware, the Federal Register

Notice of June 8th included a misprint concerning the dates for the closing of the main comment period and for this hearing. This misprint resulted in an error by the staff of the Government Printing Office that was unfortunately out of our control.

We apologize for any inconveniences that this may have caused and you will now have until August the 9th for the close of reply comments. As with our actions to the extent feasible, the agency will consider other comments provided to it beyond that date within the constraints of our overall rulemaking.

If, during the course of the hearing, any of you have any questions that you would like the hearing panel to ask the people that are testifying, I'd request that you write them down on a card or a sheet of paper and give them to the hearing clerk that's located up here in the front and she will pass them to the hearing panel to ask.

In addition, if there are any other people that are not on the agenda for the hearing today that believe they have information that is relevant to this rulemaking and would like to present it, we will consider that to the extent feasible within our time constraints of the hearing today.

So if anyone does want to provide some additional information, I request that you see me sometime during the

day and I will talk with you and see if we can make appropriate arrangements.

There are agendas for the hearing located on the table just as you come in the door -- excuse me, it's outside the door.

At this time, I'd like to introduce the remainder of the hearing panel for this informal hearing. Way down at the end on my left is Amy Moll. Amy is one of the economists with the Economics and Technology Division in the Office of Toxic Substances.

Next to her is Laura Campbell. Laura is with the Office of Pesticides and Toxic Substances Enforcement and has been working with us with respect to enforcement issues on the rule.

Next to Laura is Bill Gunter. Bill is the team leader for the PCB Regulations Team in the Office of Toxic Substances.

To my immediate left is Alan Carpien. Alan is the attorney with the Office of General Counsel who has served as a legal advisor on these PCB rulemaking.

To my right is John Smith with the Exposure Evaluation Division of the Office of Toxic Substances. John has been the principal chemist in the development of the guidance on the methods for sample collection.

To his right is Dave Redford, also of the Exposure

Evaluation Division. Dave is a project manager of the Midwest Research Institute contract that is assisting us in the development of analytical methodology for the rulemaking.

To my far right is Denise Keehner who is a biologist on the PCB Regulations Team and is the lead staff member for this rulemaking.

At this time, I'll turn the microphone over to Alan Carpien who has some remarks regarding the procedural aspects of the rulemaking in this hearing.

MR. CARPIEN: I'd like to stress, first of all, that this is an informal hearing and we're going to try to remain as flexible as possible as a hearing panel. However, after saying that, I also want to point out that we have procedural rules under Volume 40 of the Code of Federal Regulations, Part 750, Subpart A, and there are copies of those regulations on the table as you come in.

I will be available for any questions about any of the procedures involved in these rules during any breaks.

I believe Rich said that reply comments will be due two weeks from the day the hearing ends. Under our current schedule, we expect the hearing to end today and that would mean that reply comments would be due by August 9th.

Let me comment briefly on how we are going to

proceed. We ask all participants to first identify themselves and their affiliation to the court reporter before they begin speaking. This is in order to help us later as we review the transcript.

Any additional material you have, any additional written material or any other material that the panel might request from you should be given to the hearing clerk for insertion in the record. Although participants are not sworn, I would like to remind everyone they are subject to 18 USC 10001 which is the False Reports to the Government.

Following each speaker's presentation, each member of the panel will have an opportunity to ask questions and as Rich said before, we will ask any reasonable questions submitted by the audience. If anybody on the panel should ask a question or if any speaker has anything to say that is of a confidential business nature in the speaker's opinion, please note that.

You can later present your response in a close session if that's necessary, but present the information in writing on a confidential basis under agency rules for the submission of confidential material, the agency regulations for submission of confidential material will found in Part 2 of Volume 40 of the Code of Federal

Regulations. That's all I have.

MR. GUIMOND: Then I guess we'll begin with CMA?

STATEMENT OF GERALDINE COX, CMA

MS. COX: My name is Geraldine Cox. I am Vice-President and Technical -- Director of the Chemical Manufacturers Association. The Chemical Manufacturers Association is a trade association representing the manufacturers of more than 90 percent of the basic industrial chemicals in the United States.

CMA and its special programs panel on PCBs welcome the opportunity to discuss EPA's proposed rule for closed and controlled waste manufacturing processes with you this morning. CMA shares EPA's concern that PCBs do not pose unreasonable risk to man or to the environment.

As you know, in this country, intentional manufacture of PCBs ceased more than five years ago and we do not advocate such manufacture be reinstated. The chemical industry has worked diligently to develop substitutes for these uses for which PCBs were invaluable in the past.

CMA further agrees with EPA that if the current uses of previously intentionally generated PC -- I'm sorry, if there are current uses of previously intentionally generated PCBs that pose unreasonable risk, adequate controls should be developed and if there are any specific circumstances where unreasonable risks are presented by

small quantity of unintentionally generally PCBs found as impurities in a wide variety of chemicals, controls to reduce human and environmental exposures would be appropriate.

However, CMA cannot support EPA's present proposal for what it terms "closed and controlled waste manufacturing processes." That proposal is premised on the scientifically and legally flawed assumption that any exposure to PCB is significant.

Not only is this premise wrong, as a matter of science for any chemical, it also mischaracterizes what we know about the toxicity of PCBs. Contrary to what might have been believed by some in the past, including Congress, PCBs are not uniquely toxic.

As the recent epidemiology studies of the -- incident and the heavily exposed capacitor worker have demonstrated significant health risks will not be posed at the low levels from inadvertent generation that EPA is now considering regulating.

Once EPA reviews the health evidence in light of the exposure levels at issue, we are confident that the agency will agree with us that inadvertent generation poses no significant risks to man or the environment. CMA's special program panel has proposed a reasonable regulatory program for inadvertent generation of PCBs, although we do

not believe that likely -- believe the likely exposures that would occur if PCBs were below 50 parts per million in product and waste streams would pose any significant risks.

We would support a regulatory scheme based on such a quantified cutoff. By employing this cutoff, EPA could assure the public that no reasonable risks will be posed and industry, that it will be allowed to continue to produce the many valuable chemicals under reasonable regulations.

Here today to spell out in detail CMA's positions are Dr. Kenneth Burgess, Chairman of our Special Program Panel on PCBs, and Dr. Robert Kaley of the Panel's Analytical Task Force. I encourage you to listen closely to their presentations and to ask them questions in order to assure that EPA clearly understands CMA's position on the issues raised by its closed and controlled proposal.

Dr. Burgess?

STATEMENT OF DR. KENNETH BURGESS, CMA

DR. BURGESS: Thank you. Good morning. My name is Kenneth Burgess and I am Chairman of the Chemical Manufacturers Association Special Program Panel on PCBs. With me today is Dr. Robert Kaley of the Program Panel's Analytical Task Force who will also be presenting testimony and at the conclusion of Dr. Kaley's testimony, I will be

glad to answer your questions and refer them to Dr. Kaley, as appropriate.

Also with us today are Tim Hardy and John Jackrison of the firm of Kirkland & Ellis, counsel to the PCB Special Panel.

CMA has repeatedly urged that EPA conduct a thorough review of potential exposures to substances containing inadvertently generated PCBs and the relative consequent health and environmental effects of the PCB content in response to the Court of Appeals remand of EPA's 1979 PCB regulations.

With respect to both intentionally manufactured PCBs still in use in electrical equipment and inadvertently generated PCBs in a number of basic chemicals, CMA acknowledges any unreasonable risk as defined by TSCA Section 6(c) should be eliminated pursuant to EPA's authority under the Toxic Substance Control Act.

However, EPA to date in both the electrical equipment proposal and its most recent closed and controlled waste proposal, failed to review the exposure data or the health and environmental evidence. Both EPA proposals suffer from the absence of a straightforward description of the record evidence demonstrating that the trace quantities of PCB now entering the environment pose no significant, let alone unreasonable risks.

In particular, these proposals fail to consider several recently released studies of PCB health effects that demonstrate no significant risk will be posed by the trivial exposures the agency is now considering regulating. Such studies include, among others, the Kashimoto, et al. study, "Role of Polychlorinated Dibenzofurans in Yusho PCB Poisoning" published in Volume 36, No. 6 of the Archives of Environmental Health, and Brown and Jones "Mortality and Industrial Hygiene Study of Workers Exposed to Chlorinated Biphenyls," also in Volume 36, No. 3 of the Archives of Environmental Health.

EPA's failure to address the de minimis risks created by unintentional PCB generation explains in large part why CMA has urged the agency to withdraw its closed and controlled waste proposal. As our July 8th comments detailed, that proposal is of little value to anyone.

It provides no assurance that public health will be protected. It never answers the court's questions in EDF v. EPA of whether any unreasonable risks are posed by inadvertent generation of PCBs and it will not provide industry any assurance in inadvertently generated PCBs in closed processes will be excluded from TSCA regulation, even though any release is trivial.

The analytical guidelines are so uncertain that although we doubt any process will be excluded, this is

speculation, -- not fact. In fact, the proposed rule may create considerable opportunity for supplier-customer controversy as to whether PCBs in customer plants or plant waste were generated by the customer or received as part of raw material from the supplier.

We have thus urged EPA to publish a new proposal that conforms with congressional intent in TSCA and the mandate of the Court of Appeals to address unreasonable risks. That proposal would recognize that no significant risks are posed when PCBs, in products or waste streams, are in concentrations below 50 ppm.

Such a proposal would appropriately address the TSCA Section 6(c) criteria, health effects and exposure to humans and the environment, benefit of the regulations and cost of regulating substances containing inadvertently generated PCBs, and determine that inadvertently generated PCBs pose no unreasonable risks.

A 50 ppm cutoff has been the law of the land for three years, although the exposure and health evidence would support a higher regulatory cutoff, CMA would not object to the continuance of such a regulation.

EPA's closed and controlled waste proposal begins with the appropriate initial premise, namely, that there is no reasonable rationale for any regulatory concern about levels of PCB insider manufacturing equipment. As long as

inadvertently generated PCBs are within chemical plant equipment, no environmental or human exposure occurs.

The concentrations of concern are those to which humans and the environment might be exposed, in air, water, or products. However, the proposal's nonquantifiable approach is not a rational approach to the correctly perceived regulatory issue.

This morning, I would like to provide some background information to explain further why CMA urges that EPA withdraw its nonquantifiable proposal.

First, and most importantly, EPA's proposal bears no articulated relationship to protection of the public health as required under TSCA Section 6, and as requested by the court in EDF v. EPA. Although EPA justifies its proposal as being as close to zero release as practically possible, the agency has not in fact sought to determine that levels -- what levels of PCB its proposal will allow in the various media.

Moreover, the agency has made no attempt to determine to what extent any such concentration will lead to human or environmental exposures, not to mention whether the likely trivial exposures pose any significant risks or outweigh the cost of regulation that must be balance against risk before making an unreasonable risk determination.

The proposal cannot withstand review under the

statutory standards of TSCA which call for close scrutiny of risk and which were in the forefront of the court's reversal of EPA's '79 PCB regulations.

As CMA demonstrated in its comments, current inadvertent generation of PCB does not pose unreasonable risks. The questions asked by the Court of Appeals whether regulation of inadvertent PCBs has other than trivial health and environmental benefits or whether potential risks are unreasonable, can and should be answered in the negative.

EPA's current proposal, however, has not answered these questions and because it is not based on a definite limit on PCB concentrations, it is incapable of doing so.

Second, the nonquantifiable approach is analytically unsound and administratively impractical. FDA considered use of this approach to implement the "no-residue" requirement of the Delaney clause for animal feeds, but rejected it as "unreasonable, unmanageable, and making no sense from the perspective of public health."

CMA has for a long time recognized the importance of analytical chemistry issues -- developing reasonable PCB regulations. Nearly a year ago, we submitted to EPA a report on "Analysis of Chlorinated Biphenyls" and have attempted to assist EPA in developing reasonable analytical approaches to low-level PCB quantification in chemical matrices.

We were thus quite dismayed by the serious

analytical inadequacies of the current proposal. We are also quite concerned about the continuing failure of EPA to make available the essential guidelines documents explaining its analytical proposals.

The two documents we have received were not made available to the public until the week after comments on the proposal were due and the promised guidelines for theoretical assessment has not been released to this day.

Dr. Kaley will further discuss the many scientific flaws in the analytical section of the current proposal.

Third, the proposal's new requirement that any quantifiable PCB in a waste stream from closed and controlled processes, even if concentrations below 50 ppm be disposed of in an EPA-approved PCB disposal facility, is without justification.

The existing 50 ppm cutoff for waste disposal has never been challenged and no justification exists for changing it now. To require any waste with less than 50 ppm but quantifiable PCBs to be handled by PCB disposal techniques would be tremendously expensive with no consequent meaningful reduction in risk. As much as a billion dollars annually could be required for such disposal.

In promulgating the May 31st, '79 PCB rules, the agency required PCB-approved disposal for substances containing 50 ppm PCBs, rather than the previously proposed

500 ppm PCBs. However, in taking this step, the agency recognized the additional economic burden and alleviated it by allowing less stringent methods of disposal for substances containing more than 50 but less than 500 ppm PCBs.

The agency should now recognize that a major part of that relief, high intensity boilers, will not be available for most waste products containing less than 50 ppm PCBs. High intensity boilers are operated to generate steam for a variety of uses.

Mineral oil, containing trace quantities of PCBs, may be a suitable fuel for operating such units, but chemical waste streams will not normally be acceptable since they do not represent a consistant fuel and may have components other than PCBs that could lead to unacceptable boiler operations.

Before turning to Dr. Kaley and the issues related to the analytical guidelines which are at the core of EPA's proposal and of the inadequacy of the guidelines, I would like to provide the panel with a better perspective on why PCBs are inadvertently generated, some aspects of the fate of such PCBs, and how the chemicals in which they are contained are handled.

Trace polychlorinated biphenyls are likely to be formed in most chemical processes where hydrocarbons and

chlorine exist at high temperatures or if a catalyst such as iron chloride are present. Three basic types of reactions can yield chlorinated biphenyls.

One, coupling reactions with chlorinated aromatics; two, chlorination reactions where aromatic chemicals are present and temperature catalyst and/or chlorination is sufficiently intensive to cause aromatization; and three, degradation reactions where conditions are such that hydrocarbon radicals are generated in the presence of chlorine radicals.

In the first type of reaction, the point of coupling is well-defined and the number of chlorinated biphenyls are determined by the structure of the starting materials. For example, bis-2,4-dichlorobenzoyl peroxide is decomposed under certain conditions to yield trace quantities of 2,2',4.4'-tetrachlorobiphenyl.

Many variables will influence the relative yield of PCB versus the desired products, impurities, temperature, catalyst, -- effects, pressure, time, concentration, and other variables can change the relative kenetics.

Destruction or isomerization could occur under the conditions of various reactions. However, in coupling reactions, regardless of the concentration of PCBs, a single or limited number of congeners will dominate all others.

In the second basic type when chlorinating

aromatics, a substitution of chlorine for hydrogen on the aromatic -- will follow a selectivity pattern that is well-known. For example, when normal iron chloride catalyzed chlorination of monochlorobenzene will yield about 55 percent paradichlorobenzene, 40 percent orthodichlorobenzene, and only 5 percent metadichlorobensene.

Conditions may modify the ratio slightly, but the basic selection will continue to exist. Thus, several congeners may exist but a few will dominate.

To review the analysis -- a review of the analysis of commercial PCBs produced by the chlorination of aromatic -- de -- aromatic -- biphenyl -- indicate that the most prevalent congener ranges from 32 percent of the total mixture in lower chlorinated biphenyls to 9 percent of the total mixture in higher chlorinated products.

PCBs generated during incidental chlorination should have similar selectivity in the ratio of total PCB to the most prevalent congener should vary from 3 to 1 to 11 to 1. From this, it is obvious that a 1 ppm per congener sensitivity limit means that the undetectable limit for total PCB is 3 to 11 ppm.

Another chlorination of aromatic material yielded PCB contamination with 26 identifiable congeners, but a ratio of 150 between the most and least prevalent congener. The relative concentration of PCB versus desired chemical is

subject to all the same variables as listed above and any single change will normally affect yield of both the impurity and the product and the relative ratio must then be redetermined.

The third basic type of reaction leading to chlorinated biphenyl is degradation. Catalyst, high temperature processes, or hot spots with any process will yield a large number of chemicals and perhaps some PCBs.

These chemicals in turn degrade based on thermodynamic stability since PCBs are quite stable, some may survive. Steric and electronic effects dictate that different structures will have different thermodynamic stability.

The relative concentration of reactants will dictate the approximate degree of chlorination. Such generation may yield many congeners but thermodynamic stability will determine that a few of these congeners will be prevalent probably in about the same ratio as is present in the chlorination reactions.

If a chemical reaction yields trace quantities of PCBs, those impurities may end up in product, waste, or recycled stream and the ratio of such distribution will depend on the separation technique. No separation technique is 100 percent effective, thus there will always be some molecules in every stream.

The physical property differences, namely, vapor pressure and water solubility, will determine the ease of separation and to some extent, the ratio of the constituents between the streams, whereas it is technically feasible to get good separation of decachlorobiphenyl from low boiling products, the same degree of separation may not be feasible for trichlorobiphenyl in products that boil between 150 and 200 degrees centigrade.

Since these properties vary across the series of PCBs, separation techniques may change the congener distribution as well as the congener concentration. Irrespective of separation, a few congeners will still predominate.

Regardless of which of these three basic reaction types occur, the levels of PCB in final products are released to air and water during processing are in almost all substances -- instances -- very low, usually because some degree of separation has occurred and most of the PCBs are concentrated in the waste streams.

As CMA has indicated in its comments, a regulatory cutoff of 50 ppm for PCBs in products is frequently achievable, meaning that products will typically contain less than 25 ppm. I am not sure many people recognize what a small quantity of PCBs are being discussed when I say 25 ppm. A 25 ppm concentration represents only one part

out of 40,000 or 0.0025 percent.

In order to dramatize the triviality of such concentrations, I would like to put the numbers in terms more easily comprehended. For example, if 660 pounds of PCBs representing a total annual quantity found in commercial products in the CMA survey were contained in a chemical at 50 -- at 25 ppm concentration and were dumped on someone's doorstep, it might be considered by some that that person would have a PCB problem.

That problem, however, would be trivial compared to the problem posed by the other 26,389,020 pounds of chemical on the doorstep, enough to fill ten olympic-sized swimming pools. Not only is 660 pounds trivial compared to the more than 26 million, but it would be almost impossible to get actual exposure to all of those 660 pounds given the other 26 million that you would be faced with.

Imagine for a moment that you were standing alone just outside an athletic stadium filled with 80,000 blindfolded fans. All 80,000 are trying desperately to get out of the stadium but they don't know where the exits are and two fans are ruffians, that's 25 parts per million, while the other 79,998 members of the mob are just trying to get out.

You can see that the ruffians' probability of a fast exit are minimal, but even if they did get out, the

chance that the ruffian would have an adverse effect on you relative to the probability of being trampled by the other 79,998 is neglible. So it is with PCBs contained at such low levels in unintentionally -- in intentionally manufactured chemicals.

Carrying our example of the ten swimming pools further, where those other 26 million-plus pounds of non-PCB material water, there might be reason for concern about the 660 pounds of impurities. That is not the case. We are dealing with chemicals other than water.

Yet, EPA totally ignores the fact that chemicals containing inadvertently generated PCBs have limits for handling because they are chemicals and often are also strictly regulated by the government.

For example, carbon tetrachloride is one chemical for which PCB -- manufacturing ban exemption petitions have been filed. Carbon tetrachloride is already regulated by a myriad of agencies; the CPSC has banned -- its use in consumer products; contaminant levels have been set by EPA for drinking water; disposal is regulated under RCRA; the Department of Transportation regulates its movement; OSHA has set workplace -- standards; and the Mine Safety Hazard Act regulates the chemical's use in mines.

If PCBs exist in very low concentrations in carbon tetrachloride, human and environmental exposures to

the small amount of PCB will already be strictly controlled without a single PCB regulation. The carbon tetrachloride regulations represent an important point ignored by EPA in its proposal.

The issue in the current EPA proceeding is entirely different than that addressed by Congress in TSCA Section 6(e). PCBs were at one time intentionally manufactured and millions of pounds per year entered the assessible environment.

The absence of adequate control on such entry was a problem worthy of concern that should have been and in fact, in the last 15 years, has been addressed. Inadvertent generation is an issue of an entirely different stripe.

The issue of whether small amounts of inadvertently generated PCBs contained at very low levels in already controlled chemicals is worthy of further regulation -- of further regulatory concern and an entirely different answer is warranted.

The potential for worker exposure to PCBs inadvertently generated at some point within a chemical process facility is much less than the potential for workers servicing and rebuilding electrical transformers. The low concentrations of such chemicals in process facilities automatically reduces exposure.

A wide range or protection measures currently are

utilized by industry because of a need to protect against toxic or corrosive primary chemicals. Food, drink, and tobacco products are frequently prohibited by the work areas, employees may also be instructed to wash their hands and faces prior to eating or smoking.

If eye contact with a toxic or corrosive chamicals can occur, chemical showers and eye wash facilities ara usually provided. Equipment or process engineering and design considerations are also important in minimizing the potential for inadvertent releases in controlling intentional removal of a chemical from a process.

For instance, sample points are generally designed to be easily assessible and have appropriate purge systems. Drum filling stations generally provide for proper ventilation, pump seals and other likely leak points are generally shielded and drained to an appropriate point for clean-up and disposal.

The chemical industry routinely employs spill prevention control and countermeasure systems for storage and handling of toxic chemicals. These measures already address many of the primary chemicals with which inadvertently generated PCBs are associated.

Moreover, the OSHA Act imposes a general duty on employers to provide safe workplaces regardless of other regulations. Therefore, additional requirements addressing

the low levels of inadvertently generated PCBs are unnecessary.

In addition, if there be any doubt that the trivial quantities of inadvertently generated PCBs pose any risk, several PCB specific regulations already exist. Under the Clean Water Act, strict effluent limitations exist for PCB discharges.

OSHA regulates exposure to PCB in the workplace. FDA has set tolerance levels for PCB in food, and of course, EPA has established under TSCA 6(e) special disposal requirements for PCB concentrations of 50 ppm or above.

The case for additional regulation of inadvertently generated PCBs thus cannot be made. The risks posed, if any, are trivial and not worthy of regulatory concern. It is also worth pointing out that the substantial economic cost -- that substantial economic cost would be posed were EPA to seek -- to control unduly inadvertently generated -- inadvertent generation of PCBs.

I have already mentioned the tremendous potential cost of EPA's new proposed requirement that any waste stream with quantifiable PCB disposed in an EPA-approved manner. More significantly, it is important that the agency recognize the infeasibility of producing of many important chemicals without inadvertent PCB generation.

The risks posed by inadvertent generation are so trivial as to require no balancing of economic cost of

regulation against the risks to justify the absence of regulation. Nonetheless, it is worth noting that the potential economic impact of unreasonable regulations in light of TSCA's direction to determine unreasonable risk through such a balancing.

Many chemicals from the complex reactions for PCBs can be generated are engineered for unique properties or for highly critical specialty applications. Substitution or replacement of these materials is often impossible or at best requires long-term expensive development programs.

For example, PCBs are generated in the production of phenyl-containing silicone products typically used in highly critical military and commercial aircraft, military equipment, space vehicles, nuclear reactor applications.

Even if lower performance materials could be substituted, such substitution would require long devalopment programs. PCBs are also inadvertently generated in production of benzene phosphorus dichloride, an intermediate used in the production of a catalyst for nylon and carpeting.

No substitute has been found for this intermediate material and without it, carpet quality nylon cannot be manufactured. Withdrawal of that intermediate from the marketplace would require the producer of carpet nylong to shut down a large process line.

In order to reestablish production, a producer

would be forced to embark on substantial and expensive research program for a substitute catalyst or a substitute for carpet nylon. A carpet manufacturer would in turn -- in turn would either be forced to find a substitute fiber or go out of business.

The consumer in turn would be faced with reduced choice in carpet selection. Similar examples exist for many other chemicals that contain trace PCB impurities. In each case, the high cost of finding substitutes not containing this unintentional impurity cannot be justified by the minimal risks posed by its presence.

EPA's failure to review the exposure and effects data that demonstrate no risks worthy of regulatory concern -- that demonstrate that no risks worthy of regulatory concern exist from inadvertently generated PCBs has led the agency to propose a rule that neither assures the public that health and the environment will be protected nor assures industry that drastic regulations will not have a prohibitive impact on production of many important chemicals.

CMA thus urges the close and controlled waste proposal be withdraw and that EPA focus its attention on an achievable 50 ppm regulatory cutoff that will be more than adequate to safeguard public health.

I would now like to turn the floor over to Dr. Kaley who will discuss the important scientific flaws in

the analytical guidelines lying behind EPA's proposed rule.

STATEMENT OF ROBERT G. KALEY, II, MONSANTO COMPANY

DR. KALEY: Good morning and thank you for this opportunity to testify. My name is Dr. Robert G. Kaley. I am currently a Senior Research Specialist with Monsanto Company and a member of CMA's PCB Analytical Task Group.

I received my Ph.D. in analytical chemistry from the University of Illinois in 1974. Since that time, I have been employed at Monsanto in various analytical capacities. In particular, I have had over eight years experience in the analysis for PCBs.

I have co-authored several journal articles and presentations dealing with analyses for PCBs. In addition, I have served as Chairman of the PCB Task Group for ASTM Committee D-19 on Water.

At Monsanto, I was initially involved in developing analytical methods for Monsanto's PCB Trademark Aroclor products in a variety of environmental and experimental matrices.

More recently, I have been involved both actively and in a supervisory capacity in the development and implementation of analytical methods for the determination of inadvertently generated PCBs in various media.

As my testimony today should make clear, method development and analysis of inadvertently generated PCBs is

a totally different and more arduous time-consuming and analytically exacting task than the analysis for commercially produced PCB mixtures in environmental samples.

In addition to developing these in-house methods, our laboratory has participated in several inter-laboratory tests of PCB methods, including the recent CMA round-robin.

CMA has long considered sound analytical principles to be central to the development of appropriate PCB regulations, particularly in the context of inadvertently generated PCBs. For this reason, the CMA PCB Analytical Task Group was formed and has developed and submitted substantial analytical comments on several occasions in conjunction with EPA's rulemaking.

We have appreciated these opportunities and look forward to providing additional analytical comments where appropriate. While I have included some comments on MRI's guideline protocols here, because of their complexity and because full comments are not possible until the methods have been run on actual samples, we hope to be able to make more detailed comments later.

Consistent with its past interest, CMA's PCB Analytical Task Group has carefully evaluated EPA's proposed closed and controlled waste rule. We conclude that EPA's proposal is analytically unsound and inappropriate.

A nonquantifiable cutoff using any analytical

method will result in arbitrary and inconsistent regulatory results involving a moving regulatory target. Moreover, EPA's proposal does not establish a validated, workable method that can be followed by the analytical chemist since it leaves critical analytical procedures to his discretion.

The only way to develop a rule consistent with the principles of analytical chemistry is to establish a previously determined regulatory cutoff and develop analytical methodology to enforce it.

With unlimited financial and analytical resources, analytical techniques can be refined to quantify lower and lower PCB amounts. Consequently, absent a previously specified cutoff, the analytical chemist has not way of determining when to stop seeking PCBs.

In fact, EPA's proposed rule and guidelines essentially specify an analytical search for zero. Using an analytical method to identify the absence of a chemical as EPA's proposal in reality is intended to do is an unsound use of analytical principles.

The analytical chemist can never warrant that a substance is not present in a sample but only that its concentration does not exceed a given level. As a result, a nonquantifiable cutoff constitutes no more than an indirect regulatory cutoff defined by the chemist himself.

It is imperative that EPA establish this cutoff

directly presumably by examining the relevant hazard information and not indirectly through the development of analytical methods which bear no relationship to that hazard evidence.

EPA's proposed nonquantifiable cutoff reflects a lack of appreciation of both analytical chemistry's limits and the complexity of the analytical problem posed by inadvertently generated PCBs.

For a variety of reasons which I will explore in more detail later in my testimony, a nonquantifiable cutoff provides no target for the analytical chemist. With enough analytical resources, a chemist would ultimately be able to quantify extremely low levels of PCBs which may be present in matrices associated with processes unintentionally generating PCBs.

Accordingly, the principles of analytical chemistry do not and cannot tell the analytical chemist how extensively to analyze his samples as EPA seems to expect. But even if they could, because of the analytical complexity of inadvertently generated PCBs, a nonquantifiable approach will have inconsistent, arbitrary, and unfair regulatory results.

Substances having similar PCB level and similar exposure potentials will be regulated differently simply because of analytical peculiarities associated with

inadvertently generated PCBs.

Moreover, a nonquantifiable approach will result in a moving regulatory cutoff even with the MRI's protocol guidelines.

Our July 8th comments highlighted some of the irrational results of a nonquantifiable rule. For example, due to the isotopic properties of chlorine in an electron impact ion source, monochlorinated biphenyls will be more consistently quantifiable than decachlorinated biphenyl and other higher chlorinated biphenyls.

Upon electron impact, monochlorobiphenyls generate two predominant ions, while decachlorobiphenyl generate six ions of 20 percent or greater relative intensity. This, in effect, dilutes the analytical signal for decachlorobiphenyl.

As a result, an amount of mono will generate a more intense signal than the same amount of deca and is consequently more likely to be quantifiable and thus regulated. Other analytical problems exist under a non-quantifiable system.

None of the chromatographic systems described by MRI or yet developed is capable of separating all possible PCB congeners. Columns with different operational properties thus resolve congeners differently.

For example, two different pentachlorinated biphenyl isomers will show two peaks on the recommended DB-5

capillary column, but only one larger peak on a dexsil 410 capillary column which is also permitted under MRI's guidelines.

Under some circumstances, the larger cumulative peak will be quantifiable, whereas the same amount of PCBs divided between the two peaks will not be leading to a different regulatory result.

Even if PCBs themselves were analytically less complex, the nonquantifiable approach will inevitably lead to inconsistent results. Since the limit of quantitation is a function of the analytical noise level of the total method which is directly dependent on the properties of the matrix, it would be purely fortuitous analytically if the limit of quantitation turned out to be the same in any two different matrices.

Given the wide range of matrices, liquid to solid, simple to complex, halogenated to non-halogenated, limits of connotations will stand several orders of magnitude under EPA's closed and control rule. As a result, if EPA's rule excludes any processes at all, it will still include widely varying quantities of PCBs for regulation.

Not only will the limits of quantitation vary widely among substances, it will also vary over time for any given substance. That is, the approach establishes a moving regulatory cutoff. Significant improvements in

analytical hardware have occurred over the past several years.

Take, for instance, the mass spectrometer. Some older models tuned for optimal operation as specified by the MRI protocol exhibit more than an order of magnitude higher minimum detectable quantities than a newer instrument similarly tuned.

Similar differences exist between older capillary columns and new ones with different bonded phases. Continued improvements are inevitable, thus even if the protocols were precisely defined and there were no other source of analytical variability, the regulatory cutoff would decrease as this analytical hardware is improved.

Moreover, as methods and instruments are further improved, EPA's rule provides no assurance that the protocols will not be modified repeatedly to incorporate new methods with lower limits of quantitation. Such changes will necessitate costly revalidation with each incorporated improvement.

The uncertainty and inevitable inconsistency of a nonquantifiable approach is greatly magnified under EPA's proposal since the proposal fails to establish a validated, workable, analytical method for the analytical chemist leaving him to determine the limit of quantitation on his own.

EPA's proposal in the Federal Register, of course,

does not more than specify the measurement technique to be used, capillary GC electron impact, mass spectrometry, leaving the full analytical method as an unvalidated series of nebulous options.

Even EPA's guidelins as described in MRI's interim protocols leave the most critical decisions to the individual analytical chemists and are largely unworkable and still unvalidated. Ironically, in contrast to EPA's original proposal, these guidelines offer a choice of separation techniques, either packed column or capillary column gas chromatography.

While the CMA approves this choice as scientifically justified, this new choice highlights the great range of decisions left to the individual analyst. This choice, like most of those left to the chemist, will affect ultimate quantifiability of certain isomers or isomer pairs.

In addition to offering this choice of separation techniques, MRI's guidelines leave totally open the question of extraction, clean-up, or concentration procedures. MRI's guidelines permit dilution or direct injection, that is, no sample pretreatment at all or a choice of numerous extraction methods.

The guidelines explicitly state in describing liquid-liquid extraction, the solvent -- number of extractions, solvent-to-sample ratio, and other parameters

uniquely dependent on the nature of the original matrix. The other chemicals it may contain at various levels and similar factors and the limit of quantitation can only be specified after proper method validation.

Indeed, in the analytical task group's experience, many of the techniques described in MRI's guidelines have proven unworkable or impractical for inadvertently generated PCBs in organic matrices with analytical properties similar to those of PCBs themselves.

The extraction and clean-up techniques suggested in the guidelines were designed for use on environmental or other samples containing commercial PCB mixtures such as Aroclor, Kaneclor, and other fluids. Such methods are not readily transferable to the types of analyses required under this rule.

For example, an environmental matrices which normally contain a relatively small quantity of chemicals with properties similar to those of PCBs, the amount of absorbent and solvent needed in the recommended clean-ups to separate interferences is manageable, but in product or waste matrices in which the ratio of interferences to PCBs is orders of magnitude larger, the amount of needed absorbent and solvent is unmanagebly high.

Similarly, none of the proposed extraction-clean-up techniques is applicable to tarry matrices which sometimes

are chosen at the analyst's discretion. Similarly for clean-up, the guidelines describe eight alternative techniques but state only that a surrogate spiked sample is to be cleaned up at the discretion of the analyst.

The degree and rigor or extraction and clean-up are central both to the ultimate performance and limits of quantitation of any PCB analytical method and to its cost.

In the experience of the members of the task group, these steps in a procedure affect ultimate quantifiability by several orders of magnitude. Indeed, limits of detection and quantitation for PCBs in environmental samples have fallen several orders of magnitude over the past 10 to 15 years because of improvements in sample clean-up which removed interfering pesticide residues.

Similar differences in limits of quantitation are likely to exist between those samples under this rule which are subjected to clean-up and those which are not. It is not surprising that EPA has been unable to specify these method steps.

No capillary GC electron impact mass spec method has yet been validated for use on the types of samples to which the method pertains and many of the suggested alternatives have never been tried with analyses for inadvertently generated PCBs.

Proper extraction and clean-up techniques are

will have to be analyzed. Even worse, some of the matrices which contain inadvertently generated PCBs are themselves the best solvents for PCBs making any extraction or clean-up virtually impossible.

In short, EPA's proposed nonquantifiable cutoff will have arbitrary and inconsistent results. A non-quantifiable cutoff will result in substances with similar PCB levels being regulated differently, both because of the substantially differing matrices and because of the complexity of analyzing all 209 chlorobiphenyl congeners.

This inconsistency is compounded by EPA's failure and ultimate inability to specify the required analytical procedures. Most importantly, the nonquantifiable cutoff provides no analytical target at all thus requiring the analytical chemist himself to define the regulatory cutoff instead of the regulatory authority.

The only analytically sensible way to define excluded processes is to specify in advance the regulatory cutoff, that is, the performance standard or criteria the analyst must meet. Only a cutoff, determined primarily on the basis of appropriate health and exposure related factors gives the analytical chemist the guidance necessary to make decisions concerning necessary analytical procedures.

Moreover, only a cutoff set at an analytically feasible level can eliminate the irrational and

irreconcilable results of EPA's nonquantifiable approach. Of course, even a cutoff must be accompanied by appropriate analytical guidelines to guide compliance and enforcement.

As I suggested at the output -- outset -- a nonquantifiable cutoff with no lower limit presents the analytical chemist with an impossible dilemma. As analytical techniques have improved, analytical chemists have concluded that it is virtually impossible to state that any chemical is absent from a particular matrix.

In the case of PCBs, by investing greater and greater resources into the analysis of any given sample, lower and lower amounts of PCB congeners will become quantifiable almost without limit. For example, by using successive exhaustive and highly expensive chromatographic clean-up procedures, some samples could be cleaned up and interferences removed sufficiently to make low part per billion or part per trillion concentrations of some PCB congeners quantifiable.

Since only a single congener need be quantifiable to eliminate the regulatory exclusion, the limit of quantitation in this light is an extremely low threshold. Similarly, adjustments in the mass spectrometer can be devised to further reduce the limit of quantitation.

Of course, the cost in terms of time and resources become prohibitive for routine usage of such procedures.

In light of these possibilities, when can the analyst stop analyzing his samples and honestly say that PCBs are not quantifiable? Analytical chemistry itself provides no answer. Indeed, EPA's guidelines designed to answer this question suggest that the chemist must investigate available procedures and analyze his samples until he quantifies PCBs without any limit.

For example, MRI specified GC-MS operating parameters are described as minimum suggesting that a more sensitive parameter may, or perhaps should be used. MRI's guidelines on Page B-13. The guidelines specify that simple volumetric dilution rather than extraction may be used where the PCB concentration is high implying that alternate and continually more rigorous procedures must be chosen when low concentrations are involved.

Most significantly, in a somewhat ambiguous reference, the protocol states that upon an injection of a sample aliquot, if the responses of any PCB ion are below the mass spectrometer's working range, recheck system performance, concentrate the sample, emphasized, and reanalyze.

It is difficult to escape the conclusion that samples are to be analyzed using whatever procedures are necessary to detect and measure PCBs. Indeed, EPA's proposal itself suggests the same thing. It is apparently

designed to exclude from regulation only those processes emitting zero PCBs or as close to zero as can be measured under the most exacting procedures.

As our comments point out, FDA considered and rejected an identical regulatory search for zero regime as unreasonable and unmanageable. EPA should do the same.

In short, analytical chemistry cannot answer the fundamental question of the level of PCBs the analytical chemist should seek in his samples. Moreover, were EPA to attempt to define precisely and unambiguously the required analytical procedure, it would face the same questions faced by the analytical chemist under the rule; what procedures are sufficient?

Specification of a procedure will thus constitute a de factor, albeit variable, regulatory cutoff. Only an independent determination of the acceptable PCB levels can begin to provide the information necessary to answer the question of what the cutoff should be.

Moreover, only a cutoff can eliminate the irrationality and uncertainty which are inevitable under a nonquantifiable approach. A known specified cutoff provides the chemist a target toward which he can calibrate and develop his methods.

Knowing the general composition of his samples and performance of his analytical techniques on those samples,

he can develop techniques sensitive enough to assure that the sum of all possible congeners cannot exceed the cutoff if it is set at an analytically feasible level.

If his product contains lower chlorinated biphenyls which generate fewer but more intense peaks than the higher chlorinated congeners, he may be able to use different clean-up techniques to assure that he would be able to measure these congeners at the cutoff level.

Similarly, if two congeners co-allude on his column, his calculation procedure would account for this and would be adequate to determine whether he meets the cutoff. Of course, a regulatory cutoff can only be enforced using analytical methods.

Accordingly, a cutoff must be accompanied by appropriate analytical guidelines both to promote uniform compliance with the rule and to guide enforcement.

CMA's PCB Analytical Task Group will gladly assist the agency in developing appropriate guidelines. We feel such guidelines should contain, first, a description of the analytical method to be used for enforcement purposes. GC-MS techniques are the preferred measurement techniques, though as out previous comments show, extraction and clean-up techniques are inevitably unique to the matrix under study.

Secondly, a deecription of appropriate validation criteria. Every method must be validated according to such

criteria before its use for regulatory purposes to ensure data reliability. Validation must be accomplished on the matrix to which the method is to be applied and be performed over a range of concentrations above and below the cutoff level.

Thirdly, a description of appropriate quality assurance procedures to assure data reliability in ongoing analyses. Quality assurance procedures should be adopted to assure purity of standards, to establish the performance of laboratory equipment, and to assess method performance criteria.

Most importantly, guidelines accompanying any cutoff must recognize the uncertainty inherent in any analytical methodology. Validated methods include a measure of variability which must be acknowledged in making regulatory decisions.

Recent commentators have reemphasized this important point and I'd like to quote the following from a statement which has appeared in Analytical Chemistry by L. B. Rogers, et al.

"Analytical chemical data are central to governmental and industrial decisions relevant to regulations that can have far-reaching impacts on society. When the results of chemical analysis are used for regulatory purpose, the information must be reliable and creditable from

a scientific point of view."

"Analytical chemists must always emphasize to the public that the single most important characteristic of any analytical chemical result obtained is an adequate statement of its uncertainty interval. It is critical that the public appreciate the existence and nature of uncertainty in scientific measurement."

In other words, every method has a definable precision which delineates how the results of repetitive analyses of a given sample will vary around the measured value. This range of variability is statistically characterized as the method standard deviation often expressed as relative standard deviation or confidence interval.

Because of this variation, one can never have perfect confidence that he has identified the true value contained in a sample. Every measurement is accompanied by a confidence interval. Guidelines accompanying a regulatory cutoff should recognize this variability and indicate that analyses must provide at least 95 percent confidence that the cutoff has been exceeded before regulatory action is taken.

In addition to those points discussed above, EPA's proposal has certain technical deficiencies in other aspects which deserve comment.

First, as noted in our comments, EPA's rule appears to be based on an incorrect concept of limit of quantitation. To summarize, the proposal appears to base quantifiability on the noise level generated by the instrument itself in the absence of the matrix to be analyzed.

Such a definition is not based on sound analytical principles and cannot be justified. The American Chemical Society, in discussing method development and validation, has confirmed this point recognizing that for some samples, relative variation due to matrix effects is substantial.

The ACS committee concluded that, and I quote, "If the field blank, actual or simulated, is not properly defined in the protocol, then the results are invalid." EPA's protocol clearly must base the limit of quantitation on the ratio of the signal to the noise from the total method run on the actual matrix.

Second, I wish to emphasize that EPA's proposal will impose substantial analytical costs that have not been considered in EPA's assessment. These costs are likely to be especially onerous for small businesses with processes potentially generating incidental PCBs because they often do not have the sophisticated analytical capability or sufficient analytical resources.

Our comments mention that EPA's assessment omitted consideration of significant method development costs. In

addition, we stated that MRI's method was not routine and that therefore, EPA's estimate of monitoring costs may be underestimated substantially.

Further review of MRI's guidelines confirms that its protocol does not constitute a routine method and will be extremely costly to operate. In particular, the guidelines impose quality assurance criteria that far exceed routine monitoring requirements, particularly where one is monitoring a manufactured substance not subject to wide variability.

Most significantly, the method requires the laboretory demonstrate recoveries from 80 to 120 percent with relative standard deviation of plus or minus 10 percent. For some matrices, these are exacting costly standards if they are attainable at all.

In addition, the method contemplates daily documentation of performance criteria and requires that 10 percent of the qualitative determinations and 10 percent of the quantitative measurements be checked by a second mass spectrometer.

Indeed, many of the industries affected by this proposed rule do not even have one mass spectrometer. These and other requirements will add dramatically to costs incurred by both industrial and regulatory laboratories for analyses which already average about $1,000 a sample.

Finally and most important, EPA's claim concerning

the validation of MRI's protocol deserves comment. EPA suggests that MRI's preliminary validation tests indicate that the proposed method is applicable and useful for the analyses of PCBs in the matrices study.

The available data do not demonstrate the adequacy of MRI's method. Indeed, based on those data, it is premature to conclude that MRI's protocol is workable and reliable for the matrices of concern here. Until very recently, MRI's methods had never been tested on any matrices like those to which it must be applied under the rule.

MRI attempted to validate selected clean-up steps by analyzing a mixture of 11 calibration standard congeners in an appropriate solvent. As we have repeatedly stated, validation must take place on actual matrices since it is the similarity of matrices to PCB that makes analysis and clean-up for inadvertently generated PCBs so difficult.

Accordingly, MRI's standard solution validation says little about the performance of the method in actual matrices. Indeed, MRI indicated that the experiment should be repeated.

In late May, CMA sent MRI aliquots of the samples used in CMA's round-robin for further validation work. While five samples were sent, analyses of only two are reported. The extraction and clean-up procedures used

are not specified.

Recovery values for each analysis are not reported either. MRI reports the average PCB level it found in samples CMA-A as 400 parts per million. This average, during CMA's round-robin -- excuse me, the average during CMA's round-robin of 25 determinations in nine laboratories, eight of which used GC-MS on that sample, was 280 parts per million.

The highest value reported in the round-robin from a single laboratory was 412 parts per million using the relatively nonspecific electron capture detector. MRI's validation results for sample CMA-E were similar. MRI's average was about 18 parts per million, twice that of the round-robin.

These results raise significant concerns about the applicability of MRI's methods as currently written to these types of samples, especially since these are not the most difficult matrices encountered by the CMA task group laboratories.

Whatever the procedures used, they resulted in values up to 100 percent higher than those of laboratories more experienced in these types of analyses. Consequently, these data surely do not provide a basis for supporting the applicability of MRI's methods and suggest that the methods as written have potential substantial high bias which is

significant when dealing with a nonquantifiable cutoff.

Finally, MRI's validation fails to address perhaps the most important consideration for this rule. It does not specify or even estimate the limit of quantitation for these or any other samples. Limit of quantitation is not even addressed in MRI's interim guidelines.

Moreover, the guidelines provide no practical information how to determine LOQ for any particular sample. Since the limit of quantitation is clearly the most critical performance parameter for this proposed rule, it must be experimentally determined in a statistically reliable way for each individual matrix.

MRI has failed to provide information on how to determine LOQ or how to validate LOQ determination in any specific samples. Accordingly, EPA's proposed method is far from validated and is not practically usable to comply with or enforce EPA's proposed rules.

MRI's protocols are, by and large, technically competent though EPA cannot assume that they are suitable for use with its rule. But this overall technical competence should not obscure the fundamental point that EPA's whole nonquantifiable approach is analytically unsound.

It will lead to inconsistent and irrational results. It does not provide a validated, workable,

enforcement or compliance method and in essence, requires each individual analytical chemist to define the level of PCBs that is quantifiable.

Only a specified regulatory cutoff can remedy these problems. Indeed, only a prior determination of the permissible PCB level allows sensible decisions concerning necessary analytical procedures. EPA must make this determination directly.

It is unfair and surely inappropriate to shift this decision to the analytical chemist in the regulated industry as the current rule does.

I appreciate this opportunity to testify and wish to thank the members of the CMA Analytical Task Group for their assistance. Ken will be happy now to address any questions.

DR. BURGESS: Mr. Guimond, Dr. Cox did have to leave but I think Dr. Raley and myself will at least try to answer whatever questions you have.

MR. GUIMOND: Fine, thank you very much. I'm sure we'll have a number of questions from the various members of the panel. I'd like to start off on my left with Alan Carpien.

MR. CARPIEN: I only have two brief statements, questions, much of what we'll be discussing here obviously will be of a technical nature and I'm sure -- by the way,

thank you very much for your highly competent technical scientific testimony.

I want to make one clarification. Several times during the testimony, the statements were made -- see if I can find the exact page -- that this regulation is designed to exclude from regulation only those processes emitting zero PCBs or as close to zero as can be measured under the most exacting procedures.

I'd like to point out that while EPA has stated that we're excluding these processes, a class of processes within this rule, I don't believe -- it's not a question of not believing -- at no point in the regulation or at any time during this procedure have we ever said that only these processes will be excluded from regulation.

EPA has always maintained that we have a third rule -- you know, we've talked about the electrical use rule, we talk about this rule, and we know there's a third rule. While this rule does exclude certain processes, we have by no means ever stated that it is the only, these are the only processes, or that this rule will establish a regulatory cutoff.

My only question really, I guess, that I could ask that -- it's sort of related to that and that would be suppose this rule went out as is or substantially as is with changes based upon many of the comments and in the

third rule we were to propose or consider a 50 part per million cutoff, would CMA, as an association, have objections to that?

DR. BURGESS: I think -- we've got to look at the two things quite separately. We have heard about potential Rule 3, we've seen nothing nor heard about the specifics of Rule 3. As we have said, we think a 50 ppm cutoff is a reasonable, justifiable cutoff, and what resemblance it bears to this rule or why continue working on this rule if such a thing is to be a part of Rule 3 is a little hard to comprehend.

MR. CARPIEN: Again, thank you very much for your testimony and let's get on with the technical aspects of this. Thank you.

MR. GUIMOND: Bill?

MR. GUNTER: Dr. Burgess, I'd like to follow-up on that question. It seems to me there are two possibilities with respect to this rule that EPA could go forward with it or they could do as CMA suggests, to withdraw it, and there are two possibilities with respect to Rule No. 3, that EPA could pursue the course that CMA recommends by promulgating a cutoff or we could pursue some other regulatory approach and I'd like to look at the various combinations of those approaches.

Case No. 1 would be if we went ahead and issued

this rule and then came out with a cutoff in Rule 3.

Case No. 2 would be if we did not proceed with this rule and came out with a cutoff in Rule 3.

Can you explain to me how anybody would be any better off under Case No. 2 than under Case No. 1?

DR. BURGESS: I'm not sure what you mean by anyone. No. 1, we could get at the real issues earlier if we discontinued Case No. 1. If Case No. 1, as we have presumed, and I must say again, as I did in my comments, that we think there is no benefit to anyone from Rule 2 or whatever you want to call this rule, but the analytical thing is so definite -- so indefinite -- that maybe there's benefits there that I haven't seen.

I've heard analytical chemists, pretty intelligent people, arguing at fairly great length as to just what analytical procedure is and what limit of quantification relative to what has been proposed is going to be and I have to admit that as a non-analytical chemists, I can sit back and say that the order of magnitude that Dr. Raley was talking about frightens me but from what I heard, it's not an an order of magnitude, it's several orders of magnitude.

MR. GUIMOND: Could you speak closer to the microphone?

DR. BURGESS: I'll aim it at my -- perhaps that

will -- is it better in the back?

Testing one, two, three, four -- can you hear me now?

It would depend on the timing, on the sequence in what is Rule 3. You're asking a question to which really there is no definitive answer.

MR. GUNTER: If Rule 3 were cut off, would anybody be better of by EPA not promulgating Rule 2 as a result?

DR. BURGESS: It depends on what the cutoff is, it depends on many factors. I guess I can turn it around. Would anyone -- would the effort that's going into Rule 2 have produced any results? You know, you're spending time, we're spending time.

MR. GUNTER: Let me go back to some of the origins of this rule. This rule was suggested originally by CMA in discussions that followed the decision of the Court of Appeals and now CMA seems to be almost totally reversing themselves.

Is it because you've rethought the matter or is there some particular aspect of the way EPA is implementing this that troubles you? I think you have identified two of those issues today, one being the nonquantifiable approach versus setting some limit and the other being the disposal cost.

Is it that those aspects are so different from

what you originally conceived that you no longer support the idea or have you had second thoughts about the concept in general?

DR. BURGESS: The concept as I identified in my testimony, we still agree with. I think it's probably a case of poor communications between ourselves and the people in the agency when we originally proposed that thing. I think everyone in the industry recognised that a limit of detection or limit of quantification would be totally unacceptable. That was the worst thing in my estimation and I expressed it to many people many times, that the worst thing would be a limit of detection or limit of quantification.

To go with a no-regulated quantity released, and by that in my mind, I was talking 50 ppm, was what we were talking -- I think it was a case of very bad miscommunication between the two groups. Certainly anyone who has ever worked with FDA and the Delaney clause recognised the problem of zero.

MR. GUNTER: Would CMA's objection be at least partially satisfied if EPA specified for purposes of this rule only numerical values that would be approximately equal to currently achievable LOQ's?

DR. BURGESS: I guess I would have to review that in some detail. Number one, as Dr. Kaley has testified, numerical values limited to LOQ's is going to be considerably

different for different congeners and different matrices. So I'm not sure how you're going to do that.

In one case, you may be at 10 parts per billion and another case at 100 parts per million.

MR. GUNTER: Dr. Raley, your testimony indicated that this regulatory approach put quite a burden on the analytical chemist and -- much better from his point of view if there were some value established and then a procedure designed to meet that value and that's the point I'm trying to get at.

DR. BURGESS: Well, Mr. Gunter, I have used an analogy -- I'm getting a reputation for analogies, I guess -- I have used an analogy that I think is appropriate here for the analytical chemist. It's like telling an engineer design a car to go 100 miles an hour efficiently or design a car to go as fast as it will go efficienty.

Those are two different things, orders of magnitude difference in what you're asking the engineer or in this case, the analytical chemist to do, and I think here when you say limit of quantification, you're asking the analytical chemist to design a process that will do the best it can.

MR. GUNTER: But my question was that if EPA specified numbers that would give the analytical chemist a specific target to shoot for such as the 100 miles per hour

in your analogy, would that meet at least some of CMA's objections?

DR. KALEY: Well, first of all, I guess it's obvious to both of us that that depends on what those numbers might be. I think the answer to the rest of the question is in certain cases, I think that would be a benefit. The advantage to us would be that it would allow us to target our resources to those matrices which we do not feel we are at present capable of reaching a cutoff analysis in.

So if we had a reasonable analytical cutoff or a regulatory cutoff, then we would have a feel for where those resources needed to be aimed in order to clear up the questions we still have. In the current proposed rule, we have to assume that all of our resources have to be applied to all of the samples in order to determine our limit of quantitation in every particular sample and it's just an economic and analytical impossibility.

End Tape 2)

MR. GUNTER: One more follow up question. You don't have to respond today, but you could give it some thought and perhaps give us your answer in reply comments.

In your opinion, what should that analytical base value be for the various media?

I would like to turn finally to one last point, and that is the disposal costs that you cited, Dr. Burgess, for the waste generated from these processes.

And, you pointed out that when EPA lowered the concentration cut off for the disposal from 500 to 50 parts per million, we specified certain alternate, less stringent disposal methods.

Could you suggest any alternate, less stringent disposal methods for these wastes that have under 50 parts per million PCB's?

DR. BURGESS: Of course, many of those wastes contain, as do many chemical plant wastes, contain hazardous substances other than PCB's and are currently being processed as such.

To go into the limit -- the available PCB approved disposal, whereas many -- it would be a problem because as I say, many of them are already going to incinerators as the CMA document indicated and if you are talking, as your end numbers came up with 100,000 pounds of material, if all of that were going to an incinerator, which were 99.9

versus the 99.999 on an Amex One incinerator that would be required if we went to PCB approved incineration, you are talking the difference between one pound and 99 pounds or something such as that. I didn't -- I'm not sure of my numbers, but it's not very significantly different.

And, yet, the 99.9 incinverator is in general not going to be available to us. Many of those wastes should be incinerated. There is little doubt about that. Many of those wastes should be incinerated. Most of the incinerators where they are now going are perfectly competent to handle them, are probably over 99.9.

Some of them, in this case it would not make the same degree of difference, could go to landfill and be handled that way.

MR. GUNTER: Would it make much of a dent in that one million dollar figure if EPA defined incineration to be in any RCRA approved facility for those that do fall in the category you mentioned of being hazardous wastes?

DR. BURGESS: Certainly, if some of the RCRA definitions were included in that and those incinerators, I'm not that familiar with RCRA. I know some of those are called process units, rather than incinerators, and there are a lot of different definitions.

But, that type of thing would certainly help.

MR. GUNTER: That's all I have. Thank you.

DR. BURGESS: Before I leave today, I should point out that much of that waste, which is going to contribute significantly to the large number and we are trying to get a more definite fix on this number and hope to have it by the time of the reply comments, one of the big problems is water.

And the incineration of water is an expensive operation. It can be done, but it is expensive.

MS. CAMPBELL: My first question relates to the issue of water which you just brought up, PCB contaminated water.

I was wondering how the costs were increased by this regulation, since the effluent guidelines limitations are already lower than anything we are proposing in this rule?

DR. BURGESS: But you're requiring that waste be disposed of by a PCB approved disposal facility. And those facilities are different than RCRA or effluent guidelines or any other facility.

MS. CAMPBELL: Okay. The other question we asked in the regulation, but I was wondering if you have any data related to the number of accidental or unplanned releases of PCB's and, if so, what amount of PCB's would be released during those events?

DR. BURGESS: I think the data that was submitted in the Versar report is as accurate as anything that we would have, relative to that. Certainly, spills -- we don't

have any hard data, but -- and, I think they treat that quite fairly.

They didn't really deal with explosions. Those are such infrequent things that we don't have good statistics on it. Certainly, it's something we try to avoid rather vigorously and when we have an explosion, the problem is usually not the PCB's, the explosion of PCB's; if you have an explosion, you have a number of elements that you have to take care of, people injured by shrapnel, people burned, something such as that, and you have a clean up procedure that you have to go through, whether there are PCB's there or not.

But, the frequency of such things is so de minimis that I don't have good data on that.

MS. CAMPBELL: I would also be interested in the type of protective clothing and the kind of material in the clothing used during the times of worker exposure that were indicated in the CMA submission.

DR. BURGESS: It will vary with different plants and different chemicals. If -- and, it is primarily aimed at the primary chemical. The protection will be aimed at the primary chemicals.

Most plants will have procedures for so-called hazardous operations as line opening. If you are going to do a maintenance job and have to open the line.

The normal requirement there would be face shield, as well as, in most, just common working, you would have eye protection and probably gloves.

If you are handling waste streams, normally you are going to have gloves on. Versar, even though they found the exposure quite small, did assume that that exposure came from the fact that anyone handling waste had both hands constantly wet on both sides during the entire operation of handling wastes.

I would certainly hope no one would practice that, whether you were doing it yourself or asking someone else. That type of thing would not be done.

Certainly, some nomex clothing in some cases, if there is hazard from fire from the primary chemicals, but very little of that would be aimed at the PCB. It would be aimed at the primary chemicals.

MR. GUNTER: Amy Moll?

MS. MOLL: You continually cite in your analysis the fact that EPA should call for a method validiation and also that EPA underestimated its costs because it did not include the cost of method development and method validation.

You probably don't have figures on the tip of your tongue, but if you could provide us with some estimates of the costs of method development and method

validation, that would be helpful to us.

DR. BURGESS: Well, obviously, the more validations you do on the more streams, the second one is not going to be as expensive as the first, but it is still an expensive procedure.

Rob, did you want to have any comment or should we just comment in reply comments?

DR. KALEY: Well, I think primarily anything more specific that we might have to say will have to be in the reply comments.

I think we did make some limited information available in conjunction with both our first submission, "The Analysis of Chlorinated Biphenyls" and in the report on the round robin experiment.

And, I'm not sure we've really got anything better than that. We have discussed these issues at our various meetings and it becomes difficult because, frankly, we don't know what it is going to take to validate a method such as proposed in the variety of matrixes that we will have to encounter.

And, the limited quantitation issue just makes even more critical, because our validation, instead of being some relatively workable level, like 50 parts per million, has to -- essentially, to be done right, extend below our limit of quantitation and we're really not sure how to

address that at this point.

I will take down your question. We will do our best to get some more -- get some firm answers to you in the reply comments.

MS. MOLL: Do you feel that the method will have to be validated on every single different process that we encounter?

DR. KALEY: Yes, we definitely do feel that.

MS. MOLL: Okay.

DR. KALEY: That's one of the primary issues of my testimony, is that validation must be on the matrix of interest. So, for every regulated or excluded matrix, we will have to have a validated method.

DR. BURGESS: Your question there, you use the term process; we use the term matrix. They may be analogous, but there may be situations where they aren't also.

MS. MOLL: Okay. You cited, Dr. Kaley, you cited the potentially large burden on small businesses, that could result from this rule.

Do you have any idea as to the number of small businesses that might be affected?

DR. BURGESS: I think it would be pure speculation. Versar has listed the processes that, although I'm not sure that that is comprehensive, but it

would be pure speculation to go beyond that list that Versar has already compiled.

MS. MOLL: Okay. And, I have one more follow up on Bill's question. He asked you about suggestions for destruction of PCB's in concentrations below 50 parts per million.

Once you've come up with that suggestion, can you give us any idea as to the differences in costs between the methods that discharge each of these in concentrations greater than 50 parts per million and those that you might suggest are less than 50 parts per million?

DR. BURGESS: Well, I think the main thing that we are looking at, the last figure that I heard for destruction of PCB's in an Amex One incinerator was around 60 cents a pound and that is what is quoted in our comments.

That certainly is a figure that is much higher and whether it's 5 times higher or 10 times higher than incineration of normal wastes, but I think we're talking in that ballpark, that most wastes can be incinerated for -- maybe it's somewhere between 5 and 20 cents a pound, although water is unique again. Whereas, the Amex One commercial incinerators are, the last I knew, were quoting about 60 cents a pound.

MS. MOLL: Okay. That's all I have.

MR. GUIMOND: Okay. I have a few questions.

If I understand your testimony today and some of the comments that you made previously, you'd prefer that we withdrew this and than went out and said that inadvertent PCB's are not covered and, therefore, exclude everything on that basis. And, in the alternative, withdraw this and put a 50 ppm cut off. Am I correct?

DR. BURGESS: Yes, I think we feel that this proposal is -- you are taking your resources and ours away from the real issue of what is the risk to incidental generated PCB's.

MR. GUIMOND: Okay. If I take that first option or proposal of yours and withdraw this and propose that inadvertent PCB's not covered by TOSCA, how would you define inadvertent PCB's?

DR. BURGESS: I haven't given specific thought to that. We are having a panel meeting tomorrow.

Basically, it is those PCB's generated -- maybe you could use something like the FDA has in their constituent policy that have no function in the product. They are not there for any preferred properties. They are unintentional, they are unwanted in general.

We would be glad to sit down and work out some kind of --

MR. GUIMOND: Would you envision something that was regardless of concentration or amount or something, just

as long as you don't want it, it would qualify as unintentional?

DR. BURGESS: I think that those cases that we are aware of today, concentrations are extremely low. I know -- at least that I know of.

I know of no situation where we're talking percents of PCB's. Certainly, in that situation, if someone comes along and is going to sell a product that is 49 percent and call that inadvertent, I guess probably we ought to define that out obviously.

MR. GUIMOND: Okay. That, I think, is one potential problem, is a definitional issue. But, in any event, -- okay.

Then, if I -- your second alternative then, which was, okay, withdraw this, put a 50 ppm cut off or somehow put one 50 ppm cut off, wherever possible. then on page 8. in your comments. I noted the last paragraph on the page, it says, "Due to unique circumstances of this proceeding, however, another course is open to EPA. CMA would be prepared to support an approach permitting PCB's and closed processes and in waste streams, disposed of under EPA's PCB disposal requirement, providing that there were a regulatory cut off of at least 50 ppm for products in waste streams".

Am I to interpret that, that you mean that you --

is this the same alternative as your overall 50 ppm or is it a third alternative in which you would say if we were to define closed systems so that it was defined at 50 ppm and products and waste streams qualified you, that that would be acceptable to you?

DR. BURGESS: Basically, it's going back to the original concept which was discussed with with obvious misunderstanding.

The current rule, if you have in a recycle stream, a thousand parts per million, you must get an exemption for that process.

It is still, I think -- as long as that's in a recycle stream, it's going around a pipe, it never gets out. So, if the product and the waste are below 50, you don't have any real concern about what's in that recycle stream.

We maintain no, that there isn't. So that we are still interested in getting that recycle stream or any at the bottom of a still or some --

MR. GUIMOND: I guess what I'm driving at here is that if you recall the proposal that now sits, it sits that it is non-quantifiable for effluents, emissions, for waste products, waste streams to be closed and controlled.

And, then, for control, you can dispose of the waste, as you have said in there, and then you could qualify

As I read this, if you're saying that if we change the products and wastes portions of that definition, to state that 50 ppm number for those two portions of the definition, that would be acceptable to you, is that correct?

DR. BURGESS: Basically, we are saying no, if the emissions are not above a regulated level, whether they are in product or waste of air or water; the emissions are not above a regulated level.

That is what we have thought we were talking about a year and a half ago.

MR. GUIMOND: So, waste streams, too, means more than just waste; it means effluents and emissions, too, is that correct?

DR. BURGESS: I think we've got to look at the entire -- whatever is coming out, relative to exposure.

MR. GUIMOND: Okay, okay. So, you mean 50 ppm all over, this is not a subset. What I was trying to determine was whether you were talking about a subset products and wastes as opposed to effluents and emissions. You mean the whole shebang?

DR. BURGESS: I'm talking about regulated quantities being dissipated into the environment or for exposure.

MR. GUIMOND: Okay. Thank you. I guess I've been a little bit puzzled and trying to answer the question

myself, as to this misunderstanding that we apparently have, and I went back and took a look at some of the historical information that we've had here relative to this, and if you take a look at the EPA submission to the Court back in January, I guess, of '81, on page 18 of that, there is a section that states, this was done subsequent to discussions we had with yourselves and a variety of other groups, "The industry representatives participating in the discussions of the EPA and EDF believe that most of the PCB's which are generated in concentrations below 50 ppm are generated either in closed chemical processes in which the PCB's are both generated and destroyed, to the present levels of detectability, within the processes, without ever leaving the closed process (closed system) or in chemical processes where any PCB's are removed from the process as wastes which are either incinerated or disposed of in EPA approved landfills or stored for such disposal (controlled wastes)."

"Some chemical processes may produce low concentrations of PCB's which are released to the environment, appear in the final product, are disposed of in non-EPA approved landfills or by other disposal means (uncontrolled releases). These are thought to account for a much smaller portion of the total generation of PCB's below 50 ppm".

You know, we have sort of been operating for a long

period of time that that's the way we thought the world was and so, from the standpoint of what I hear you saying in your comments today, you are indicating to us that, in fact, the reverse is true, very few processes would qualify for closed or controlled wastes as presented there and most would fit into the other category. Is that correct?

DR. BURGESS: I think two things have happened: we have learned more about our processes. Also, the fact that you have been working on the analytical methods and we have been working on the analytical methods, and as Dr. Kaley has indicated, analytical methods move, I think we know a lot more how to analyze for things today than we did 18 months ago when we were talking.

I don't know whether the limit of quantification has been cut by a factor of 2 or 10 or 100, but I'm sure that the limit of quantification has gone down and we certainly know how to quantify at lower levels today.

We also learned more about our processes and I guess, again, I think there is some misunderstanding and I can't argue with what you have written because I haven't read it.

But, there certainly was considerable emphasis that we could not go to a detectable limit. At the time one of the orders was to be written or was being written for the Court, the word detectable PCB showed up in the thing and

we had a considerable emergency in trying to get some of the CMA people to go talk with the people, your people who were writing that to try and get the word detectable out of the document.

I think, as I say, it's an unfortunate case of misunderstanding.

MR. GUIMOND: Okay. If, again, I understand your testimony, you indicated that you felt very few -- this exclusion proposed rule would have very little good since few, if any, people would likely qualify.

DR. BURGESS: If we understand the analytical, I think it is technology forcing, if we understand it correctly and that the limit of quantification is going to be considerably different.

As Dr. Raley said, you give those analytical chemists enough money and enough time and they can change the limit of quantification.

MR. GUIMOND: We have received some comments, that some people have felt that they believe they may qualify for this. But, to pursue your question, then you did indicate further that the costs associated with the proposed rule would be very high.

If few people are going to qualify, obviously, there would be no reason for them to try to take advantage of the exclusion, so they would have no cost in doing that, would that

be correct?

DR. BURGESS: Excuse me. I don't --

MR. GUIMOND: Well, if you don't think you qualify for this, you're not going to undertake an extensive monitoring program or theoretical assessment or what have you, where you anticipate the cost are going to be, to show that you qualify for this. So, in fact, there would not be high costs if, as you indicate, that there would be few people qualifying for the thing.

DR. BURGESS: Well, if you are ready to say we will file for an annual exemption, there is great incentive to not have to file for an annual exemption.

Certainly, if you were ready to say we are just going to file for an annual exemption, then all your costs are involved with filing for the annual exemption.

There again, we get back to what is Rule 3 going to say? And, I have no idea. I hope at some point we find out.

MR. GUIMOND: So, you're saying a lot of people would really like to be able to qualify for this and so the costs would be involved in trying to see if they can possibly determine whether they could qualify?

DR. BURGESS: An annual exemption for an on-going chemical process is very onerous.

MR. GUIMOND: Okay. So, again, if I interpret

that, you would indicate that a lot of people, because of the onerousness of the annual exemption and the uncertainty associated with Rule 3 at thie stage, would very much like to try to qualify for this exclusion, if they feasibly could, and, therefore, would undertake a considerable monitoring effort to assure themselves or to try to qualify?

DR. BURGESS: Right. Again, it's dependent on what happens with Rule 3. You could get halfway through it and find Rule 3 took care of you.

MR. GUIMOND: The -- this is a question for either you or Dr. Kaley, I'm not quite sure which one of you would want to take it.

Right now, you had indicated some problem associated with -- throughout your testimony, problems associated with the detection of the PCB's in difficult media, tar, solvents, what have you, and what I'm wondering right now is what techniques are people using to insure compliance with 50 ppm?

Are they having any problems with detecting the 50 ppm detectable everywhere?

DR. KALEY: I can answer the last part of your question, and then I will let Ken address the second part, because I, frankly, don't know the answer.

The true is that no, 50 parts per million are not detectable in some matrices. The submission we gave EPA

concerning the "Analysis of Chlorinated Biphenyls" showed an example of actual chromatograms where, I believe it was one hundred parts per million spike into one of these tarry, crumby matrices that in essence showed no detectable peaks above baseline for the PCB's.

This was 100 parts per million total PCB's. I don't frankly know what the individual congener concentrations might have been. There certainly are matrices where these problems exist, and what is done with these matrices, frankly, I don't know, after the numbers are reported.

But, certainly, we still report numbers, non-detected, less than 100 parts per million. That type of thing. Okay. Let me -- our plea for a cut off is that let us have our resources to go after those hard problems, so that we can try different ways of cleaning up or separation or whatever for those difficult problems, so that we can help our engineers or our environmental people make those decisions wisely.

MR. GUIMOND: Okay. Now, -- so, 50 ppm is not -- you cannot detect it in certain difficult media at the moment?

DR. BURGESS: I think that's true.

DR. KALEY: That's true. You are basically dealing with waste streams when you are --

MR. GUIMOND: Processes, too?

DR. BURGESS: There may be some -- I'm not familiar with them, but there may be some fairly complex processes where it's inside the equipment. Certainly, the 50 ppm cut off has been technology forcing and continues to be.

MR. GUIMOND: Then, but if I understand you correctly, you are willing to accept that?

DR. BURGESS: That's what we have proposed, yes.

MR. GUIMOND: In which case, you -- what would be the net result, either now you would have to develop methodology to be able to achieve that or, secondly, you would just well, we can't find it, it's not there, 50 ppm?

DR. KALEY: Well, there is another alternative in which -- you know, hopefully -- I don't want to speak for anybody, but at certain points, you would assume that the PCB's might be at a higher level and treat that material as if they were PCB contaminated. I don't know.

MR. GUIMOND: Okay. On some kind of a theoretical basis or something?

DR. KALEY: Well, if you would expect that PCB's might be in that type of matrix.

MR. GUIMOND: Okay.

DR. KALEY: I mean, in general, we signals. If we cannot define whether that signal is or is not a PCB, then, you know, we have to almost assume that the PCB's could be in there, up to that limit of quantification.

DR. BURGESS: I think I would like to just add to what Dr. Kaley has said. I think the product streams and anything that is being distributed has been pretty well worked out. We maybe dealing in the question of 50 ppm which is fairly complex waste streams, most of which are being handled according and to the best of my knowledge -- obviously they are all complying with the law, so they would be handled, whether they are 50 ppm or not. They would be handled as a PCB stream.

Stuff in the process, for those people who have not -- who have filed for an exemption petition, they may have filed not knowing whether they were at 40 or 400 and still file for the exemption petition.

Again, I can't speak to that type of thing. But, as Dr. Kaley has indicated, that is an option that you have, rather than trying to pin down are you at 40 or 50 or 60. You could certainly file for the exemption petition, rather than -- because -- perhaps the likelihood is high that you are going to be there anyhow.

MR. GUIMOND: Okay. You indicated in your testimony today that you did not believe that the proposal we had provided any additional public health protection.

I guess my question is how would your proposed solutions provide additional public health protection than ours does now?

DR. BURGESS: I think our comment, at least what I meant to say, is that we have not justified -- this proposal doesn't do any calculation as to whether the public health is protected to a greater extent or not.

What we need to do is to do a risk assessment on the incidental manufactured material and what happens to it, what the exposures are, what the health effects from such environmental effects are, and determine what is an unreasonable risk.

MR. GUIMOND: Okay. Also, in comments, written comments, you indicated that you did not believe anyone would take advantage of the theoretical analysis that we have made optionable. Everybody would go out and monitor.

In fact, today, aren't a lot of people taking advantage of the theoretical analysis as opposed to 50 ppm? Everybody going out and measuring to see if they are under 50 ppm? It was my impression from talking to a lot of industry people that a lot of people are saying 1 or 50 ppm.

So, in essence, they are doing that theoretical type of thing as opposed to anything more than that. I mean, as an example, your own data -- an example of your own data from the survey that you sent to us, much of the data in there was not data reported from monitoring results, but was data reported from theoretical calculations that

people did indicating that they, in fact, felt that they may very well generate some PCB's, but they did a calculation and it was, you know, well under 50 or whatever.

I'm trying to see what --

DR. BURGESS: Calculating as to whether you are meeting 50 ppm requirements or whether you are meeting a quantifiable limit, is two different things.

I suspect also that your definition of a theoretical calculation may be different than ours and we have not seen yours, so we can't compare them.

As to whether or not anyone would take advantage of it, is certainly going to depend on what are the limits of such a theoretical calculation.

MR. GUIMOND: I would anticipate that the individual processes would probably be as noted in your particular data you submitted to us, are in the best position to run their own stychiometry and their own calculations out --

DR. BURGESS: When you are dealing with quantifiable levels in the part per million range, stychiometry isn't of much help. You know, I can account for 990,000 pounds, 999,999 pounds and I've still got a hundred pounds, a hundred plus million out there. You can't even pump liquids with that kind of accuracy.

MR. GUIMOND: But, wouldn't that give you the

same problem at 50 ppm than the other?

DR. BURGESS: But, we have a tool then, we have the analytical chemist has said with some effort, we can get these analytical things worked down to where we can determine 50 part per million.

MR. GUIMOND: Okay. Then, to pursue just a little bit more one point that Bill was talking about earlier, is that you do make a very significant push for quantifying something, getting you a target, some number to shoot at here. And, do I hear that as, you know, 50 or not, some particular number other than a real embarrassment in trying to go and find a specific number that we can give you that is going to give you not necessarily a 100 percent assurance that you're going to beat it all the time, but a target to shoot at frequently, since even 50 ppm doesn't give you the 100 percent assurance?

DR. BURGESS: From an analytical standpoint, if you have -- if the analytical chemist is assigned the job of coming up with a method which is sensitive to some limit, that is vastly different than being assigned the job of defining what is quantifiable.

MR. GUIMOND: You don't mind working hard to find the stuff, you just like to make sure how hard you've got to look or exactly what you're got to look for, is that right?

DR. BURGESS: Well, I think if we look at the

definition of significance, perhaps that's -- we hate to keep looking at something that is insignificant. Obviously, at some level, PCB's, like most other chemicals, the exposure is insignificant.

Let's find out what is significant and what isn't. Let's find out what represents an unreasonable risk and aim our efforts at controlling those unreasonable risks.

MR. GUIMOND: Okay. I think I asked you this question during our lunch period, but I'll ask it again relative to this.

You just mentioned significance here. With respect to the type of things we're talking about, what are -- are there any significant exposures?

DR. BURGESS: Of the chemicals that I'm aware of, I don't know of any that I consider to be a significant exposure, to the PCB.

Again, you've got -- in this situation, you have two separate risk factors involved. One is the exposure to PCB, does it exist in the toxicity and that type of thing, but you also have the relative hazards of exposure to the primary chemical. And, you know, drinking chlorobenzene with or without PCB is not my choice regardless.

MR. GUIMOND: So, you're saying that the fact that PCB is in most of the stuff, doesn't change the hazard

associatad with one iota and, therefore, forget the PCB's.

DR. BURGESS: I'm sure that in most of the situations, PCB's are well below 50 ppm. But, chlorobenzene, carbon tetrachloride, the chemicals that we're talking about, at 500 ppm, PCB does not represent a risk. The chemical -- we've got all kinds of handling techniques for those chemicals and the chemicals are the problem, tha relative risk from the PCB is extremely small, de minimis, whatever you want to call those very small numbers.

MR. GUIMOND: Okay. Thank you very much. John?

MR. SMITH: No one has really spoken that much about sampling here. My questions are related to sampling and since no one has really spoken about them, you needn't answer now, but perhaps in the reply comments.

EPA has proposed a sequential sampling scheme which involves sample collection from randomly selected locations, at randomly selected times, within the process cycle.

Could you describe the procedure you would use to select samples to represent a process? Include the maximum number of samples that you would select to represent a process and why you selected this number, exactly how you would select the sites and times for collecting these samples, and the sample volume or waste you would collect for air, water and other matrices.

DR. BURGESS: Could -- in late late week, in trying

to discuss the sampling documents that we received, there was obviously some misunderstandings and questions as to what it really meant, and we decided we could not address it at this time because we just didn't have it resolved.

Your question sounds rather complex to me, at least. We can certainly attempt to answer that question: if we could have it in writing, it would be very helpful.

MR. SMITH: Fine. That's all I have.

MR. GUNTER: Okay. Dave?

MR. REDFORD: Before I attempt to verbalize my question, let me clarify an issue you brought up before, that in the Federal Register, it spoke about noise being determined just by using carrier gas.

That that was a misprint, I would like to let you know. Neither myself nor MIR would agree with what was stated in the Federal Register. It has to be done with the matrix. We agree with you.

Okay. In your testimony, you pointed out that some of the MIR protocols are a little too loose and you spoke about clean up and you said it was a little loose and it was left up to the analysts, a lot of the things.

Later on, in your conclusion, you recommend that we develop an analytical method and leave the clean up up to the analysts. That, I think, was your final recommendation, since it's media specific, matric specific.

Could you clarify what you mean by these two statements? They don't seem to agree with one another.

DR. KALEY: Those two statements are made in what we feel are different contexts. The first statement is made in the context that a non-quantifiable limit in which the analytical chemist is asked to define at what limit his chemical or his PCB's are going to be regulated.

So that we feel that if we are given a series of options, we have no guarantee that someone in an enforcement position won't make a different series of options that come up with a different quantifiable limit and, thus, we will be found in violation.

The second recommendation for leaving clean up and separation options open to the chemist is made in the context of regulatory cut offs, at which point we know the target level that we must be able to measure our PCB's and in that case, we can design our experiments in the way we find most effective to clean up our particular matrix and still be assured that somebody else using a different methodology will still find us in compliance at that cut off.

MR. REDFORD: So, if you're -- you're saying that if we use -- stick with the limit of quantification, you want us to come up with some kind of a very strict protocol that would need to be followed. Do you think that sort of thing is feasible?

DR. KALEY: I think that for us to be sure of compliance, we need the agency to come up with a very strict protocol that they will follow.

MR. REDFORD: You yourself have stated that, in a different matrix, though, that that's not possible.

DR. KALEY: I agree. That is the basis of our concern with this non-quantifiable approach. We don't know when to stop looking and we don't know when anybody else is going to stop looking.

End T 3

Beg T 4

DR. BURGESS: I think it's important to note that the difference between enforcement and the analytical group is also going to be a difference between supplier and customer. And, it can lead to all kinds of problems if the customer analyzes his product and finds quantifiable PCB's.

His first reaction is going to be, it must have been supplied to him from the supplier, who said it did not have quantifiable PCB's. And, he's going to go back and with a little work he may well find it in tha supplier's company. You are going to have all kinds of customer/supplier relationships.

MR. REDFORD: All right. We came out with a number that was 50 and we only came out with, say, an analytical method to clean up and we left all that loose, wouldn't the same situation exist as far as when EPA comes in to check you? If they went in and used a different method, it would

be the same situation as if it was limit of quantification. They could do whatever they felt and you could have done something completely different.

DR. KALEY: I know. But, at that point, we're talking about exceeding a previously established limit. If we do the best job that we have done, we are confident that we have done a sufficient job to determine that the PCB's in any given particular sample are less than 50 parts per million. We can be confident that EPA or anyone else coming in, a supplier, competitor, whatever, will also find that the PCB's in that particular sample are less than 50 parts per million.

Okay? In the case of non-quantifiables, we may determine that our limit of quantification is 10 parts per million. Somebody else may come in, do something different with the sample, spend 6 months trying to lower their limit of quantification, and, say, ah, but, now, I've found that my limit of quantification is one part per million on those samples and look, you've got 5. Okay?

So, we've got an order of magnitude different. I say I lower my limit of quantification to 10, somebody else says, you're above my limit of quantification at 1 and they are both telling the truth. There is no disputing of facts.

But, if the cut off is set at 50 or whatever number, then I think there would be agreement that both are

below that point.

MR. REDFORD: But, they both could come out with different numbers even if there was a limit?

DR. KALEY: I think our round robin experience, our individual laboratory experience, has shown that clearly two people analyzing the same samples of the types we're talking about, will get different numbers. The analytical variability we're talking about, I think, our round robin results have shown variabilities of plus or minus 70 percent. But, we need -- even with that, we should be sure we are still below 50 parts per million, based on our analytical variability and what the true value was.

DR. BURGESS: We have a target which is very difficult to hit and if you start swinging it around and moving it all over the place or don't tell us what the target is, it makes it even more difficult to hit.

MR. REDFORD: Okay. All right. There has been a lot of comments made from yourself and others in the written comments we've received talking about the MRI method not being validated.

If -- I'm going to have to go to two different possibilities. If we either stuck with the limit of quantitation or if we came out with a number, what do you think would be an acceptable level of validation work before you would say that the method was validated? How much

effort would you think would be needed before we could say that the method was validated?

I realize you're saying that we can't validate the clean up methods because we have to do it for a particular matrix. What about just the analytical, just the instrumental? What level do you think would be needed just for that part?

DR. KALEY: I don't think --

MR. REDFORD: Where are you going to draw the line, and stop saying that EPA hasn't validate the method?

DR. KALEY: Okay. This gets back to our basic question and I'm not sure. I think it does matter whether it's a cut off or a non-quantifiable limit.

I think validation must include the total method run on an actual sample. And, I know that you agree with that.

At that point, I think that the validation burden rests with the industry on their particular samples. I think the agency can give guidelines on what is suitable validation, so that we have some idea of what kind of statistics the agency feels we need to develop for our samples.

Okay. This gets back to the question, your very first question. In terms -- you know, we want the

options for clean up and separation and measurement in terms of a cut off type regulation, and we, speaking for myself, certainly in our laboratory and I know that at least some members of the group were willing to accept those burdens of validation, we're going to have to do them anyway.

Okay. If we talk in terms of a limit of quantitation system, frankly, I don't have an answer to your question. That's one of our concerns. I don't see how we can validate everyone of our methods as a limit of quantitation for all the matrices given a specific protocol and I don't see how the agency can either.

We both, as analytical chemists, we all have the same problems with this rule.

DR. BURGESS: Your .. analytical chemists, if they go to enforcement, aren't going to have the same kind of problem of whatever method you're using is going to have to be validated for that specific media matrix also.

MR. REDFORD: Sure, okay. If we did go to the established limit, to the number, do you think that the guidelines, the analytical guidelines that MRI had in their documents, do you think they are acceptable to that sort of a method?

DR. KALEY: Okay. I can't speak in total, but I think I made a statement, I certainly agree with it, that I think MRI people have done a fine job as far as they have

gone. They have certainly studied the field of analysis of 4 PCB's and whatever matrices were available and literature references.

I think they have identified some options which have worked in the past. Our experience is that some of these options do not work in the matrices we're talking about, but MRI has no way of knowing that because they haven't tried them on those matrices.

I think the MRI documents stands as a fine starting point for any laboratory which needs to comply with the regulatory limit. However, I don't think that the documents should necessarily be considered complete by the EPA. I think the industrial laboratories, who have more experience in these types of systems, should be allowed to modify and/or use alternative techniques to reach the regulatory cut off as long as those techniques are documented and the quality of assurance and method performance criteria are documented in that industrial laboratory.

In other words, I don't think, because something is mentioned in the MRI -- is not mentioned in the MRI documents, it should be excluded from useage for methods to comply with the regulatory cut off.

However, I think the MRI documents does serve as a very fine starting point for somebody that is going to have to comply with this cut off.

MR. REDFORD: All right. In -- if EPA has to establish a set analytical procedure, as you are recommending, analytically, not clean up, do you think we should stay with the GC MS or do you think we should leave that open like the way the MRI documents is, that you can use packed or capillary column, or -- I mean, if you want us to narrow it down, we have to narrow it down.

Just how loose are you saying?

DR. KALEY: Okay. I think --

MR. REDFORD: I'm asking you to be explicit as to what method you think EPA should follow.

DR. KALEY: I think everything we have supplied to the agency, expresses our preference for electronic impact, mass spectrometry as the preferred enforcement or compliance method.

We feel that in the matrices we're talking about, that is, in many cases, the only instrument which will allow you to determine PCB's at 50 parts per million, if you can do them at all, at that point, we would -- we feel that the agency should have a reference method which they feel will work on the samples, absent clean up procedures, so that we know what standard we are going to be judged against.

But, we also feel that the agency ought to allow the use of equivalent methods if the industry, the regulated industry, can develop information showing the equivalency

of those methods to the primary method.

In other words, we don't particularly object to havin to analyze a set number of samples by GCMS, but certain of the regulated laboratories, for certain of the products, can do an excellent job with a short packed column and an electron captured detector. We don't feel that those groups, who now have validated methods and are doing that to meet the 50 part per million cut off, ought to be -- ought to have to go out and buy a mass spectrometer or send all of their samples to a contract laboratory.

Does that answer your question?

MR. REDFORD: Yes. All right. In one of the comments that we had received, it was suggested that we acquire a specific minimum extraction recovery percentage efficiency, and that was something like 90 percent.

In whichever way we go, do you think that specifying what we require to be the extraction efficiency is a good idea, of the surrogates that MRI has prepared, that we require someone to have a specific extraction efficiency?

DR. KALEY: I would hate to see it in terms of a requirement. Certainly, we feel that guidelines are useful in giving us a target, but there are matrices in which 60 to 70 percent recoveries must be considered good.

There are matrices in which plus or minus 50 percent relative standard deviations must be considered good.

So, certainly, we don't want to be told that we have to do something which is going to be a virtual impossibility.

I think one of the points we made, plus or minus 10 relative standard deviation on some of these matrices, we work with is an extremely exacting thing. As long as we know our analytical variability and know the projected value given our recovery and precision, then I feel we can operate effectively below a cut off.

MR. REDFORD: No matter which way EPA should go, what forms of QA and QC and what intensity QA and QC do you think EPA should require? Such as interlaboratory studies, laboratory certification, the use of surrogates, blanks, dupes?

DR. KALEY: Could we address that -- could I address that in the reply comments, in the group's reply comments?

MR. REDFORD: Sure. I think I'm about questioned out.

MR. GUNTER: You're done? Okay. Denise?

MS. KEEITNER: I'd like to direct this to Dr. Burgess. In your testimony here today, you commented that you doubt that any processes will qualify for this exclusion.

Do you have any information on what criteria under the definitions of closed and controlled waste

processes will be least likely met? In other words, are releases in air most likely to disqualify people from excluding or releases in water or the releases in products?

DR. BURGESS: Again, it would be speculation on my part. I think as the industry has become more familiar with these things, there are unique situations that have come up, vacuum pump problems which would give some release in air. Very low levels, very low quantities, but fairly high concentrations would be detectable in air, because a vacuum pump doesn't move that much air.

Water, per se, I don't -- I'm not sure. It would depend a great deal on which PCB you were talking of because the partition coefficient is such that decachlorobiphenyl is exceedingly insolube, has very low solubility in water. So, I can't visualize very much decachloro getting in water if the water is in contact with some organic stream.

But, there again, in some of the other materials that have some water solubility, you could get problems. A year ago, we were looking monthly at the product consideration. I think as we have moved through this, we have realized there are some air and water concerns and the extent of them or the ratio of them, I don't know.

MS. KEEITNER: One of the comments received in response to the proposal suggested that we define process,

release, product and waste more carefully in the proposal so that people know where exactly the sampling should occur.

For example, do we mean effluents from some type of water treatment, on-site water treatment, or do we mean water effluent directly from the process.

Do you have any suggestions on how that should be defined or some recommendations, on those four?

DR. BURGESS: I've debated some on that within our group. Is heat exchanger water included or not included? Is a water aspirator included or not included? And, I think we would have to sit down and work on those definitions in order to get anything specific. We can try to address some of that in our reply comment.

MS. KEEITNER: In your main comments, you state that the quantities of PCB's inadvertently produced in the United States today is miniscule. You use that information to a great degree to support your contention that the risks proposed are de minimis.

The data on the PCB levels are the amounts of PCB's produced as reported in the survey, were gathered by different analytical methods and by best theoretical estimates by each CMA member firm that responded to the survey.

The survey did not require actual analysis, did not specify analytical schemes as a standard and did not

define sample size, extraction procedure, the clean up procedure. Is it possible that the data reported in the survey are inaccurate and the actual amounts of PCB's present could vary by several orders of magnitude?

DR. BURGESS: I don't think by orders of magnitude. Are they inaccurate Certainly, they are estimates and any estimate is subject to consideration. Is it a factor of two. Certainly, some people were reporting high, some people were reporting low.

I don't know what the inaccurecy figure is. Is it 50 percent, 100 percent, 500 percent? I don't think we're orders of magnitude and I think the work that you have done in looking at the exemption petition, where we are dealing with materials over 50 ppm, would confirm that, that we are in the right ballpark, whether it's 13,600, I'm -- I like to use statistically significant numbers, even to say 13,600 makes me shudder a little bit, but that's what we need to say in order to get the things to add up.

Now, somewhere -- I guess I'd say somewhere around 15,000, plus or minus some number, and I worry about saying 13,600, but it -- but, that is, I think, the limit of our technology at the present time in saying that.

MS. KEEITNER: Are you aware of the analytical method that EPA compliance monitoring personnel are currently using to enforce the 50 part per million cut off it has set

on manufacture?

DR. BURGESS: I'm not, but I'm sure I can find an analytical chemist who is.

MS. KEEITNER: Aren't you concerned about not being in compliance?

DR. BURGESS: Am I concerned about not being in compliance? For three years, I have been concerned about not being in compliance. A great deal -- but, as far as -- if that is being derived from your other question about the analytical chemistry, irrespective of how concerned I was about being in compliance, I would not spend much time on the analytical method because I have analytical chemists who are much more profound at reading those things and doing it than I am.

MS. KEEITNER: Thank you. That's all the questions I have.

MR. GUIMOND: Thank you, Denise. There are follow up questions. If there are any from the panel, I've got a couple myself I would like to ask, and then move on.

On your written testimony, page 35 and then again on page 52, you note that all these processes that we're talking about -- I guess if we don't accept any of the other alternatives, all these processes should be considered as totally enclosed uses of PCB's as opposed to manufacturing, and I guess I would like to expand a little

bit on that, as to why you believe this is a totally enclosed use.

DR. BURGESS: Well, certainly, we have not intended to manufacture, process or distribute PCB's. This is not a commercial venture. It is something which the PCB is an inadvertent thing that occurs in the use of the chemical itself.

I think we can develop those arguments further, if you are interested, certainly I would like to get a legal counsel more vitally involved in it.

MR. GUIMOND: Yes, I -- that was an interesting concept to me, too.

Let me just expound on another question here that you were talking with Dave Redford.

If I understood you correctly, Dr. Kaley, you indicated that if we specified a specific number, you felt that it would be up to individual companies to accept the burden for individual validation?

DR. KALEY: Well, in the climate today of good laboratory practices and things like that, I think that is a perfectly reasonable expectation and that, certainly in our laboratory, I know of many others, feel that we cannot use methods for regulatory purposes or for any purposes at all unless they have been fully validated in our laboratory and we know at what level they are able to perform.

MR. GUIMOND: Okay.

DR. BURGESS: But, simultaneously, we would expect you to have your method validated.

DR. KALEY: Right. We would like --

MR. GUIMOND: But, if I heard you correctly, not necessarily to the extent that you would. You would not expect us to validate our method for each and every possibility.

DR. KALEY: If it's going to be used for enforcement on that matrix, I think -- yes, sir. Certainly, it would need to be demonstrated that it gave reliable results by some statistically significant manner.

MR. GUIMOND: Even with respect to enforcement action, but I gather from the standpoint of promulgation of the regulation, 'n the first place, you would not anticipate that we would have to validate it for each and every possible --

DR. KALEY: We realize that's an impossibility.

MR. GUIMOND: Okay.

DR. KALEY: That's one of our points with non-quantifiable being a problem.

MR. GUIMOND: I see. Any other follow up questions? Bill?

MR. GUNTER: I'd like to follow up on a point that Denise raised about the data in the CMA survey and it also relates to an exchange that you had with Rich about the

information that was given to the Court over a year ago.

In reading the instructions that were mailed out with the questionnaire that was used for that survey, in defining what a closed system was, you indicated "this is a special case and requires estimating pounds produced in manufacturing operations without detectable PCB concentration in any output strain".

Now, your discussion related to Rich's question, you indicated that you might not have communicated the concept very well, but what you really had in mind was something less than the 50 part per million regulatory cut off or -- is that correct?

DR. BURGESS: Yes, it is.

MR. GUNTER: Do you think that there were errors made in responding to the survey based on that same mis-communication, with this kind of language in the instructions?

DR. BURGESS: I think most of the people responding to the survey had telephone communication which would have straightened that out.

Is it possible there were errors? Yes, it certainly is possible, but I think, again, this kind of a survey that we were doing, we were ballpark numbering.

But, most people were basically looking at is it a PCB by rule, 50 part per million.

MR. GUNTER: Even with the language like without

detectable PCB concentration in the instructions, do you think that's what happened?

DR. BURGESS: I certainly -- I guess I -- it's somewhat speculation as I try to remember back, but I think most of the people did call in and that we were talking pretty much 50 part per million.

MR. GUNTER: That's all I have.

MR. GUIMOND: Any additional questions?

MR. REDFORD: Yes, I have another one. This is along the same vein as one of my questions before.

If you had a new product, a new matrix, could you explain what types of things you would do with that product to validate your analytical method to say -- to make you comfortable now, say yes or no, this is what the concentration of PCB's is?

Could you just explain what kind of validation procedures you would go through?

DR. KALEY: Well, I can't -- I cannot speak for the panel on this point, but let me just give an example of what -- maybe how I would start. Okay.

A sample comes in and the guy says I want to know if you've got 50 ppm PCB's in it. So, I look at it, you know, pick a matrix. Well, say, it's pretty bad. If I say well, first thing I'm going to try to do is dilute it and shoot it. Okay. So, we dilute it. Okay. Let's say

that works. We can dilute it by a factor of 10 to 50 or something and it looks like the baseline is going to be clean enough, we can do PCB's.

At that point, we establish the working range we are going to need for standards to quantify 50 parts per million or less PCB's in that system. We run a series of at least three standards, in replicates of 5, to determine our linear range, the reproduceability of our stnadard.

We try to then spike -- first of all, hopefully, we can have a blank sample. Somehow, either we've got generate one or we've got to hope that we can somehow -- one of the samples is truly clean, gets no PCB signal or a very small PCB signal under those circumstances.

At that point, we spike the sample at three different levels in repliactes of 5 determinations each to determine our recovery and precision of the PCB's in that matrix at those various levels. And, then, that presumably would give us at least a baseline validation.

Then, from that point on, on-going checks of standard responses and spiked samples and replicats samples run and compared against those previously established performance criteria in either a controlled chart system or at least some sort of documented system to tell when we were exceeding our specified limit of precision and accuracy.

Basically, we're talking about three levels in

replicates of 5 to establish our statistics in our laboratory. The other members may agree or disagree.

MR. REDFORD: Okay. Thank you.

MR. GUIMOND: No more questions? Thank you very much, Dr. Burgess, Dr. Kaley. Are there any questions from the floor that we didn't get? I don't think we got any yet. (No response)

Okay. Thank you very much. At this time, rather than starting on NRDC, although we have finished up a little earlier than I had anticipated, I think we will break for lunch and plan on coming back -- I think we'll plan on coming back at 1 o'clock rather than 1:30 and get on a bit early.

(Whereupon, at 11:40 o'clock a.m., the hearing was recessed, to reconvene this same day, Monday, July 26, 1982, at 1:00 p.m.)

JD1

AFTERNOON SESSION

1:10 P.M.

MR. GUIMOND: The first testimony this afternoon will be by the Environmental Defense Fund and NRDC. Jackie.

STATEMENT OF JACQUELINE WARREN, & ELLEN SILBERGELD, ENVIRONMENTAL DEFENSE FUND, NRDC

MS. WARREN: Thank you, we don't have extensive testimony prepared for this afternoon.

MR. GUIMOND: Would you identify yourself, please?

MS. WARREN: I'm sorry. Jacqueline Warren with Natural Resources Defense Council and Ellen Silbergeld who is a scientist with Environmental Defense Fund.

I wrote in the request to testify at the hearing that we would address five particular subjects. I really think we are only going to speak to four of them because with the proposed guidelines, there seems still some confusion with --

VOICE: Louder, please.

MS. WARREN: The change to now saying that packed column, GS Mass Spec is acceptable as capillary wise. We have been talking about, I received a very small guidelines document in the mail and I didn't see any particular difficulties with it. But I am not going to speak to it this afternoon.

The first thing, in our testimony we started out by saying that we didn't think the LOQ was an appropriate

point to differentiate between PCBs which would be in the category for further consideration in the next rulemaking, as opposed to PCBs that wouldn't be.

And after considering the various problems, many of which were discussed this morning and which have been in the written testimony, we really have come to the point to agree that it is a moving target and it would be better to specify a number.

I have never been opposed to a number in the first place. The objections that we had with the 50 parts per million limitation had everything to do with the apparently very arbitrary choice of it, the applicability of it to all PCBs regardless of the medium and the pathway to the environment and any consideration of what the health effects would be.

What we would really like to see is the agency starting from the point that the statute was intended to address, which is the prevention of the addition of PCBs to the environment. The court opinion spoke about reaching point sources of PCBs and we think that you can do that by setting a number which is in the range of what the limit of detection would be.

Since the statute says no one may manufature any PCBs, obviously you are going to be concerned about the presence of any PCBs. Once you find them, you have another

problem and that, obviously, is whether you are going to do anything about that or do something about some aspects of those PCBs.

But the first question you have to ask is are there any, which is why we said start with the LOD. But if it is easier for people to look for, in the product and waste stream, a number which is approximately in the range of where the LOD would be, I think that might clarify some of the difficulties.

I realize the range can differ, but it doesn't differ by orders of magnitude in what you are looking for, presence. We would like the number to be at the low end of the spectrum, obviously, because we are concerned about the health effects. Even though there has been a lot introduced in this record purporting to show that PCBs are not hazardous, since they are persistent bio-accumulating compounds, the question is not what risk does this molecule of PCB pose, but what risk is going to be posed to a person at the point of actual exposure where that PCB is no longer one molecule.

Having said that, we do stand behind the position we took in the written testimony, with the exception of saying, rather than specifying LOD, we would rather see you come up with a number that everybody can then attempt to gear their analytical procedures to finding.

I think you would be heading in that direction

at some point anyway because of the variability of what LOD or LOQ means to the various hearers and it was very clear to me here that, since CMA's survey was asking people for no detectable PCBs and people were interpreting that as 50 parts per million, the opportunities for mistakes, misunderstandings and variability are great unless you do set a number. So I think you should.

With respect to the demonstration of eligibility for an exception, I have a great deal of concern about the approach that is taken in the proposal because, first of all, this is an exception from a statutory prohibition. Wherever you draw the line, you are still going to be -- if you are going to be accepting people as de minimis risk, people who qualify for saying that their releases are de minimis, the agency, I think, has to understand the basis for that claim of eligibility and if a manufacturer simply announces to himself that he is eligible and files the paper signed on the bottom line in the drawer, you don't know about it.

The full burden is on the agency to find out who those people may be, which out of the group deserves the expenditure of your very limited, and every increasing limited, enforcement resources.

I think it would be much more appropriate for the people who are claiming eligibility to come forward and show you they are eligible and how they got there. And we will

be speaking in a moment to the question of the appropriateness of the theoretical calculation to get there.

But I think at the very minimum the agency should have the information presented to it as to who those people are who claim to be eligible and what that claim is based on. There wasn't any description of what enforcement strategy the agency plans to follow. I don't know whether you are ever going to publicize what that enforcement strategy is, but I find it practically an unenforceable proposal ths way it is worded now.

Not only that, but the statute does allow for citizen enforcement actions and that kind of proposal where the relevant information remains in the file of the company means that the public is completely excluded from access to that information, which, were it in your files, would be available under the Freedom of Information Act. It completely defeats the ability of anyone to enforce -- you or a member of the public, who I believe is entitled to know that somebody is still producing PCBs, even though the statutory intent was that that be, either entirely eliminated or only permitted when EPA was aware of it and could make a finding as to no unreasonable risk.

I don't think the no unreasonable risk finding is applicable to de minimis exceptions from the law. If you read the court's opinion, they weren't talking about

balancing risks and benefits, having found that the benefit is there as a matter of law. You would have to find that the regulation was trivial or of no value, but it is not strictly an unreasonable risk test, although the unreasonable risk test certainly comes into play with the exemption process.

I fully understand the difficulty of an annual application from thousands of producers and I am not advocating that you get involved in that. I think that a de minimis risk approach is an appropriate way to be proceeding. But I do have a lot of problem with starting from 50 parts per million as has been advocated.

The 50 parts per million level, as far as I can see, has no magic about it. It was an arbitrary choice to begin with. It was never justified by an rationale that I could understand and it is being promoted here as if it has some rationale inherent in it, which I don't believe to be the case.

A previous witness testified that the fact that 50 parts per million was drawn as the limitation has been a technology forcing -- a fact of life and many companies have changed their processes and fine-tuned their analytical procedures to be able to comply with that.

If that is the case, it is within the intent of the statute for you to be forcing further action on it. By analogy to the example of dioxin of 2,4,5T where dioxin

is an inadvertent contaminant in the manufacture of 2,4,5T because of the concern about the toxicological properties of dioxin, companies have learned to look for it at lower levels than they ever thought they would be able to and manufacturing processes have been changed in order to minimize the presence of the contaminant. And I think we should be looking for the same result with this.

For that reason, if and when you do set a number for this, I think you should be bearing in mind that it is desirable for companies to be changing their processes in order to minimize the presence of the contaminant. Considering how many processes there are and how shaky the data are on the number of PCBs that are actually being generated and being released into the environment, I think it behooves all of us to be working toward a reduction in the production of that quantity.

I also think it would be appropriate for you to have a number of different limits so that if you are concerned about the release of PCBs into the air, it would be appropriate to have one number for that and the release of PCBs into the water, another number for that, if the ability of the analytical methodolgies to get down to different numbers depending on the medium is as variable as it is. And the hardest part is dealing with the complicated matrices such as

tarry matrices that people were talking about. But one number, I think, has inherent difficulties with it and you ought to be looking at varieties so that they are media specific and always keep to the health effects that you found as a matter of findings of fact in the previous proceeding and in the effluent discharge proceeding that the FDA has also found and which remain the current peer reviewed and unrebutted findings of fact with respect to the health effects of PCBs.

Ellen will speak to the question of theoretical analyses.

MS. SILBERGELD: We understand that some burden has been placed on the use of theoretical rather than actual analyses of materials in order to determine exemptions. We have some concern about this as a process to be relied upon.

For the most part in environmental and other types of regulation, theoretical analyses are usually invoked when it is difficult, if not impossible, to do empirical analysis. For example, in air pollution when calculations based on models of dispersion, entrainment and other phenomena are obviously appropriate because the cost of doing adequate empirical studies would be enormous and of dubious reliability.

In this instance we are not convinced, however, that the barriers to actual empirical chemical analysis of

product, process, streams or waste streams are so great, the barriers to doing this are so great as to encourage theoretical analysis.

We are, moreover, concerned that the agency and others be satisfied of the errors inherent in theoretical analysis so as to determine, really, the bounds to which these types of analyses can be used in regulation.

For example, I would assume that the way these analyses are going to be conducted will be to set up a chemical engineering flow diagram of the various reactions that are thought to occur in producing a certain product and, therefore, demonstrate how many molecules of PCBs would be produced per molecule of product or other such factors.

However, in most chemical engineering streams, chemical processing streams, one is usually dealing with great excesses of precursors or catalysts because yields are considerably below 100 percent, even under optimum conditions.

Small changes in the conditions under which those processes occur, such as temperature, aerobic or anaerobic conditions and the like, can, of course, drive chemical reactions in different ways by considerable factors.

Therefore, we would have to obtain a very clear understanding of what the likely range of error in the final

calculation based on theoretical analysis of PCBs. Indeed, if one were to do such analyses thoroughly and carefully, we wonder if much effort or time would be saved over doing actual empirical analyses, and, indeed, whether the reliability would be such that both companies and the public would be satisfied by that approach.

MS. WARREN: I wanted to speak to one other issue. In our written comments for July 8th we addressed a number of statements that EPA made with respect to the risks of inadvertently manufactured PCBs. On page 11 of the testimony I quoted one statement in the Preamble about exposure levels during routine operations are not expected to result in significant exposurs, presumably to workers, because of measures already instituted in the industry to reduce exposures.

With respect to that, I wanted to call your attention to a document that NIOSH published in January of 1981 where they were evaluating the permeation of protective garment material by liquid halogenated ethanes and PCBs.

With respect to PCBs, with the exception of one material, the PCBs permeated the protective material in under three minutes and most of them in less than a minute. So there is a real question about how effective those protective materials really are. I will submit that

for the record with the reply comments, but I wantad you to be aware of it.

We have heard a lot of testimony, representations about how protective those protective garments actually are and have not heard a lot from the unions on it. I assume and understand that some testimony is going to be submitted by them, but I wanted to get that into the record because that's a very significant difference from what we have heard if it is in fact true that PCBs come through in less then a minute through most of the materials.

That's all.

MR. GUIMOND: Thank you, Jackie, Ellen.

Why don't we start the questioning at my far right. Denise.

MS. KEEHNER: In your testimony you spoke of limited detection. What do you believe is limited detection for PCBs?

MS. WARREN: I think it depends on the medium you are looking at.

MS. KEEHNER: In products.

MS. WARREN: In products? I think what we've heard today is that it depends on the particular matrix that it's in. But I think a range of what the likely PCB concentrations are is something that could be identified.

I'm not in a position to say what that limited detection would be.

MS. KEEHNER: If EPA were to withdraw this proposal and not proceed with the third rulemaking and let the TSCA Section 6-E ban go into effect, what type of analytical method would you propose that EPA would use to enforce the total ban?

MS. WARREN: I don't think it's realistic for the agency to really consider that as an alternative, after everything that has been heard about the number of processes. Otherwise you just wouldn't be enforcing it. I can't imagine that the agency is going to take a step that would be as economically disruptive as that.

MS. KEEHNER: That's all the questions I have.

MR. GUIMOND: Dave.

MR. REDFORD: I guess I have, really, one question. If we were to pick a number near the detection limit or whatever, do you think we should just use detection limit as something to find it, to define that number?

Like you are saying that it would be a good idea to have different numbers for different media, air, water, etc. What do you think we should use to determine that number?

MS. SILBERGELD: Well, obviously, if you go to setting a number, and I think for many reasons we endorse

that as a procedure rather than the rather murky concepts that are based on current technologies which may or may not rspresent the best available technologies, or current average practices in analytic laboratories which may or may not represent the best possible practices using a specific technology, once you go to a number several things inform the choice of that number.

One is, obviously, the ability to detect the substance. But the other, and which most be an overriding factor, are knowledge and estimates of the adverse health and environmental effects of any given amount or presence of the compound.

It may well be, as in the case of dioxins and other substances, that there may be reason to believe that in some instances the levels of a toxic substance known or suspected to have adverse health effects may, indeed, be lower than a generally established level of detection currently available.

In those instancee, then, the health concern is overriding and really drives the analytic technology to develop methods sensitive enough to reflect that concern. That certainly has been the case with dioxins and probably is also the case with the dibensofurans.

MR. REDFORD: Thank you.

MR. SMITH: I have no questions.

MR. GUIMOND: Okay, I have just a couple.

In your written testimony you indicate that you don't think the control waste should be excluded. Could you expand on that a little bit more?

MS. WARREN: Yes, the major thrust of the section 6-E that deals with manufacturing is that manufacturing of PCBs was to end. If you are going to allow unlimited manufacture of PCBs as long as the waste is going to some sort of controlled disposal source, than I think you are just ignoring the initial statutory requirement.

I am not persuaded that any of the disposal technologies available are all that adequate in dealing with the PCBs. Certainly landfilling and things like that are not and there are a lot of questions about incineration, about whether it is being done right and what the by-products and combustion products of it are.

Just to allow any amount of PCBs to go out as long as it is what you are calling controlled waste seems to me to be getting around the basic point of Section 6E.

MR. GUIMOND: You would not see, then, any advantage to the environment or public health from, perhaps, the incentive that might create. That is someone that alternately might have what you would call uncotrolled PCBs, but could conceivably, via the test of an exemption, not have an unreasonable risk, that there would be an incentive

for them to try to qualify for an exclusion by taking their wastes and getting rid of them in this manner as opposed to some other way and thus actually presenting less risk than might otherwise be done if you handled --

MS. WARREN: There are a lot of ifs and maybes in that and it is clear to me that the final rule has any guarantee whatsoever that the waste is going to have to go to an appropriate facility.

There was a question raised this morning about, what if it is a RCRA facility as opposed to a PCB facility. Well, RCRA leaves the control of PCB disposal to TSCA so I don't know what sort of RCRA requirements would apply that would be appropriate for PCBs.

With that uncertainty, I don't like the idea that the quantity of PCBs could be increasing in the waste or in a process and that that would be all right as long as it goes to the right facility.

I would rather have a cap on the amount.

MR. GUIMOND: Okay, let me see if I can understand your proposal. You would suggest that we go with a closed system exclusion, with the definition, basically, being that we would establish some kind of numerical value, probably near the general level of detector limit -- limit of detection that might be applicable to these things for air, water, products, waste, is that correct?

MS. SILBERGELD: Not necessarily, if I didn't make that clear. When I said if you go towards setting a specific number, then the overriding concern must be the evaluation of the actual potential and adverse effects to human health and environment. You cannot then soley rely upon level of detection or level of quantification as the criterion for setting a number. Insofar as what you state about varying levels for varying sources of PCB's, that may well be appropriate.

MR. GUIMOND: Okay. As you know, there probably is some dissension among a veriety of people relative to how serious the health effects are, environmental effects associated with PCB's.

I guess I am trying to translate if I was to practically try to take your recommendations today and translate those into some kind of regulatory requirements, how would I go about changing what I currently have in the rule as proposed.

And if I translate them right, one thing I would do is that I would either eliminate the control waste exclusion, or, if I was going to include it, I would have to include it with some kind of a total quantity amount and, I gather, and/or a concentration value for it, too.

And then for the close waste exclusion, I would put in a numerical limit for air, water, product, waste and I would select that limit by looking at something around the

level of detection, assuming that I convince myself that at that level I am not going to have serious health effects. Am I correct, is that what you are advocating?

MS. WARREN: I think if you go back to the statutory statement that no one should be doing any, you are going to want to be somewhere near the limit of detection in setting the number.

That doesn't mean that you are then going to be regulating and imposing a ban on what you measured. But it means that you have now differentiated the category for purposes of this rulemaking that you are not going to worry about any more or that you are going to worry about further.

For purposes of making that kind of differentiation I think the number would have to be somewhere around the limit of detection.

MR. GUIMOND: As it exists today presently?

MS. WARREN: I think you can updata it as appropriate. I don't think the limits of detection change that frequently.

Or you could leave it as it is. There are other regulatory procedures where numbers are set. They tend to get engraved in stone, even though the ability to deal with them better.

MR. GUIMOND: Well, let me use as an example, if --

and I am just using this as an example.

If, for example, a limit of detection in products -- we looked at a bunch of products and we found that it looked like it was 50 parts per million for clearly a majority of the products, 75 percent or more, and we did the same thing for wastes. We looked at air and water and found it was, maybe, a factor of 100 less for air and water, maybe even more.

You could live with that kind of approach?

MS. WARREN: I would like to know where the products are going, what route into the environment are those PCBs really taking.

MR. GUIMOND: So you are saying, not only limit of detection, but limit of detection with some kind of risk assessment, if you will, that assures us that these are not interacting in the environment directly or exposing humans directly.

MS. WARREN: And what quantity the product is being produced every year.

MR. GUIMOND: Do you see an overall quantity limit established to this whole thing, too?

MS. WARREN: I think so because, first of all, just drawing the line at any one number doesn't take into account the kind of concerns that we were expressing all the way along with the 50 parts per million cutoff.

If the route into the environment is getting out into the water, getting into fish which is the major route into the diet, the number should be a lot lower than 50. It ought to be a number that corresponds to what we know about PCBs and how much of the percentage of diet is really involved with the eating of fish, that kind of thing.

You can do the same thing with exposure releases into the air, but to do that you have to know where the product is going or how much of it is coming out, not only in terms of parts per million or parts per billion, but over the course of a year what is the total quantity as well.

I'm just saying that it is a difficult problem because you don't want to just say the same thing goes for any PCB as long as it is below a certain level. I have the same difficulty with any level that you could come up with. That's why I suggested that you have different ones that are geared more to the medium that you are concerned about.

I am less concerned about PCBs found within a matrix where they are not very likely to get out and, depending on what the use of the product is, or if it is in the waystream and the waste is going to a controlled disposal, the fact that the number is higher than a number that would be going out into the water or going into the air doesn't bother me so much.

MR. GUIMOND: Obviously, we can't have an infinite

number of limits, we have to have some finite number of limits.

MS. WARREN: How about one for air, one for water for starters.

MR. GUIMOND: Okay, one for products, all products --

MS. WARREN: Well, there are different kinds of -- well, if you can categorize the products into separate, descret subsets so that you wouldn't have too many of them.

MR. GUIMOND: Same thing for waste, perhaps, depending on what happens to the waste.

MS. WARREN: I think probably the waste you don't need to differentiate the same way.

MR. GUIMOND: I'd like to talk just a little about your points relative to eligibility, how somebody determines eligibility, how they should certify or self-certify.

Again, if I interpret whay you are saying, you believe that whatever -- whether this was done on an analytical basis or whether it was done on a theoretical basis, that the agency should require reporting of that information, is that correct?

MS. WARREN: Initially, yes.

MR. GUIMOND: For example, in the proposed rule we indicate that one must self-certify each time your self - certification becomes no longer --

MS. WARREN: It's a qualitative difference.

MR. GUIMOND: Right.

MS. WARREN: But they're not telling you that, they're telling themselves that. That's the problem that I have with it, I think EPA should know.

MR. GUIMOND: So you would say we should have them certify to us each time that occurs.

MS. WARREN: Yes.

MR. GUIMOND: And --

MS. WARREN: That's an alternative to an annual exemption petition so, unless their process changes more frequently than that, I would imagine it is not going to be as often as annually the first time and then whenever the process changes qualitatively enough that the quantity of PCBs that's being generated changes.

MR. GUIMOND: I guess somewhat on a philosophical plane relative to this, if you create this thing as an exclusion, it is supposedly an exclusion, as you pointed out, from the court's language, is because there is de minimis risk or little benefit associated with regulation of the thing. Then, via that same thing, you are then saying that, basically, these things I am excluding because I am not concerned about them, I don't have that much interest in them.

So, philosophically, wouldn't you also think that

you would not want to create a major effort on these people's part or our part, for example, to determine that you, in fact are eligible for something that the agency doesn't care that much because of the health risk.

MS. WARREN: Well I just wanted you to know that you don't care. I don't trust them because they don't think it's hazardous. So I think you can get a lot of theoretical calculations that are done by just putting your hands over your eyes and theorizing about it.

Where the numbers could be quite high and, unless you happened to discover them through enforcement which I also don't think is that likely, you are not going to know about it.

MR. GUIMOND: Well, as far as enforcement and everything, do you have any suggestions for a strategy? For example, when we approached -- when you take a look at some of this, we've got the information from the exemption petitions that we have and, as we note in the proposed rule, we utilize that as one effort in developing an enforcement strategy.

You would see this other information as sort of, in addition to that, it would help us focus on people that may have, in fact, not even provided an exemption petition?

MS. WARREN: I don't understand the second part.

MR. GUIMOND: I am trying to get at what extra

pieces of information you think you might get from all of these people. Potentially we could have a lot of paper coming in here, right, if we asked for a lot of the people who qualify -- they actually qualify for this exclusion how they did it. We could have a lot of paper in here and I'm generally somewhat concerned about having a lot of paper coming to us from reports that may or may not be useful for us in doing something. Then there are the burdens associated with having that paper created and, of course, the burdens of us doing something with it, too.

I'm not 100 percent clear --

MS. WARREN: How many pieces of paper are we talking about?

MR. GUIMOND: Well, if you made everybody --

MS. WARREN: You already have the group that was producing inadvertently about 50 parts per million. If you confined yourself to the group that was below that --

MR. GUIMOND: I don't know how many pieces of paper we may have. I have had estimates coming in from various people ranging from a few hundred to thousands.

MS. WARREN: The alternative is to say we just trust the industry to do it and given their concerns or lack of concerns about PCBs, it doesn't seem to me that it is reasonable to just assume that it's going to be adequately done.

MR. GUIMOND: Okay, so this is basically a safeguard. You feel it would put more pressure on them to do it right and to do it in the first place, is that correct?

MS. WARREN: Yes.

MR. GUIMOND: Thank you. I don't have any more questions. Alan?

MR. CARPIEN: I don't have any questions.

MR. GUNTER: I'd like to follow up on Rich's last one. In your comments you indicated that EPA should then, after these pieces of paper come in, do something to verify the information. Reading your description of what EPA should do, I got the idea that we would be creating another kind of exemption procedure, albeit on a one time basis.

What did you really have in mind here that we should do with the papers when they come in?

MS. WARREN: I thought that you would look through them and then see which out of the group of people that are inadvertently producing PCBs look like candidates for enforcement. The likeliest ones to be producing levels that oughtn't be excluded. At least it will tell you who they are. You don't even really know who they are.

MR. GUNTER: So the verification you really had in mind was really enforcement of the rule?

MS. WARREN: Yes. I don't see how you are going to enforce this by -- with no information about what processes and what companies, except for the ones -- you know about the ones over fifty who have already applied to you for exemptions. You have no idea really who the ones under fifty are.

MR. GUNTER: With regard to the establishment of a series of cutoffs for various media, you have suggested that these should be in the neighborhood of the LOD. Wouldn't these numbers of necessity have to be around the LOQs, since otherwise you wouldn't be able to make quantatative measurements, it would be below what you would be able to quantify.

MS. WARREN: My understanding is that there are ways to figure out how to quantify once you have detected them. That might not be correct, but I understood that it's possible to develop a procedure so that you could measure what you really have.

But it's more than just measuring what you have. The other questions are, how much of this product contains whatever it is that you have measured that you have, and where is it going? Which are the things that I am more concerned about. I am really less concerned about whatever point you pick and what the ultimate environmental fate of it would be and what the exposures involved in it are.

MR. GUNTER: Turning to the question of controlled waste processes, when this concept was originally introduced by CMA and submitted to the court in paperwork that we initiated, EDF did not object to that concept then and now you are rsising some objections. What about it has changed your mind?

MS. WARREN: I think we didn't realize that the amount of PCBs could really keep increasing and that production could -- as you have even acknowledged in your Preamble, that production could increase significantly as long as it goes to a controlled disposal site.

I didn't envision any concluaion to this proceeding that allowed the amount of PCBs that are being produced to increase. That's really the main reason I changed my mind about it.

MR. GUNTER: Turning now to the disposal of waste from controlled waste processes, it's true that PCBs are not a listed waste under RCRA but would there be any legal problem or other problem with specifying in the PCB regulations that disposal of wastes be done in a facility approved under the RCRA regulations as an incinerator of organic waste?

MS. WARREN: The problem is that if PCBs are not incinerated at the right temperature for the right amount of time, you get Dibenzofuran and other toxic intermediate combustion products. You still get them as long as there are PCBs, and I think if you are not going to control the

incineration of them properly that's going to be a problem.

If that could be taken care of by some specifications in the RCRA regs then I have less problem with it. But I am concerned about the PCBs still getting out into the environment and to the extent that they go into landfills that aren't appropriate for them or are incinerated under inproper conditions for them, you are not solving the problem that you set out to solve.

MR. GUNTER: That's all the questions I have, thank you.

MR. GUIMOND: Laura.

MS. CAMPBELL: I don't have any questions.

MR. GUIMOND: Amy.

MS. MOLL: I don't have any either.

MR. GUIMOND: I have a few questions from the floor, let me take care of. One of them is regarding, I think this is a comment, and Jackie, you can respond to it if you would like, regarding Ms. Warren's statement on the protection -- worker protection and clothing barriers. NIOSH document by Dr. Weeks has since published an arrata statement. Are you aware of this? The errata shows Dr. Weeks was in error in his PCBs -- in that his PCB sample was not PCBs, but contained over fifty percent of a highly chlorinated aromatic compound known to permeate rubber.

MS. WARREN: Well, unless that condition could never

occur in the manufacturing processes in which the protective clothing was being used, where PCBs were present as a contaminate, I think what he said was still relevant.

MR. GUIMOND: Okay. Second one, if an exposure and health effects assessment demonstrates no significant risks from PCBs with a one hundred PPM cutoff, would you be satisfied with a cutoff of one hundred PPM?

MS. WARREN: Depending on how you reach the determination that no significant exposure could occur. If you change your definition of what is a significant exposure, probably I will have a problem with that.

MR. GUIMOND: Do you mean a BPA change from no detectable?

MS. WARREN: No, from what your determination of what constitutes a significant exposure, which you are proposing to keep the same definition of significant exposure that you had in the previous rulemaking.

MR. GUIMOND: Okay. For the record, would Ms. Silbergeld please state her education and possible experiences with industry practices or alternatively, your qualifications to give testimony today on engineering and analytical technology.

MS. SILBERGELD: Okay. I am the chief toxic scientist of the Environmental Defense Fund. I have a Ph.D. in environmental engineering from Johns Hopkins University,

and post-doctural training in toxicology and biochemistry. For three years I was the Kennedy fellow in neuro-sciences at Johns Hopkins Medical School and for seven years a scientist at the National Institutes of Health, ending up as chief of the Neurotoxicology Section. I have also been trained in GCMS and other aspects of chemical engineering and analysis.

MR. GUIMOND: Thank you. This is another point relative to the errata sheet that I just mentioned in the other comment from NIOSH. This is question that I will read and if you would like to comment on it you can. I am not quite sure exactly how it would fit in.

The question is, doesn't FWPCA preempt the regulation of PCBs by TSCA in the control of liquid waste streams or how will the proposed rule effect the regulation of liquid waste streams by FWPCA?

MS. WARREN: I don't think that the Clean Water Act does preempt it. In fact, in the Clean Water proceeding back in 1977, where EPA was reaching to direct charges of PCB manufacture and had a very narrow category of sources, at that time it was just PCB manufacturers, deliberate PCB manufacturers, transformer and capacitor manufacturers, some parties in the proceeding including the EDF, for which I was employed at the time, argued that there were many other sources of PCB discharge which weren't being included and the answer was we will reach them under other statutes and under the permit

program. So, at that point, the agency wasn't considering the Clean Water Act to preempt it.

This statute allows the administrator to deal with any problem under the statute or another statute if one or the other seems more appropriate and it's entirely discretionary. I don't think that it is preempted.

MR. GUIMOND: Okay. Do you really believe, as EPA said in the past --

MS. WARREN: Yes.

MR. GUIMOND: Okay. Do you really believe, as EPA said in the past, that any exposure to PCBs is significant? Is not such a statement incorract as a matter of science?

MS. SILBERGELD: I will be glad to answar it as a matter of science. Jackie, perhaps, can answer it in its historical oontext. I think one of the major problems with a substance like PCBs, as Jackie mentioned, is that it doesn't occur in a vacuum. Both its entrance into the environment is into a context that is already considerably contaminated by its presance, and certainly ite uptake and residence time in humans or any other organism is for a very long period of time.

So, it's very difficult to say would one part per billion of PCBs in my tuna fish sandwich today represent a significant event. It would depend very largely what I was doing physiologically in my life at that time. For example,

if I were involved in reproduction, it might be very significant. It would also depend very much as to my historical encounters with PCBs.

MR. GUIMOND: Anything to add?

MS. WARREN: I already answered the question.

MR. GUIMOND: Are there any other comments from the floor? Questions?

MR. REDFORD: I have two.

MR. GUIMOND: Go ahead.

MR. REDFORD: In regard to the setting of limits using the LOD, Dr. Kailey, earlier this morning, spoke about the LOD for some pruducts being far greater than fifty parts per million. What would be your reaction to a rule that reflected this type of a limit, well above the fifty?

MS. WARREN: I think that we would find that unacceptable but on the basis of the potential health effects of it and the LOD itself is just not enough, you need to know more about where the product is going, how much of it -- If you know there are PCBS there -- They know there are PCBS there even though the limit of detection because of the nature of what they are trying to detect it in, doesn't permit them to find it except at relatively high levels but they know it's there.

It seems to me that that information plus the answers to those other questions about where is it going,

should determine what the regulatory response is going to be. LOD by itself, or a numerical equivalent of LOD, is not adequate all by itself.

MR. REDFORD: My other question is on back to the theoretical analysis part. There are a lot of products out there that, I think, will fall into the category that we are talking about, and we will have to, the way I understand it with your suggestion, is send in something saying that they have looked at it and have determined that it doesn't have PCBs.

What about products that -- I mean, how far are we going to go? How far do you suggest we go? Should US Steel have to check steel parts, steel I beams -- I mean, where do we draw our line on the amount of paper work that we are going to accept? Virtually anybody out there who makes a product could end up having to send us in something saying we don't think we have PCBs. Where do we draw our line?

MS. WARREN: The drawing of lines is something -- it's necessarily arbitrary and it's something that regulatory agencies have to do and that is what they are in business to do. I am not going to be able to sit here and say to you this is where you do it. You have some inherent authority on the basis of administrative necessity to draw the line at a point that I might be unhappy with, but which you, for justifiable reasons, can't deal with beyond that point.

That's something that you are going to have to do on your own. But it's impossible -- it's something that you face in everyday --

MR. REDFORD: What would you suggest? I mean, what could we use to even attempt to come to that kind of a line? I have no idea. You don't have to answer if you don't want to. Have you got a suggestion?

MS. WARREN: I don't think I have an answer off the top of my head right now.

MR. GUIMOND: Any other followup questions? Okay, thank you very much. Are the representatives from General Electric here?

MR. BLUME: We are here today to represent General Electric Company's Silicone Products Division. I am Richard Blume, our Division Counsel. To my right is Dr. Dan Silva, General Manager of our Technology Development Department. To Dr. Silva's right is Mike Scarbel, our Manager of Quality Assurance. To my left is Jeffrey Cerar, our outside litigation counsel, with the Washington law firm of Squirers, Sanders and Dempsey. Dr. Silva will lead off our presentation today.

DR. SILVA: Thank you for the opportunity to participate in this informal hearing. The General Electric Company requested this opportunity so that we make explain the effect that EPA's recent proposal for the regulation of PCBs enclosed and controlled waste manufacturing systems will have on G.E.,

its customers, and the public.

G.E. has invested a considerable amount of time and expense in efforts to respond to the PCB issue. Individually, and as a member of the Chemical Manufacturers Association, we recently submitted comments on EPA's June 8, 1982 proposal for the regulation of PCBs and inadvertently generated enclosed manufacturing systems with controlled waste processes.

I direct your attention to those commenst as a statement of G.E.'s concerns with the overall regulatory approach that EPA has chosen to follow respecting incidential PCBs. Those comments explain that as currently formulated, the EPA proposal does not provide relief from the ban for G.E.'s carefully controlled process.

Today, I would like to concentrate on a number of aspects of this subject. Number one, the nature of the G.E. process within which incidental PCBs are generated. Number two, the importance of G.E.'s manufactured products to U.S. industry and national security. Three, G.E.'s efforts to eliminate incidental generated PCBs. Four, General Electric's efforts to develop alternative processes and reformulate its products. And five, the economic impact of the EPA proposal.

G.E.'s involvement in this proceeding stems from our phenylchlorosilane production process at General Electric's Silicone Products Division in Waterford, New York. An unwanted biproduct, monochlorobiphenyl and dichlorobiphenyl, unavoidably

result from the chemical reaction by which Phenylchlorosilanes are produced.

These unwanted by-products occur within General Electric's process equipment and are removed for destruction in an incineration facility approved by EPA, Region II, in compliance with the PCB disposal and marking regulations. This integrated process releases PCBs well below the EPA permitted values to the air and water and only trace amounts of mono- and dichlorobiphenyl in concentrations below the fifty part per million level end up in the products.

Phenylchlorosilanes are essential precursors in the production of certain highly engineered silicone products due to their superior high and low temperatue performance, radiation resistance, clarity and flexibility. Silicone products are used extensively in the aerospace, automotive, construction, defense equipment, electrical, electronic, and energy industries.

Typical uses for silicone products containing phenylchlorosilanes include seals, hoses, insulation, adhesives, coatings, lubricants and fluids where properties of high and low temperature performance are required. Phenylchlorosilane based silicone products are used for thermal insulation and sealants in aircraft, spacecraft and communication satellites. Our Versilube F-50 silicone fluid is the only fluid available for use in the constant speed drive of the A-4 aircraft flown

by the Navy.

G.E. products in the RTV-500 series are used in rocket motors and re-entry body assemblies of the Trident fleet ballistic missle, and are the only materials which are qualified for such use. Phenylchlorosilane based silicone products are used as an adhesive for the thermal tiles of the space shuttle due to their ability to withstand extreme temperatures upon re-entry to the atmosphere.

They are also an essential part of our daily life as sealants and as coolants in car engines as well as weatherproof coatings for construction materials and insulators for electrical television components.

Historically, in 1975, the General Electric Silicone Products Department concluded that the presence of mono- and dichlorobiphenyl products in silicone products derived from phenylchlorosilanes, even at low levels, was likely to become a public concern.

Without waiting for legislative or regulatory action, General Electric voluntarily undertook an extensive and comprehensive technical program with the objective of ensuring that PCB materials were not distributed in commerce and did not enter the environment as a result of phenylchlorosilane manufacturing.

In 1975, no one for saw that unintentional formation of PCB byproducts enclosed in controlled systems would be

subject to a regulatory ban. Between 1975 and 1979, General Electric devoted substantial, highly sophisticated scientific facilities and human resources to the effort to reduce PCB generation.

Over those four years we attempted to find a substitute process for phenylchlorosilane production that would not produce by-product PCBs, and to modify our current direct process to reduce the percentage of by-product PCBs produced, to develop substitute products for phenylchlorosilanes and to develop processes which would remove and destroy unwanted by-product PCBs from the phenylchlorosilane process.

Since 1979, General Electric has had an ongoing program to identify substitute products and to attempt to discover a new process that would not involve by-product PCBs. The specifics of that program were supplied in a confidential submittal to EPA on July 31, 1979. To date, this program has resulted in only limited improvement in General Electric's ability to substitute products or to develop a new process.

We have been successful, however, in removing PCBs from our current process and destroying them. As early as 1976, General Electric's Silicone Products Division reduced the PCBs in the process to a sufficient degree that by-product PCB concentrations in products are below fifty parts per million. Moreover, our on-site disposal facility, which we

installed at a cost of tens of millions of dollars, assures the safe and efficient incineration of PCBs.

EPa's ban on incidental by-products in 1979 came as an unpleasant surprise to General Electric, particularly because it applied to PCBs generated inside process equipment, where there is no exposure. EPA must have assumed that the number of processes generating an incidental by-product was small and intended to use the annual exemptions to deal with the phenomenon.

G.E. filed a request for a manufacturing exemption in order to continue operating the phenylchlorosilanes process. Because the 1979 regulation defined PCBs to include only those substances that contain PCBs in concentrations of fifty parts per million or greater, the processors, distributors, and end users of our products did not require exemptions.

General Electric filed a law suit challenging the regulation on the basis that Section 6E of the Toxic Substances Control Act did not apply to incidental by-products. However, when the EDF court decision necessitated a new rulemaking, General Electric chose to postpone its law suit in the belief that EPA would formulate an appropriate, regulatory solution for incidental by-products in that rulemaking.

One final avenue of relief General Electric has sought is the exclusion of mono- and dichlorobiphenyl from the definition of PCBs. Based on our belief that there is

ample justification for that action, General Electric petitioned EPA on July 14, 1982, to amend the PCB regulation in that respect.

This is what the picture looks like in 1982 for General Electric Company. Our exemption request, originally filed in 1978, has never been acted upon by EPA. On August 2, General Electric will file, at EPA's request, a renewal application for exemption. The fifty part per million cutoff in now in doubt, meaning that even if General Electric gets a one year manufacturing exemption, the processing, distribution and use of our phenylchlorosilane based silicone products may still be prohibited.

What General Electric is hoping for is that EPA will recognize the strong justification for excluding our system and products from the ban. However, EPA has been working since November of 1980 on developing a rule to deal with the incidental PCBs and other PCBs in low concentrations, and no relief is yet in sight.

Given the history of this rulemaking, it is clear that EPA's notice of proposed rulemaking of June 8, 1982, is an attempt to come to grips with incidental by-products. In that proposal, EPA announced its conclusion that excluding from the ban incidental PCBs produced in closed and controlled waste manufacturing systems would not pose unreasonable risk to health or the environment.

However, EPA failed to establish a meaningful, di minimis standard by which incidentally generated PCBs can be regulated. The current proposal therefore offers no relief to General Electric and others who can quantify PCBs of their end products. As the June 8, 1982 proposal is structured, regardless of whether trace amounts of PCBs found in end-products of these processes cause minimal or no risk to health or the environment, all processes and end products in which trace PCBs can be found, will be banned.

We at General Electric are very concerned. The date which the court's mandate goes back into effect is less than three months away. EPA was to have completed work on a di minimis standard by then, yet EPA has given no indication when, if at all, it will propoee a di minimis standard by which companies in our position continue to operate.

Unless the court once more extends the stay of its mandate, companies such as General Electric, who can quantify trace amounts of PCB impurities in their end product will see their products banned. Even if EPA publishes the regulation as currently proposed, industrial users and supplies of these products will also be prohibited from using or distributing products containing trace amounts of PCBs after this date.

If this ban continues, General Electric will have only one alternative to ceasing production of phenylchloro-silane based silicone products. It will have to rely upon EPA

action on its exemption request.

As General Electric has already pointed out in its comment of November 16, 1981, submitted in response to the May 20, 1981 advance notice of proposed rulemaking in this proceeding, the exemption process is an inadequate solution to the problem, dus to the unjustified expense and administrative burden that it places upon industry and EPA alike.

If General Electric's only hope is to rely upon submitting its exemption request to EPA each year in order to continue producing phenylchlorosilanes, then General Electric must consider the likelihood that it will have to discontinue production of phenylchlorosilane based silicone products. The loss of its phenylchlorosilane based product line will not topple G.E. However, the impact of this event upon General Electric, its employees, consumers, and indeed our national defense, will be severe.

Currently General Electric sells hundreds of products derived from the precursor phenylchlorosilanes to thousands of direct customers. The immediate economic effects to General Electric of discontinuing its phenylchlorosilane based products include the immediate loss of tens of millions of dollars per year in sales and the estimated direct loss of more than 200 jobs at its Waterford, New York facility.

In addition, this would represent a loss of our substantial investment in developing a process for removal of

by product PCBs from phenylchlorosilane -- from the phenylchlorosilane process, along with the loss of present facilities for the production of phenylchlorosilane and ramoval of by products, mono- and dichlorosiphenyls. The combined value of these facilities is estimated in the tens of millions of dollars. The majority of the capacity of these facilities can not be used for any other applications.

Further, the unavailability of phenylchlorosilane based silicone products would have a severe, adverse economic impact on direct customers and other users. As indicated above, phenyl containing silicones are typically used in the highly critical applications such as military, commercial aircraft, military equipment, and our nations' highly visible space shuttle.

In many applications, phenylchlorosilane containing silicone products are specifically required by customer specifications. The consequences to commercial customers would be substantial, both in terms of lost profits and sales, and the inability to find substitutes.

Even if lower performance materials for substitution could be found, this would require development programs estimated to range in duration from one to ten years. The most critical applications would tend to require longer development and evaluation time. Numerous General Electric customers have written to EPA to emphasize the importance of our products to

them.

Most recently, on July 12, 1982, the Department of the Navy wrote to EPA that a ban would ground the A-4 aircraft and would necessitate a several year program to replace the constant speed drives on all effected aircraft at a cost of more than $16 million.

Other adverse effects of the discontinuance of General Electric's phenylchlorosilane based silicone products, include the substantial loss of sales and jobs for suppliers of goods and service to the Waterford plant. The discontinuance of General Electric's phenylchlorosilane process will have an impact, not only on the Waterford, New York aree, but on the national etonomy as well.

Use of the annual exemption process to deal with the large number of processes and products involving incidental PCB by products would be most unfortunate as a matter of public policy. Such a solution to the problem would be illusionary. Not only the administrative burdens that it places upon EPA and industry alike, but because it fails to address the real issue posed by incidental PCBs.

The real issue in this entire proceeding is whether regulating PCBs as a defined regulatory cutoff would adequately balance the interests of industry, government, and consumers. The exemption process is cumbersome and time-consuming and is designed to deal with case by case issues. It is not

the proper forum to address major issues that cut across all the interests involved.

Such an ad hoc approach will necessarily make a sham of the exemption mechanism. Either the annual exemption will be pending for years, as has already happened, or EPA will rush through applications with a cursory view that does not address anybody's interests. Meanwhile, the applicants are left hanging in the balance wondering when an adverse decision will put them out of business.

I have attempted to emphasize to you today the efforts that have been made by General Electric to solve the PCB problem. So far, these efforts have not guaranteed us the right to operate our process nor has the substantial amount of time and money invested in the administrative process by private industry and government achieved such a guarantee.

I have outlined the severe economic impact EPA's most recent proposal will have on General Electric and its customers. We have no doubt that the proposal equally effects many other companies. EPA itself recognized in its June 8, 1982 proposal, that a ban on incidental by products would cost billions of dollars and cause the elimination of a wide variety of products with great social value.

If this is the ultimate result of EPA's efforts on PCBs, we submit a major public policy mistake will have been

made. We must reach a solution to the dilemma of incidental by products as soon as possible. October is already close at hand for EPA to be equivical on this issue. If EPA is not prepared to agree that the statute does not ban incidental PCB by products, then it must achieve a practical compromise, setting a meaningful regulatory cutoff for the manufacture, processing, distribution and end use of incidental PCBs, can adequately balance the interest involved in this proceeding.

Until EPA takes action to resolve the current dilemma, the uncertainty and confusion will continue. Thank you.

MR. GUIMOND: Thank you. If I understand your presentation here you, of course, are particularly concerned that G.E. is not going to make the proposal as it is now structured, right?

DR. SILVA: Correct.

MR. GUIMOND: Do you also believe that your products present little human exposure, environmental exposure?

DR. SILVA: To the best of our knowledge, that's correct.

MR. GUIMOND: You have done some kind of analysis and you feel that people are not coming in contact directly or they don't get into the environment or whatever, is that correct?

DR. SILVA: We have a wide variety of products, and

products. Many of those materials have trace levels of PCBs in a matrix which does not allow movement of that material from the matrix. I could give you a more definitive answer on that if you would submit that question to us in writing, we possibly could give you a spectrum on some of our products.

MR. GUIMOND: Okay. Let me ask a hypothetical question. You have already identified your concern that you right now do not fall into this proposed exclusion, therefore are up in the air as to what might happen in the future, whether you have to just rely on the exemption petition process, if subsequent to this rulemaking, if EPA went ahead with this current rulemaking and the way it's set up now, went final with it, and you did not qualify, and in the following rulemaking which we are currently planning to undertake, we then proposed to exclude products that presented little risk, and assuming that your's fell into that, would there be any economic impact or any problem to you at that stage? Would that be reasonable solution for you? Could you live with that?

DR. SILVA: If you are talking about, again, an annual exemption procedure, and we would have to verify the levels --

MR. GUIMOND: I am not talking about an annual exemption procedure, I am talking about --

DR. SILVA: You are talking about a permanent --

MR. GUIMOND: Let's just hypothetically assume that

we came up with a third rulemaking and the third rulemaking consisted of, part of it in any event, we proposed to exclude certain processes that presented di minimis risk or small risk, that were over and above, that were different kinds of processes from closed and controlled waste processes.

Let's hypothetically assume that your's fell into it. What would be your problem with this rulemaking in that event?

DR. SILVA: My opinion is that it would be of minimal impact, assuming that we had quantative limits on what you are talking about in terms of risk. We would want a quantative set of specifications.

MR. BLUME: I am not certain to what you are referring with respect to the next phase of the rulemaking relative to a process other than that which is being referred to today.

MR. GUIMOND: Alan Carpien referred to it earlier when we talked this morning, is that we are doing this closed and controlled rulemaking response to the court and then we have schedules to do a third rulemaking that deals with uncontrolled PCBs, and it has always been our intent in the closed and controlled one to deal with a category which was described from -- started from original discussions with industry and then was ultimately -- a deal, if you will, was cut in an order with the court.

What I am saying is that that does not preclude us

from excluding additional processes because they present di minimis risk although they may not be closed and controlled waste processes. What I am just trying to find out is that if you feel -- Let's assume you don't qualify for this, and we fix this so you still don't qualify, in the third rule-making you still conceivably might qualify for an exclusion depending upon the risk associated with what you are doing and how that gets crafted.

If, in fact, you did qualify in that third rule-making, would there be any particular impact or negative problems created for General Electric by this current rule-making? What I am trying to get at, it seems that you are calling this one a large impediment, this is a problem because you are not included in it.

The response, I guess, or the thing is that the rule may not have been crafted for inclusion of your kinds of things. It does not mean that your kinds of processes would be banned. I am trying to find out, given that as an assumption, do you have any additional problems with this rule-making?

MR. BLUME: At the risk of reducing the question to basics, I gather the question is, that if a further phase of the rulemaking were to come up with parameters be fashioned along lines which would exclude our process, would we be warm and happy?

MR. GUIMOND: Yes, you have got it.

MR. BLUME: The answer to that is definitely yes.

MR. GUIMOND: A real fuzzy feeling.

MR. BLUNE: Jeff, did you have something?

MR. CERAR: Yes. I'm Jeff Cerar. I am counsel to G.E. on this rulemaking. The thing that troubles me about the question is that it was precisely our kind of process that this deal that was struck was supposed to be addressing. That is why we have difficulty with it. When we listened to your questions this morning of CMA, where you read from a January 1981 submission to the court, I think it's a mistake to characterize our positions today as inconsistent with what was said back then.

For example, the closed system, as defined in that submission, and defined in some of our discussions, we had trouble with the concept of any detectible PCBs, but as a matter of fact, the closed system was supposed to be -- the attempt was being made there to define something that was almost a theoretical possibility. That was a system in which PCBs come and go and they are created and disappear and never go anywhere.

Nobody has ever believed, the CMA people have never believed that there would be very many systems falling into that category. The controlled waste system, as you have called it, and as was part of the discussion back in 1981, 1980, is

really the one that we are talking about and it's the one that G.E. would hope to qualify for. That's one where there are PCBs that come out of the system in the products and in the waste.

The problem with the mechanism that you fashioned here is that it goes down to levels that are so low that nobody can qualify for it. If there are people who can qualify for it, then our surmise is in error, but G.E. can quantify at such low levels that the system, as set up, is of no practical value.

Sure, it would make G.E. very happy to be excluded one way or the other from this, and in that sense, this proposal wouldn't pose an impediment. But, this proposal was supposed to deal with precisely the kind of problem that we have brought to your attention.

MR. GUIMOND: Okay, thank you. I am, unfortunately, going to have to leave for a few minutes to go to a meeting I can't avoid. In my absence, Bill Gunter will be the Chairman of the panel.

MR. GUNTER: Amy Moll.

MS. MOLL: Would you say that most of the processes that you say would not be excluded under this rulemaking, would not be excluded on the basis of the concentration of PCBs in their products, like in G.E.'s case?

DR. SILVA: If I can repeat the question a little

and see if I understood what you are saying, you are saying the exclusion would not be granted based on the levels in the final products, is that correct?

MS. MOLL: Yes.

DR. SILVA: I, speaking for our own process, I believe that's correct and I think for many other processes that I am familiar with I would also agree.

MS. MOLL: You mentioned that G.E. has filed exemption petitions in the past. Can you give us any idea as to what the costs of filing those exemptions has been for your company? Or if you could submit that information.

DR. SILVA: Well, the cost is -- if you want to try to calculate the direct costs, you might want to try to look at xeroxing. I am trying to be a little facetious here, but it's the indirect costs that get you on these proposals. For instance, the exhaustive analysis of our product line and the precursors in many of our product lines are the type of indirect costs that are built into these exemption petitions.

Having to do this yearly would mean we would have to update our anaylsis every year and, in fact, I would put the cost in the range of several -- tens of thousands of dollars -- certainly over one hundred thousand dollars cumulative for preparing just our petition.

MS. MOLL: Does that include doing all the research to find alternative --

DR. SILVA: No, no. That's why I say, if you want to include the actual testing, et cetera, that went into being able to prepare the petition, it's in the range of hundreds of thousands of dollars. As we get into the efforts I outlined regarding alternative processes, we are talking millions of dollars, and that did not include those efforts.

MS. MOLL: What would you say are the closest substitutes for phenylchlorosilanes at this point?

DR. SILVA: I wish I knew. I think we have looked at some materials which come close, but having the right mix of overall properties is the issue, flexibility, low temperature, high temperature, electrical resistance, radiation resistance, having all those things in the right molecule is pretty tough to come by.

It's many of those problems that have caused many of our customers to come to us for these specific materials. The space shuttle is a good example. There is no material that has been able to achieve the type of adhesion and thermal resistance to date.

MS. MOLL: That's all I have.

MR. GUNTER: Laura.

MS. CAMPBELL: My first question relates to worker exposure to PCBs. What measures has your company taken to avoid worker exposure or deal with this problem to PCBs during the production of phenylchlorosilanes?

DR. SILVA: Okay. Phenylchlorosilanes are produced in a closed system. The work place monitoring is done routinely at Waterford and has looked at very low levels of PCBs in the air. All those anaylses have been, if you will, analyzed and processed and are done routinely. I am not exactly sure of the time frame in which we are doing them now, but it is essentially an air sampling type of technique.

Some procedures involve the operators wearing actual sampling devices which are then analyzed as part of the whole site survey.

Mike has commented that some of that data is present in the 1979 exemption petition.

MS. CAMPBELL: We also asked for information in the notice of proposed rulemaking and I was wondering if you have any data indicating both the number of accidental or unplanned releases of PCBs, and if so, the amount of PCBs released during such events?

DR. SILVA: I am not familiar with what information we have submitted to date. Dick, would you like to --

MR. BLUME: We certainly don't have that information with us today, but to the extent that such incidents are required to be reported, they of course are, and that information is available to you.

MS. CAMPBELL: Okay, I am interested particularly in if those incidents have occurred, what measures have been

taken to protect the workers or to prevent environmental exposure, clean-up procedures.

DR. SILVA: We have standard procedures for all the proceeses that involve phenylchlorosilanes which contain PCBs. Those are documented procedures in terms of how operators and various other workers can -- must, if you will, handle the materials which are spilled or whatever. Dick pointed out that there is a notification procedure involving PCB releases, and to my knowledge we have been following that procedure. I do not have the specific information relating to how much or if there have been any releases.

MS. CAMPBELL: Thank you.

MR. GUNTER: Dr. Silva, in your prepared statement, you indicated that the date on which -- on page 7, you communicated that the date on which the court's mandate goes back into effect is less than three months away. Are you not eware that that mandate has been extended -- that the mandate has been extended to December 1?

DR. SILVA: No, I was --

MR. CARPIEN: It is stated in the Preamble. It has been requested in the Preamble and the court granted the request and gave the date. It is April 15 or 9, I can't remember exactly the date.

DR. SILVA: Okay, so we have an additional month. It doesn't help us -- it would be nice for a Christmas present

MR. GUNTER: I would like to address this next question to the two attorneys. If EPA is to go back to the court, as we are currently scheduled to do on November 1, with a plan as to how we are going to address the third part of the rulemaking, wouldn't our credibility with the court be improved if we had gone forward with the promulgation of a final rule on closed and controlled systems as the court had ordered us to do, rather than to withdraw that and report to the court that we are simply dropping back to rethink the whole situation?

MR. CERAR: I agree with your basic premise that it is always better to show some action when you are going back to the court, particularly action that you said you were going to take. But, if we are correct that it doesn't do anything, that isn't a very satisfactory kind of action. Maybe at this point we ought to say that we haven't asked you to withdraw this proposal. General Electric has not.

What General Electric would like would be this proposal with an acceptable cutoff substituted for the level of detection criteria and that is doable within the period directed by the court.

MR. GUNTER: You would like to see an acceptable cutoff based on the highest di minimis standard which could be supported, is that correct?

MR. BLUME: That's correct.

MR. GUNTER: How would EPA manage to get all of that done before December 1?

MR. CERAR: You have got the information in the record. There has been a good deal of health effects information submitted to you. The main problem with the current schedule is that even with an extension until December 1, what you are going to be doing at that point is going back to the court and asking for a further extension on the basis of a plan that you will be laying before it at that time.

MR. GUNTER: That was precisely the point of my question on credibility. Wouldn't we be in much better shape in getting that plan and further state of mandate approved if we had done exactly what we had told the court earlier that we were going to do then if we hadn't?

MR. CERAR: I think that's quite true. It's unfortunate that you can't accomplish the whole thing by doing something meaningful at the same time. I'm not trying to be facetious there. It seems to me it must be -- I mean, I hope it's possible to anaylze all of that information by the time-- by December 1, ideally.

But the thing that makes a company sitting here waiting for all of this so insecure is that the court may or may not grant the extension. They have granted -- the court issued an opinion over two years ago, or almost two years ago now, and they have allowed their mandate not to go into effect.

and to keep coming back and asking for more time is a bit precarious.

MR. BLUME: I gather that EPA has no assurances on that score.

MR. GUNTER: Not from the court.

MR. CARPIEN: Obviously the court doesn't say what it is going to do, but in the original order, the court broke up the incidental manufacture of PCBs into two different rule-making. One, of course, is the one we are doing now, and the other one was the so-called uncontrolled PCB regulation. It seems to me the court wouldn't have made that statement, wouldn't have allowed the rule to be broken up into that other rulemaking if it did not intend to grant some kind of stay of its mandate, given the fact that we could make the appropriate showing.

It is certainly implicit in that stay of the mandate would be, I would imagine, at least a good chance of being able to have that mandate extended. The question would be how long, I think, would be our main problem.

MR. GUNTER: I have one last question. Back in 1975, you said you became aware of the possibility, the likelihood of public concern over the presence of mono- and dichlorophenyl in your products. How did you arrive at that conclusion?

DR. SILVA: Well, from a quality assurance prospective

and some, if you will, anaylsis of our upstream processes, we concluded that the levels we were currently running with in our finished products could be reduced and should be reduced.

I think it was a culmination of some studies we had going on internally and I think certainly some public reports concerning the effects of PCBs on a larger scale. We took the initiative because we felt it was appropriate to remove the mono- and dichlorobiphenyls that were present in our process.

I would like to point out that we do not have any trichloro or higher chloronated PCBs in our phenylchloro-silanes process and that the mono- and dichlorobiphenyl materials are not as long lived in the environment as some of the very highly chloronated biphenyls are.

However, we felt that we could do something about the problem and we took that action in 1976.

MR. GUNTER: It has been G.E.'s position, I believe consistently throughout all these proceedings, that the incidental manufacture of PCB should not be subject to Section 6(e) of TSCA. If you were aware of this problem back as early as 1975 when TSCA was being considered, why didn't you try and get Congress to make clarification that would have helped that position?

DR. SILVA: I think I will ask Jeff here to comment on that. Let me just say that I quoted in the text, that we always viewed incidental by products where we had a closed

system and we do have an integrated closed system involving both incineration and some absorption type of processes. We did not anticipate a ban based on incidental by products.

MR. BLUME: I can answer that question to the extent we are able. Neither Mr. Cerar nor myself were around in that era and we can only speculate at this juncture, so I don't know that we can give you any kind of meaningful response.

MR. GUNTER: If there are others around who were around during that time, perhaps you could give something during the reply comments. That's all I have now. Alan?

MR. CARPIEN: I have no questions.

MR. SMITH: Since I am involved with sampling, sampling relies quite a bit on the variability of the system and I have heard statements this morning about folks feel that you get relatively the same isomers in patterns. My question is, from your analytical experience with your system, do you see homogeniety in your, if you will call it contamination or side reactions, or as you get slugs, what I would call sluge of PCBs?

DR. SILVA: Well, as I mentioned earlier, we have spent a considerable amount of time and money understanding the chemical reaction with the intent of trying to reduce the amount of PCBs generated. We have obtained information which indicates that in our particular system it's essentially a steady rate of production and that the isomer content does not

change appreciably.

As I mentioned, we have monochloro and dichloro-byphenyls. There is no trichloro material. The monochloro- and dichlorobiphenyls I am sure you could get out of a standard textbook, would therefore give you nine possible isomers. We see all of those nine isomers. We understand the ratios of each one to the other. We routinely analyze for each one of those nine isomers.

MR. REDFORD: I would just like to get your reaction to the analytical methods that EPA is proposing as in the MRI document.

DR. SILVA: You are talking about GC Mass Spec, is that correct?

MR. REDFORD: Yes.

DR. SILVA: We currently use GC Mass Spec to do many of our analyses. I think it's what I would feel comfortable with in terms of some of the analyses that we do in our facility. I think, contrary to some of the comments that were made earlier, that the level of detection or, if you will, the LOQ, or whatever you want to call it is going to change continually over the next decade. It has over the past decade.

I think GC Mass Spec gives us some very good answers now and I expect to see more techniques coming along that will take that even further. I think that's the real concern on LOQ or level of detection. In a sense, if you go by level of

detection, you are going down even lower than LOQ, because most analytical chemists will tell you they need a little bit more level of detection to be able to quantify what you have.

I think we are asking a lot of our chemical engineering people as we move down and become more sophisticated in our analytical techniquas.

MR. REDFORD: Thank you.

MS. KEEHNER: If EPA modified its definition of a controlled waste process and set the cut-off for products at 50 parts per million, could you qualify for the exclusion?

MR. BLUME: Repeat the question one more time, please?

MS. KEEHNER: If EPA modified its definition of a controlled waste manufacturing process and set the level for no PCBs at 50 parts per million in the product, could you qualify for exclusion under this rule?

MR. BLUME: It's still zero quantifiable with respect to the manufacturing process and waste streams?

MS. KEEHNER: Zero in air and zero in -- well, no quantifiable in air and no quantifiable in water releases.

DR. SLIVA: I think the definition of no quantifiable would get us into a discussion immediately. I think that's, again, the problem.

Zero is a very low number and maybe that's the intent. However, from a reality position, I think we need a definition of what zero means.

MR. BLUME: And I gathered, Dr. Sliva, you are referring not only to the GE system, but virtually any system if you are going to test it in terms of zero quantifiable.

DR. SLIVA: That's correct. I believe that

whenever you can talk about one molecule escaping from a system, you've violated zero. I think there are people who try to interpret the law in that sense, even though it might not be the intent of the law to count the molecules that leave from a process.

I think that would be the difficulty that industry and General Electric would have with a statement of no quantifiable from a closed system.

MS. KEEHNER: How would you define manufacturing process, a product and a release for purposes of your system?

DR. SLIVA: How would I define -- let me take the first one, a product.

MS. KEEHNER: A process, could we try that first?

DR. SLIVA: A process.

MS. KEEHNER: Right.

DR. SLIVA: How would I define a process which would be inadvertently producing PCBs, is that --

MS. KEEHNER: Yes, I am concerned about, for instance, maybe you have more than one building on a site or a plant and you are moving things from building to building. What is the process?

Is the process the first step in a multi-stage, or would you consider everything --

DR. SLIVA: Most chemical processes do not take

take place in one particular vessel and are connected by pipes. In some cases they are connected by the movement of tank wagons.

Our process does consist of several steps. It does take place in one or more buildings and is connected by a piping system.

MS. KEEHNER: So you would consider that to be your process.

DR. SLIVA: I would call that the integrated process for the manufacture and control of phenylchlorosilane.

MS. KEEHNER: How about releases such as to water and air? Do you consider releases --

DR. SLIVA: All our vents and all our points of release are categorized and have undergone both a theoretical analysis, and I'll comment on that in a minute, and an actual empirical analysis of what those emissions are over a period of time.

There are protocols for those test procedures. I do not know what the results are, other than that we did present in a 1979 exemption petition some data relating to workplace monitoring.

In regards to the theoretical calculations, one can calculate -- can quantitatively measure with GC mass spec what the concentration of PCBs are in the materials

going to the vents. We call that theoretical because we back-calculate based on what we've found in the environment and ask ourselves is that reasonable.

In most cases the material balance did check.

MS. KEEHNER: I have no further questions.

MR. GUNTER: Follow up anyone? Thank you very much, gentlemen.

This completes the scheduled agenda of participants and, since there is time remaining before the end of the day, is anyone else present who would like to make a statement for the record? We have an opportunity to have that at this time.

(No response.)

MR. GUNTER: This hearing is closed.

(Whereupon, at 2:52 p.m. the hearing in the above-entitled matter was concluded.)

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REPORTER'S CERTIFICATE

DOCKET NUMBER:

CASE TITLE: Closed and Controlled Waste Process Rule

HEARING DATE: July 26, 1982

LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence herein are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Environmental Protection Agency and that this is a true and correct transcript of the same.

Date: July 27, 1982

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