

Hearing for the Closed and Controlled
Waste Process Rule

Monday, July 26, 1982

EPA PANEL

From R. J. Fenderheim
Ref. No. PCB-17-C
Date 7/28/82

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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

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

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

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

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

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

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

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

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

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

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

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

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

25 To his right is Dave Redford, also of the Exposure

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

5 To my far right is Deniss Keahner who is a
6 biologist on the PCB Regulations Team and is the lead staff
7 member for this rulemaking.

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

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

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

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

25 Let me comment briefly on how we are going to

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

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

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

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

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1 Regulations. That's all I have.

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

3 STATEMENT OF GERALDINE COX, CMA

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

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

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

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

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

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

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

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

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

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

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

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

18 Dr. Burgess?

19 STATEMENT OF DR. KENNETH BURGESS, CMA

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 The proposal cannot withstand review under the

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

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

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

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

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

25 We were thus quite dismayed by the serious

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

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

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

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

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

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

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1 500 ppm PCBs. However, in taking this step, the agency
2 recognized the additional economic burden and alleviated
3 it by allowing less stringent methods of disposal for
4 substances containing more than 50 but less than 500 ppm
5 PCBs.

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

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

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

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

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

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

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

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

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

25 In the second basic type when chlorinating

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

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

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

16 PCBs generated during incidental chlorination
17 should have similar selectivity in the ratio of total PCB
18 to the most prevalent congener should vary from 3 to 1 to
19 11 to 1. From this, it is obvious that a 1 ppm per congener
20 sensitivity limit means that the undetectable limit for
21 total PCB is 3 to 11 ppm.

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

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

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

9 These chemicals in turn degrade based on thermo-
10 dynamic stability since PCBs are quite stable, some may
11 survive. Steric and electronic effects dictate that
12 different structures will have different thermodynamic
13 stability.

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

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

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1 The physical property differences, namely, vapor
2 pressure and water solubility, will determine the ease of
3 separation and to some extent, the ratio of the constituents
4 between the streams, whereas it is technically feasible to
5 get good separation of decachlorobiphenyl from low boiling
6 products, the same degree of separation may not be feasible
7 for trichlorobiphenyl in products that boil between 150 and
8 200 degrees centigrade.

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

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

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

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1 out of 40,000 or 0.0025 percent.

2 In order to dramatize the triviality of such
3 concentrations, I would like to put the numbers in terms
4 more easily comprehended. For example, if 660 pounds of
5 PCBs representing a total annual quantity found in commercial
6 products in the CMA survey were contained in a chemical at
7 50 -- at 25 ppm concentration and were dumped on someone's
8 doorstep, it might be considered by some that that person
9 would have a PCB problem.

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

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

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

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1 chance that the ruffian would have an adverse effect on you
2 relative to the probability of being trampled by the other
3 79,998 is negligible. So it is with PCBs contained at such
4 low levels in unintentionally -- in intentionally manufactured
5 chemicals.

6 Carrying our example of the ten swimming pools
7 further, where those other 26 million-plus pounds of non-PCB
8 material water, there might be reason for concern about the
9 660 pounds of impurities. That is not the case. We are
10 dealing with chemicals other than water.

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

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

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

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

5 The issue in the current EPA proceeding is entirely
6 different than that addressed by Congress in TSCA Section
7 6(e). PCBs were at one time intentionally manufactured and
8 millions of pounds per year entered the assessable
9 environment.

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

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

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

25 A wide range of protection measures currently are

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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 chemicals can occur, chemical showers and eye wash facilities are 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

1 the low levels of inadvertently generated PCBs are unnecessary.

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

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

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

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

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

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

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

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

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

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

25 In order to reestablish production, a producer

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

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

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

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

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

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1 the analytical guidelines lying behind EPA's proposed rule.

2 STATEMENT OF ROBERT G. KALEY, II, MONSANTO COMPANY

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

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

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

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

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

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

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

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

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

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

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

25 A nonquantifiable cutoff using any analytical

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

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

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

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

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

25 It is imperative that EPA establish this cutoff

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

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

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

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

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

1 inadvertently generated PCBs.

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

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

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

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

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

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

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

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

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

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

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

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1 analytical hardware have occurred over the past several years.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Proper extraction and clean-up techniques are

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 a scientific point of view."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Finally and most important, EPA's claim concerning

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

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

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

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

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

1 are not specified.

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

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

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

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

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1 significant when dealing with a nonquantifiable cutoff.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 MR. GUIMOND: Bill?

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

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

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

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

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

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

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

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

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

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1 will -- is it better in the back?

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

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

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

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

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

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

25 Is it that those aspects are so different from

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

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

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

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

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

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

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

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

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

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

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

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

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

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

End Tape 2)

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

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

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

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

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

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

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

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

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

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

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

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

24 But, that type of thing would certainly help.

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

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

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

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

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

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

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

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

1 MR. GUNTER: How would EPA manage to get all of that
2 done before December 1?

3 MR. CERAR: You have got the information in the
4 record. There has been a good deal of health effects inform-
5 ation submitted to you. The main problem with the current
6 schedule is that even with an extension until December 1,
7 what you are going to be doing at that point is going back to
8 the court and asking for a further extension on the basis of
9 a plan that you will be laying before it at that time.

10 MR. GUNTER: That was precisely the point of my
11 question on credibility. Wouldn't we be in much better shape
12 in getting that plan and further state of mandate approved if
13 we had done exactly what we had told the court earlier that we
14 were going to do then if we hadn't?

15 MR. CERAR: I think that's quite true. It's unfor-
16 tunate that you can't accomplish the whole thing by doing
17 something meaningful at the same time. I'm not trying to be
18 facetious there. It seems to me it must be -- I mean, I hope
19 it's possible to analyze all of that information by the time--
20 by December 1, ideally.

21 But the thing that makes a company sitting here
22 waiting for all of this so insecure is that the court may or
23 may not grant the extension. They have granted -- the court
24 issued an opinion over two years ago, or almost two years ago
25 now, and they have allowed their mandate not to go into effect.

1 and to keep coming back and asking for more time is a bit
2 precarious.

3 MR. BLUME: I gather that EPA has no assurances on
4 that score.

5 MR. GUNTER: Not from the court.

6 MR. CARPIEN: Obviously the court doesn't say what
7 it is going to do, but in the original order, the court broke
8 up the incidental manufacture of PCBs into two different rule-
9 making. One, of course, is the one we are doing now, and the
10 other one was the so-called uncontrolled PCB regulation. It
11 seems to me the court wouldn't have made that statement,
12 wouldn't have allowed the rule to be broken up into that other
13 rulemaking if it did not intend to grant some kind of stay of
14 its mandate, given the fact that we could make the appropriate
15 showing.

16 It is certainly implicit in that stay of the mandate
17 would be, I would imagine, at least a good chance of being
18 able to have that mandate extended. The question would be
19 how long, I think, would be our main problem.

20 MR. GUNTER: I have one last question. Back in
21 1973, you said you became aware of the possibility, the
22 likelihood of public concern over the presence of mono- and
23 dichlorophenyl in your products. How did you arrive at that
24 conclusion?

25 DR. SILVA: Well, from a quality assurance perspective

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1 and some, if you will, analysis of our upstream processes, we
2 concluded that the levels we were currently running with in
3 our finished products could be reduced and should be reduced.

4 I think it was a culmination of some studies we had
5 going on internally and I think certainly some public reports
6 concerning the effects of PCBs on a larger scale. We took the
7 initiative because we felt it was appropriate to remove the
8 mono- and dichlorobiphenyls that were present in our process.

9 I would like to point out that we do not have any
10 trichloro or higher chlorinated PCBs in our phenylchloro-
11 silanes process and that the mono- and dichlorobiphenyl
12 materials are not as long lived in the environment as some of
13 the very highly chlorinated biphenyls are.

14 However, we felt that we could do something about
15 the problem and we took that action in 1976.

16 MR. GUNTER: It has been G.E.'s position, I believe
17 consistently throughout all these proceedings, that the
18 incidental manufacture of PCB should not be subject to
19 Section 6(e) of TSCA. If you were aware of this problem back
20 as early as 1975 when TSCA was being considered, why didn't
21 you try and get Congress to make clarification that would have
22 helped that position?

23 DR. SILVA: I think I will ask Jeff here to comment
24 on that. Let me just say that I quoted in the text, that we
25 always viewed incidental by products where we had a closed

1 system and we do have an integrated closed system involving
2 both incineration and some absorption type of processes. We
3 did not anticipate a ban based on incidental by products.

4 MR. BLUME: I can answer that question to the extent
5 we are able. Neither Mr. Cerar nor myself were around in that
6 era and we can only speculate at this juncture, so I don't
7 know that we can give you any kind of meaningful response.

8 MR. GUNTER: If there are others around who were
9 around during that time, perhaps you could give something
10 during the reply comments. That's all I have now. Alan?

11 MR. CARPIEN: I have no questions.

12 MR. SMITH: Since I am involved with sampling,
13 sampling relies quite a bit on the variability of the system
14 and I have heard statements this morning about folks feel that
15 you get relatively the same isomers in patterns. My question
16 is, from your analytical experience with your system, do you
17 see homogeneity in your, if you will call it contamination
18 or side reactions, or as you get slugs, what I would call
19 slugs of PCBs?

20 DR. SILVA: Well, as I mentioned earlier, we have
21 spent a considerable amount of time and money understanding
22 the chemical reaction with the intent of trying to reduce the
23 amount of PCBs generated. We have obtained information which
24 indicates that in our particular system it's essentially a
25 steady rate of production and that the isomer content does not

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1 change appreciably.

2 As I mentioned, we have monochloro and dichloro-
3 byphenyls. There is no trichloro material. The monochloro-
4 and dichlorobiphenyls I am sure you could get out of a standard
5 textbook, would therefore give you nine possible isomers. We
6 see all of those nine isomers. We understand the ratios of
7 each one to the other. We routinely analyze for each one of
8 those nine isomers.

9 MR. REDFORD: I would just like to get your reaction
10 to the analytical methods that EPA is proposing as in the MRI
11 document.

12 DR. SILVA: You are talking about GC Mass Spec, is
13 that correct?

14 MR. REDFORD: Yes.

15 DR. SILVA: We currently use GC Mass Spec to do many
16 of our analyses. I think it's what I would feel comfortable
17 with in terms of some of the analyses that we do in our
18 facility. I think, contrary to some of the comments that were
19 made earlier, that the level of detection or, if you will, the
20 LOQ, or whatever you want to call it is going to change
21 continually over the next decade. It has over the past decade.

22 I think GC Mass Spec gives us some very good answers
23 now and I expect to see more techniques coming along that will
24 take that even further. I think that's the real concern on
25 LOQ or level of detection. In a sense, if you go by level of

1 detection, you are going down even lower than LOQ, because
2 most analytical chemists will tell you they need a little bit
3 more level of detection to be able to quantify what you have.

4 I think we are asking a lot of our chemical engin-
5 eering people as we move down and become more sophisticated
6 in our analytical techniques.

7 MR. REDFORD: Thank you.
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1 MS. KEEHNER: If EPA modified its definition of
2 a controlled waste process and set the cut-off for products
3 at 50 parts per million, could you qualify for the exclusion?

4 MR. BLUME: Repeat the question one more time,
5 please?

6 MS. KEEHNER: If EPA modified its definition of
7 a controlled waste manufacturing process and set the level
8 for no PCBs at 50 parts per million in the product, could
9 you qualify for exclusion under this rule?

10 MR. BLUME: It's still zero quantifiable with
11 respect to the manufacturing process and waste streams?

12 MS. KEEHNER: Zero in air and zero in -- well,
13 no quantifiable in air and no quantifiable in water
14 releases.

15 DR. SLIVA: I think the definition of no
16 quantifiable would get us into a discussion immediately.
17 I think that's, again, the problem.

18 Zero is a very low number and maybe that's the
19 intent. However, from a reality position, I think we need
20 a definition of what zero means.

21 MR. BLUME: And I gathered, Dr. Sliva, you are
22 referring not only to the GE system, but virtually any
23 system if you are going to test it in terms of zero
24 quantifiable.

25 DR. SLIVA: That's correct. I believe that

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1 whenever you can talk about one molecule escaping from a
2 system, you've violated zero. I think there are people who
3 try to interpret the law in that sense, even though it
4 might not be the intent of the law to count the molecules
5 that leave from a process.

6 I think that would be the difficulty that
7 industry and General Electric would have with a statement
8 of no quantifiable from a closed system.

9 MS. KEEHNER: How would you define manufacturing
10 process, a product and a release for purposes of your
11 system?

12 DR. SLIVA: How would I define -- let me take
13 the first one, a product.

14 MS. KEEHNER: A process, could we try that first?

15 DR. SLIVA: A process.

16 MS. KEEHNER: Right.

17 DR. SLIVA: How would I define a process which
18 would be inadvertently producing PCBs, is that --

19 MS. KEEHNER: Yes, I am concerned about, for
20 instance, maybe you have more than one building on a site
21 or a plant and you are moving things from building to
22 building. What is the process?

23 Is the process the first step in a multi-stage,
24 or would you consider everything --

25 DR. SLIVA: Most chemical processes do not take

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1 take place in one particular vessel and are connected by
2 pipes. In some cases they are connected by the movement
3 of tank wagons.

4 Our process does consist of several steps. It does
5 take place in one or more buildings and is connected by
6 a piping system.

7 MS. KEEHNER: So you would consider that to be
8 your process.

9 DR. SLIVA: I would call that the integrated
10 process for the manufacture and control of
11 phenylchlorosilane.

12 MS. KEEHNER: How about releases such as to
13 water and air? Do you consider releases --

14 DR. SLIVA: All our vents and all our points of
15 release are categorized and have undergone both a
16 theoretical analysis, and I'll comment on that in a minute,
17 and an actual empirical analysis of what those emissions
18 are over a period of time.

19 There are protocols for those test procedures. I
20 do not know what the results are, other than that we did
21 present in a 1979 exemption petition some data relating
22 to workplace monitoring.

23 In regards to the theoretical calculations, one
24 can calculate -- can quantitatively measure with GC mass
25 spec what the concentration of PCBs are in the materials

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1 going to the vents. We call that theoretical because we
2 back-calculate based on what we've found in the environment
3 and ask ourselves is that reasonable.

4 In most cases the material balance did check.

5 MS. KEEHNER: I have no further questions.

6 MR. GUNTER: Follow up anyone? Thank you very
7 much, gentlemen.

8 This completes the scheduled agenda of
9 participants and, since there is time remaining before the
10 end of the day, is anyone else present who would like to
11 make a statement for the record? We have an opportunity
12 to have that at this time.

13 (No response.)

14 MR. GUNTER: This hearing is closed.

15 (Whereupon, at 2:52 p.m. the hearing in the
16 above-entitled matter was concluded.)

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1
2 REPORTER'S CERTIFICATE
3

4 DOCKET NUMBER:

5 CASE TITLE: Closed and Controlled Waste Process Rule

6 HEARING DATE: July 26, 1982

7 LOCATION: Washington, D.C.
8

9 I hereby certify that the proceedings and evidence
10 herein are contained fully and accurately on the tapes and
11 notes reported by me at the hearing in the above case before
12 the United States Environmental Protection Agency
13 and that this is a true and correct transcript of the same.
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1 have any hard data, but -- and, I think they treat that
2 quite fairly.

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

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

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

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

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

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

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

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

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

17 MR. GUNTER: Amy Moll?

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

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

1 validation, that would be helpful to us.

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

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

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

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

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

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

1 address that at this point.

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

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

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

9 MS. MOLL: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

1 If I understand your testimony today and some of the
2 comments that you made previously, you'd prefer that we
3 withdrew this and then went out and said that inadvertent
4 PCB's are not covered and, therefore, exclude everything on
5 that basis. And, in the alternative, withdraw this and put a
6 50 ppm cut off. Am I correct?

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

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

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

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

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

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

1 as long as you don't want it, it would qualify as unintentional?
2

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 "Some chemical processes may produce low
19 concentrations of PCB's which are released to the
20 environment, appear in the final product, are disposed of in
21 non-EPA approved landfills or by other disposal means (un-
22 controlled releases). These are thought to account for a
23 much smaller portion of the total generation of PCB's below
24 50 ppm".

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

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

7 DR. BURGESS: I think two things have happened:
8 we have learned more about our processes. Also, the fact
9 that you have been working on the analytical methods and we
10 have been working on the analytical methods, and as Dr.
11 Kaley has indicated, analytical methods move, I think we
12 know a lot more how to analyze for things today than we did
13 18 months ago when we were talking.

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

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

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

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

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

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

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

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

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

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

1 be correct?

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

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

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

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

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

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

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

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

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

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

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

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

19 Are they having any problems with detecting the
20 50 ppm detectable everywhere?

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

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

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

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

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

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

22 DR. BURGESS: I think that's true.

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

25 MR. GUIMOND: Processes, too?

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

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

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

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

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

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

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

21 MR. GUIMOND: Okay.

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

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

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

14 Again, I can't speak to that type of thing.
15 But, as Dr. Kaley has indicated, that is an option that
16 you have, rather than trying to pin down are you at 40 or
17 50 or 60. You could certainly file for the exemption
18 petition, rather than -- because -- perhaps the likelihood
19 is high that you are going to be there anyhow.

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

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

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

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

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

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

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

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

4 I'm trying to see what --

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

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

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

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

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

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

1 same problem at 50 ppm than the other?

2 DR. BURGESS: But, we have a tool then, we have
3 the analytical chemist has said with some effort, we can get
4 these analytical things worked down to where we can determine
5 50 part per million.

6 MR. GUIMOND: Okay. Then, to pursue just a little
7 bit more one point that Bill was talking about earlier, is
8 that you do make a very significant push for quantifying
9 something, getting you a target, some number to shoot at
10 here. And, do I hear that as, you know, 50 or not, some
11 particular number other than a real embarrassment in trying
12 to go and find a specific number that we can give you that
13 is going to give you not necessarily a 100 percent assurance
14 that you're going to beat it all the time, but a target to
15 shoot at frequently, since even 50 ppm doesn't give you the
16 100 percent assurance?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 MR. GUNTER: Okay. Dave?

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

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

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

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

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

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

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

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

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

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

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

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

End T 3

Seg T 4

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

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

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

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

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

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

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

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

1 below that point.

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

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

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

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

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

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

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

8 DR. KALEY: I don't think --

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

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

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

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

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

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

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

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

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

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

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

1 gone. They have certainly studied the field of analysis of
2 4 PCB's and whatever matrices were available and literature
3 references.

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

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

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

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

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

8 Just how loose are you saying?

9 DR. KALEY: Okay. I think --

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

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

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

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

1 of those methods to the primary method.

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

11 Does that answer your question?

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

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

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

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

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

3 I think one of the points we made, plus or minus
4 10 relative standard deviation on some of these matrices,
5 we work with is an extremely exacting thing. As long as we
6 know our analytical variability and know the projected value
7 given our recovery and precision, then I feel we can operate
8 effectively below a cut off.

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

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

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

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

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

24 Do you have any information on what criteria
25 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 insoluble, 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. KEETNER: One of the comments received in response to the proposal suggested that we define process,

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

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

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

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

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

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

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

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

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

10 I don't know what the inaccuracy figure is. Is it
11 50 percent, 100 percent, 500 percent? I don't think we're
12 orders of magnitude and I think the work that you have done in
13 looking at the exemption petition, where we are dealing with
14 materials over 50 ppm, would confirm that, that we are in the
15 right ballpark, whether it's 13,600, I'm -- I like to use
16 statistically significant numbers, even to say 13,600 makes
17 me shudder a little bit, but that's what we need to say in
18 order to get the things to add up.

19 Now, somewhere -- I guess I'd say somewhere around
20 15,000, plus or minus some number, and I worry about saying
21 13,600, but it -- but, that is, I think, the limit of our
22 technology at the present time in saying that.

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

1 on manufacture?

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

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

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

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

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

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

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

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

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

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

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

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

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

1 MR. GUIMOND: Okay.

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

4 DR. KALEY: Right. We would like --

5 MR. GUIMOND: But, if I heard you correctly, not
6 necessarily to the extent that you would. You would not
7 expect us to validate our method for each and every possi-
8 bility.

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

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

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

18 MR. GUIMOND: Okay.

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

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

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

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

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

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

13 DR. BURGESS: Yes, it is.

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

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

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

23 But, most people were basically looking at it as
24 PCB by rule, 50 part per million.

25 MR. GUNTER: Even with the language like without

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

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

7 MR. GUNTER: That's all I have.

8 MR. GUIMOND: Any additional questions?

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

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

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

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

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

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

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

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

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

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

25 Basically, we're talking about three levels in

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

3 MR. REDFORD: Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 I think you would be heading in that direction

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

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

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

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

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

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

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

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

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

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

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

18 A previous witness testified that the fact that
19 50 parts per million was drawn as the limitation has been a
20 technology forcing -- a fact of life and many companies have
21 changed their processes and fine-tuned their analytical
22 procedures to be able to comply with that.

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

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

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

17 I also think it would be appropriate for you to
18 have a number of different limits so that if you are concerned
19 about the release of PCBs into the air, it would be appropri-
20 ate to have one number for that and the release of PCBs into
21 the water, another number for that, if the ability of the
22 analytical methodologies to get down to different numbers
23 depending on the medium is as variable as it is. And the
24 hardest part is dealing with the complicated matrices such as
25

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

10 Ellen will speak to the question of theoretical
11 analyses.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 That's all.

12 MR. GUIMOND: Thank you, Jackie, Ellen.

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

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

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

20 MS. KEEHNER: In products.

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

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

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

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

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

15 MR. GUIMOND: Dave.

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

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

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

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

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

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

19 In those instances, then, the health concern
20 is overriding and really drives the analytic technology to
21 develop methods sensitive enough to reflect that concern.
22 That certainly has been the case with dioxine and
23 probably is also the case with the dibenzofurans.

24 MR. REDFORD: Thank you.

25 MR. SMITH: I have no questions.

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

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

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

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

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

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

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

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

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

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

18 I would rather have a cap on the amount.

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

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

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

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

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

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

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

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

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

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

17 MR. GUIMOND: As it exists today presently?

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

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

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

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1 and I am just using this as an example.

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

9 You could live with that kind of approach?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MS. WARREN: Initially, yes.

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

1 MS. WARREN: It's a qualitative difference.

2 MR. GUIMOND: Right.

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

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

8 MS. WARREN: Yes.

9 MR. GUIMOND: And --

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

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

25 So, philosophically, wouldn't you also think that

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

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

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

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

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

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

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

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

11 I'm not 100 percent clear --

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

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

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

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

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

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

8 MS. WARREN: Yes.

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

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

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

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

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

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

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

8 MR. GUNTER: With regard to the establishment of a
9 series of cutoffs for various media, you have suggested that
10 these should be in the neighborhood of the LOD. Wouldn't these
11 numbers of necessity have to be around the LOQs, since other-
12 wise you wouldn't be able to make quantitative measurements,
13 it would be below what you would be able to quantify.

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

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

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

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

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

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

20 MS. WARREN: The problem is that if PCBs are not
21 incinerated at the right temperature for the right amount of
22 time, you get Dibenzofuran and other toxic intermediate combustion
23 products. You still get them as long as there are
24 PCBs, and I think if you are not going to control the
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1 incineration of them properly that's going to be a problem.

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

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

11 MR. GUIMOND: Laura.

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

13 MR. GUIMOND: Amy.

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

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

25 MS. WARREN: Well, unless that condition could never

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1 occur in the manufacturing processes in which the protective
2 clothing was being used, where PCBs were present as a contamin-
3 ate, I think what he said was still relevant.

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

8 MS. WARREN: Depending on how you reach the deter-
9 mination that no significant exposure could occur. If you
10 change your definition of what is a significant exposure,
11 probably I will have a problem with that.

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

14 MS. WARREN: No, from what your determination of
15 what constitutes a significant exposure, which you are pro-
16 posing to keep the same definition of significant exposure
17 that you had in the previous rulemaking.

18 MR. GUIMOND: Okay. For the record, would
19 Ms. Silbergeld please state her education and possible exper-
20 iences with industry practices or alternatively, your qual-
21 ifications to give testimony today on engineering and analy-
22 tical technology.

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

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

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

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

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

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

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

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

9 MS. WARREN: Yes.

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

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

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

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1 if I were involved in reproduction, it might be very signifi-
2 cant. It would also depend very much as to my historical
3 encounters with PCBs.

4 MR. GUIMOND: Anything to add?

5 MS. WARREN: I already answered the question.

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

8 MR. REDFORD: I have two.

9 MR. GUIMOND: Go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 its customers, and the public.

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

8 I direct your attention to those comment as a
9 statement of G.E.'s concerns with the overall regulatory ap-
10 proach that EPA has chosen to follow respecting incidental
11 PCBs. Those comments explain that as currently formulated,
12 the EPA proposal does not provide relief from the ban for
13 G.E.'s carefully controlled process.

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

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

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1 result from the chemical reaction by which phenylchlorosilanes
2 are produced.

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

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

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

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1 by the Navy.

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

9 They are also an essential part of our daily life
10 as sealants and as coolants in car engines as well as weather-
11 proof coatings for construction materials and insulators for
12 electrical television components.

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

18 Without waiting for legislative or regulatory action,
19 General Electric voluntarily undertook an extensive and com-
20 prehensive technical program with the objective of ensuring
21 that PCB materials were not distributed in commerce and did
22 not enter the environment as a result of phenylchlorosilane
23 manufacturing.

24 In 1975, no one foresaw that unintentional forma-
25 tion of PCB byproducts enclosed in controlled systems would be

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

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

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

20 We have been successful, however, in removing PCBs
21 from our current process and destroying them. As early as
22 1976, General Electric's Silicone Products Division reduced
23 the PCBs in the process to a sufficient degree that by-product
24 PCB concentrations in products are below fifty parts per
25 million. Moreover, our on-site disposal facility, which we

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

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

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

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

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

1 ample justification for that action. General Electric peti-
2 tioned EPA on July 14, 1982, to amend the PCB regulation in
3 that respect.

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

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

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

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

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

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

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

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1 action on its exemption request.

2 As General Electric has already pointed out in its
3 comment of November 16, 1981, submitted in response to the
4 May 20, 1981 advance notice of proposed rulemaking in this
5 proceeding, the exemption process is an inadequate solution
6 to the problem, due to the unjustified expense and adminis-
7 trative burden that it places upon industry and EPA alike.

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

17 Currently General Electric sells hundreds of pro-
18 ducts derived from the precursor phenylchlorosilanes to thou-
19 sands of direct customers. The immediate economic effects to
20 General Electric of discontinuing its phenylchlorosilane based
21 products include the immediate loss of tens of millions of
22 dollars per year in sales and the estimated direct loss of
23 more than 200 jobs at its Waterford, New York facility.

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

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1 by product PCBs from phenylchlorosilane -- from the phenyl-
2 chlorosilane process, along with the loss of present facilities
3 for the production of phenylchlorosilane and removal of by
4 products, mono- and dichlorosiphenyls. The combined value of
5 these facilities is estimated in the tens of millions of
6 dollars. The majority of the capacity of these facilities can
7 not be used for any other applications.

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

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

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

1 them.

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

7 Other adverse effects of the discontinuance of
8 General Electric's phenylchlorosilane based silicone products,
9 include the substantial loss of sales and jobs for suppliers
10 of goods and service to the Waterford plant. The discon-
11 tinuance of General Electric's phenylchlorosilane process will
12 have an impact, not only on the Waterford, New York area, but
13 on the national economy as well.

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

21 The real issue in this entire proceeding is whether
22 regulating PCBs as a defined regulatory cutoff would adequate-
23 ly balance the interests of industry, government, and con-
24 sumers. The exemption process is cumbersome and time-consuming
25 and is designed to deal with case by case issues. It is not

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

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

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

17 I have outlined the severe economic impact EPA's
18 most recent proposal will have on General Electric and its
19 customers. We have no doubt that the proposal equally affects
20 many other companies. EPA itself recognized in its June 8,
21 1982 proposal, that a ban on incidental by products would cost
22 billions of dollars and cause the elimination of a wide variety
23 of products with great social value.

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

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

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

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

16 DR. SILVA: Correct.

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

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

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

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

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1 products. Many of those materials have trace levels of PCBs
2 in a matrix which does not allow movement of that material
3 from the matrix. I could give you a more definitive answer
4 on that if you would submit that question to us in writing,
5 we possibly could give you a spectrum on some of our products.

6 MR. GUIMOND: Okay. Let me ask a hypothetical
7 question. You have already identified your concern that you
8 right now do not fall into this proposed exclusion, therefore
9 are up in the air as to what might happen in the future,
10 whether you have to just rely on the exemption petition pro-
11 cess, if subsequent to this rulemaking, if EPA went ahead with
12 this current rulemaking and the way it's set up now, went
13 final with it, and you did not qualify, and in the following
14 rulemaking which we are currently planning to undertake, we
15 then proposed to exclude products that presented little risk,
16 and assuming that your's fell into that, would there be any
17 economic impact or any problem to you at that stage? Would
18 that be reasonable solution for you? Could you live with that?

19 DR. SILVA: If you are talking about, again, an
20 annual exemption procedure, and we would have to verify the
21 levels --

22 MR. GUIMOND: I am not talking about an annual ex-
23 emption procedure, I am talking about --

24 DR. SILVA: You are talking about a permanent --

25 MR. GUIMOND: Let's just hypothetically assume that

1 we came up with a third rulemaking and the third rulemaking
2 consisted of, part of it in any event, we proposed to exclude
3 certain processes that presented di minimis risk or small
4 risk, that were over and above, that were different kinds of
5 processes from closed and controlled waste processes.

6 Let's hypothetically assume that your's fell into it.
7 What would be your problem with this rulemaking in that event?

8 DR. SILVA: My opinion is that it would be of
9 minimal impact, assuming that we had quantitative limits on
10 what you are talking about in terms of risk. We would want a
11 quantitative set of specifications.

12 MR. BLUME: I am not certain to what you are refer-
13 ring with respect to the next phase of the rulemaking rela-
14 tive to a process other than that which is being referred to
15 today.

16 MR. GUIMOND: Alan Carpien referred to it earlier
17 when we talked this morning, is that we are doing this closed
18 and controlled rulemaking response to the court and then we
19 have schedules to do a third rulemaking that deals with un-
20 controlled PCBs, and it has always been our intent in the
21 closed and controlled one to deal with a category which was
22 described from -- started from original discussions with
23 industry and then was ultimately -- a deal, if you will, was
24 out in an order with the court.

25 What I am saying is that that does not preclude us

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1 from excluding additional processes because they present di
2 minimis risk although they may not be closed and controlled
3 waste processes. What I am just trying to find out is that
4 if you feel -- Let's assume you don't qualify for this, and
5 we fix this so you still don't qualify, in the third rule-
6 making you still conceivably might qualify for an exclusion
7 depending upon the risk associated with what you are doing
8 and how that gets crafted.

9 If, in fact, you did qualify in that third rule-
10 making, would there be any particular impact or negative
11 problems created for General Electric by this current rule-
12 making? What I am trying to get at, it seems that you are
13 calling this one a large impediment, this is a problem because
14 you are not included in it.

15 The response, I guess, or the thing is that the
16 rule may not have been crafted for inclusion of your kinds of
17 things. It does not mean that your kinds of processes would
18 be banned. I am trying to find out, given that as an assump-
19 tion, do you have any additional problems with this rule-
20 making?

21 MR. BLUME: At the risk of reducing the question to
22 basics, I gather the question is, that if a further phase of
23 the rulemaking were to come up with parameters be fashioned
24 along lines which would exclude our process, would we be warm
25 and happy?

1 MR. GUIMOND: Yes, you have got it.

2 MR. BLUME: The answer to that is definitely yes.

3 MR. GUIMOND: A real fuzzy feeling.

4 MR. BLUNE: Jeff, did you have something?

5 MR. CERAR: Yes. I'm Jeff Cerar. I am counsel to
6 G.E. on this rulemaking. The thing that troubles me about the
7 question is that it was precisely our kind of process that
8 this deal that was struck was supposed to be addressing. That
9 is why we have difficulty with it. When we listened to your
10 questions this morning of CMA, where you read from a January
11 1981 submission to the court, I think it's a mistake to
12 characterize our positions today as inconsistent with what
13 was said back then.

14 For example, the closed system, as defined in that
15 submission, and defined in some of our discussions, we had
16 trouble with the concept of any detectible PCBs, but as a
17 matter of fact, the closed system was supposed to be -- the
18 attempt was being made there to define something that was
19 almost a theoretical possibility. That was a system in which
20 PCBs come and go and they are created and disappear and never
21 go anywhere.

22 Nobody has ever believed, the CMA people have never
23 believed that there would be very many systems falling into
24 that category. The controlled waste system, as you have called
25 it, and as was part of the discussion back in 1981, 1980, is

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1 really the one that we are talking about and it's the one that
2 G.E. would hope to qualify for. That's one where there are
3 PCBs that come out of the system in the products and in the
4 waste.

5 The problem with the mechanism that you fashioned
6 here is that it goes down to levels that are so low that no-
7 body can qualify for it. If there are people who can qualify
8 for it, then our surmise is in error, but G.E. can quantify
9 at such low levels that the system, as set up, is of no
10 practical value.

11 Sure, it would make G.E. very happy to be excluded
12 one way or the other from this, and in that sense, this
13 proposal wouldn't pose an impediment. But, this proposal was
14 supposed to deal with precisely the kind of problem that we
15 have brought to your attention.

16 MR. GUIMOND: Okay, thank you. I am, unfortunately,
17 going to have to leave for a few minutes to go to a meeting
18 I can't avoid. In my absence, Bill Gunter will be the
19 Chairman of the panel.

20 MR. GUNTER: Amy Moll.

21 MS. MOLL: Would you say that most of the processes
22 that you say would not be excluded under this rulemaking,
23 would not be excluded on the basis of the concentration of
24 PCBs in their products, like in G.E.'s case?

25 DR. SILVA: If I can repeat the question a little

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1 and see if I understood what you are saying, you are saying
2 the exclusion would not be granted based on the levels in the
3 final products, is that correct?

4 MS. MOLL: Yes.

5 DR. SILVA: I, speaking for our own process, I
6 believe that's correct and I think for many other processes
7 that I am familiar with I would also agree.

8 MS. MOLL: You mentioned that G.E. has filed ex-
9 emption petitions in the past. Can you give us any idea as
10 to what the costs of filing those exemptions has been for
11 your company? Or if you could submit that information.

12 DR. SILVA: Well, the cost is -- if you want to try
13 to calculate the direct costs, you might want to try to look
14 at xeroxing. I am trying to be a little facetious here, but
15 it's the indirect costs that get you on these proposals. For
16 instance, the exhaustive analysis of our product line and the
17 precursors in many of our product lines are the type of in-
18 direct costs that are built into these exemption petitions.

19 Having to do this yearly would mean we would have
20 to update our analysis every year and, in fact, I would put
21 the cost in the range of several -- tens of thousands of
22 dollars -- certainly over one hundred thousand dollars cumu-
23 lative for preparing just our petition.

24 MS. MOLL: Does that include doing all the research
25 to find alternative --

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1 DR. SILVA: No, no. That's why I say, if you want
2 to include the actual testing, et cetera, that went into
3 being able to prepare the petition, it's in the range of
4 hundreds of thousands of dollars. As we get into the efforts
5 I outlined regarding alternative processes, we are talking
6 millions of dollars, and that did not include those efforts.

7 MS. MOLL: What would you say are the closest
8 substitutes for phenylchlorosilanes at this point?

9 DR. SILVA: I wish I knew. I think we have looked
10 at some materials which come close, but having the right mix
11 of overall properties is the issue, flexibility, low temper-
12 ature, high temperature, electrical resistance, radiation
13 resistance, having all those things in the right molecule is
14 pretty tough to come by.

15 It's many of those problems that have caused many
16 of our customers to come to us for these specific materials.
17 The space shuttle is a good example. There is no material
18 that has been able to achieve the type of adhesion and thermal
19 resistance to date.

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

21 MR. GUNTER: Laura.

22 MS. CAMPBELL: My first question relates to worker
23 exposure to PCBs. What measures has your company taken to
24 avoid worker exposure or deal with this problem to PCBs during
25 the production of phenylchlorosilanes?

1 DR. SILVA: Okay. Phenylchlorosilanes are produced
2 in a closed system. The work place monitoring is done routine-
3 ly at Waterford and has looked at very low levels of PCBs in
4 the air. All those analyses have been, if you will, analyzed
5 and processed and are done routinely. I am not exactly sure
6 of the time frame in which we are doing them now, but it is
7 essentially an air sampling type of technique.

8 Some procedures involve the operators wearing
9 actual sampling devices which are then analyzed as part of
10 the whole site survey.

11 Mike has commented that some of that data is present
12 in the 1979 exemption petition.

13 MS. CAMPBELL: We also asked for information in the
14 notice of proposed rulemaking and I was wondering if you have
15 any data indicating both the number of accidental or unplanned
16 releases of PCBs, and if so, the amount of PCBs released
17 during such events?

18 DR. SILVA: I am not familiar with what information
19 we have submitted to date. Dick, would you like to --

20 MR. BLUME: We certainly don't have that information
21 with us today, but to the extent that such incidents are
22 required to be reported, they of course are, and that inform-
23 ation is available to you.

24 MS. CAMPBELL: Okay, I am interested particularly
25 in if those incidents have occurred, what measures have been

1 taken to protect the workers or to prevent environmental ex-
2 posure, clean-up procedures.

3 DR. SILVA: We have standard procedures for all the
4 processes that involve phenylchlorosilanes which contain PCBs.
5 Those are documented procedures in terms of how operators and
6 various other workers can -- must, if you will, handle the
7 materials which are spilled or whatever. Dick pointed out
8 that there is a notification procedure involving PCB releases,
9 and to my knowledge we have been following that procedure.
10 I do not have the specific information relating to how much or
11 if there have been any releases.

12 MS. CAMPBELL: Thank you.

13 MR. GUNTER: Dr. Silva, in your prepared statement,
14 you indicated that the date on which -- on page 7, you
15 communicated that the date on which the court's mandate goes
16 back into effect is less than three months away. Are you not
17 aware that that mandate has been extended -- that the mandate
18 has been extended to December 17

19 DR. SILVA: No, I was --

20 MR. CARPIEN: It is stated in the Preamble. It has
21 been requested in the Preamble and the court granted the
22 request and gave the date. It is April 15 or 9, I can't
23 remember exactly the date.

24 DR. SILVA: Okay, so we have an additional month.
25 It doesn't help us -- it would be nice for a Christmas present

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1 MR. GUNTER: I would like to address this next
2 question to the two attorneys. If EPA is to go back to the
3 court, as we are currently scheduled to do on November 1, with
4 a plan as to how we are going to address the third part of the
5 rulemaking, wouldn't our credibility with the court be im-
6 proved if we had gone forward with the promulgation of a
7 final rule on closed and controlled systems as the court had
8 ordered us to do, rather than to withdraw that and report to
9 the court that we are simply dropping back to rethink the
10 whole situation?

11 MR. CERAR: I agree with your basic premise that it
12 is always better to show some action when you are going back
13 to the court, particularly action that you said you were going
14 to take. But, if we are correct that it doesn't do anything,
15 that isn't a very satisfactory kind of action. Maybe at this
16 point we ought to say that we haven't asked you to withdraw
17 this proposal. General Electric has not.

18 What General Electric would like would be this pro-
19 posal with an acceptable cutoff substituted for the level of
20 detection criteria and that is doable within the period
21 directed by the court.

22 MR. GUNTER: You would like to see an acceptable
23 cutoff based on the highest di minimis standard which could
24 be supported, is that correct?

25 MR. BLUME: That's correct.

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