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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

In the Matter of:

ADMINISTRATOR'S TOXIC SUBSTANCES ADVISORY COMMITTEES

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U. S. ENVIRONMENTAL PROTECTION AGENCY

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March 19, 1980
9:45 a.m.

Waterside Mall
Room M-3906-3908
Washington, D. C.

SELINA BENDIX, CHAIRPERSON

MARSHA D. RAMSEY, EXECUTIVE SECRETARY

MEMBERS:

PROF. MICHAEL S. BARAM

DR. THEODORE L. CAIRNS

DR. MAX EISENBERG

BECKY F. MOON

THOMAS W. MOONEY

DR. LOUIS E. SLESIN

DR. WILLIAM L. SUTTON

C O N T E N T S

P R O C E E D I N G S

CHAIRPERSON BENDIX: Good morning. I am Dr. Selina Bendix. J. A. Kinney, the Chairperson of this Committee, was unable to be with us today, and I am acting on her behalf.

The first item on the agenda this morning is a discussion of preliminary draft of an ATSAC report on TSCA's first three years.

And since we do not have a full complement yet here this morning, I wanted to hear those members who are here, if they would like to take a few minutes to read some of what Michael Baram has compiled, and then if other people have arrived, we can then proceed with discussion of this.

If you will look in your packet, you will see there is a thick item from Michael, a Report to the Administrator -- labeled "A Report to the Administrator,EPA," from the Advisory Committee on Toxic Substances, April 1980, with an outline at the bottom.

MR. BARAM: Let me add, Selina, this is a strict cut and paste job. There was no editing. I simply took comments that were submitted by four members -- five members and cut and paste them together.

CHAIRPERSON BENDIX: Later I will ask Michael to give us a brief report on what he has done and the range of the kinds of comments that he has received, but I would

like to defer that until more members of the Committee arrive.

MR. BARAM: It was sent in last week to Marsha, and it took time to Xerox. I should add that the comments came in from Ted Cairns, myself, Jackie Warren, Jane Kinney, and Dr. Eisenberg submitted no comments because he is a new members.

So five people are accounted for in this draft.

(Whereupon, a brief recess was taken)

CHAIRPERSON BENDIX: I would like to call the meeting back to order. I would like to discuss the agenda for the rest of the morning briefly.

As of now, I cannot see our breaking up into three committees. What I would like to propose to the group is that we drop the Section 6 Subgroup Meeting this morning, since we have, in fact, had considerable opportunity at past meetings to discuss the asbestos issue, that we ask Warren Muir if by any chance he could find it possible to arrange his schedule to come here before 11:00 so we could start the Section 4 Test Rules discussion early.

There are some changes in schedule in the items under the "Information Gathering, Public Participation, International Issues."

The schedule had been rearranged to change Item 2, the status of the public participation program, to 1:30; Item 3, the status of 8(d) and (e) reports and the 8(c)

rule to 2:15, and the OECD activity to 11:45.

I would propose that we might meet as a whole to discuss the Section 4 test rules, and when Mr. Fuller arrives at 11:45, we would have the option of either breaking up into two groups or if we feel that we are prepared to switch from Section 4, that we might all meet with him on the OECP activities.

May I have some reaction to that?

MR. MOONEY: Yes. Selina, I think it is very likely that what Mr. Fuller would have to say about OECD bears very directly on Section 4 testing.

I think, in terms of what I see as being most active in OECD right now, it relates to the testing subjects. So I am not sure they are really exclusive, and you might want to keep the whole group together.

CHAIRPERSON BENDIX: I must confess I would personally be happier that way because I would like to hear the discussion of the OECD activities.

I just don't want people who are interested in the Section 4 test rules to feel that we are cutting off discussions prematurely.

MR. MOONEY: I think there is a linkage.

CHAIRPERSON BENDIX: I agree, and I dislike breaking a group of six people up into subgroups if I could avoid it.

Marsha, could I ask you to call Warren Muir and ask if it would be possible for him to come earlier, and meanwhile we will go on the record and ask Michael Baram to discuss briefly what he did and to talk a little bit about this draft report.

MR. BARAM: Beforewe get to the draft report, I do have one question, and that is on the first page of the agenda, Selina, the only item that is being dropped from the first page of the agenda is asbestos in schools.

CHAIRPERSON BENDIX: That is correct. And Marsha will notify Mr. DeKany and Mr. Guimond.

MR. BARAM: And we will endeavor to deal with everything else in sequence as one single group.

CHAIRPERSON BENDIX: That means also we are dropping Item 1 under Information Gathering, so Mr. Bruno Vasta should also be notified--"What information is currently available to the public? How can it be used by the public?

Is there anyone else? Would you be willing to go to that rather than going to Section 4 test rules,and is there anybody else who would join Becky on that?

MS. MOON: It may be just having -- I guess you just can't make these pieces of material available.

CHAIRPERSON BENDIX: If he had any handouts that he was planning to make --

MS. RAMSEY: He was really going to talk about access to the computer system and that sort of thing. Marilyn Bracken was going to give a more general overview earlier.

MR. BARAM: I think that would be quite interesting.

MS. MOON: Yes. We have been talking about that.

CHAIRPERSON BENDIX: Somewhere we are going to have to make a decision because we can't do all these things simultaneously.

MS. MOON: I wonder if Mr. Vasta could come in at 10:00 or 10:30. Could he possibly? We were going to have Warren Muir come in earlier, weren't we?

CHAIRPERSON BENDIX: I really don't think we are going to deal with Section 4 in 45 minutes. I would rather see --

MR. BARAM: What are our priorities on the first page? The first page would be Section 4 test rules. Secondly, I think very important, are EPA's plans for hazard warning labeling.

I think that is something the Committee should discuss.

CHAIRPERSON BENDIX: That is in the afternoon.

MR. BARAM: That is in the afternoon. What other priorities do we have on the first page? What are the 3 and 4 priorities? Maybe we can drop some of the other

items.

MR. MOONEY: Well, Mr. Auerbach's concurrent meeting, labeling that is taking place right now, will that be over by 1:30? Mr. Auerbach has three days.

MS. RAMSEY: Mr. Auerbach will not be here. John DeKany was going to do this. There was a change on that.

MR. MOONEY: Okay.

CHAIRPERSON BENDIX: I think we ought to deal with the morning to start with. If we start worrying about this afternoon's schedule, we are going to get bogged down.

What I was proposing that the Section 4 test rules and the OECD item were the two priorities for this morning, and Becky has suggested that.

CHAIRPERSON BENDIX: Becky, I offered a suggestion and you made a counter suggestion about the agenda. Is there anyone else who joins Becky in wanting to have an opportunity to discuss with Marilyn Bracken and Bruno Vasta and Mr. Kovalick -- no, Kovalick is available in the afternoon, sot that is not a problem.

MS. MOON: Perhaps it would be better to postpone that until the next meeting but be sure to pick it up again because Jackie was very interested and Janie was very interested in that.

So perhaps that is what we ought to do--get those

things on the agenda next time.

CHAIRPERSON BENDIX: I think we will have an opportunity to raise some issues about public participation tomorrow with Mr. Jellinek.

MS. MOON: Let's do that.

MS. RAMSEY: The only thing we are going to do this morning is Section 4 test rules.

CHAIRPERSON BENDIX: And OECD with Mr. Fuller at 11:45.

MS. RAMSEY: Is 45 minutes long enough for the test rules?

CHAIRPERSON BENDIX: That is why we were asking you to call Warren Muir to see if he could come in.

MS. RAMSEY: If he cannot, I will see if Pep Fuller can come earlier.

MR. BARAM: Once again now, we can turn to the draft compilation of a possible committee report. At the last meeting we discussed the advisability of this Committee after 3-1/2 years of sitting in meetings and trying to play a constructive role, the advisability of this Committee putting together a consensus report which would establish some overall guidance and constructive criticism and praise, where justified, on the program.

Without reaching any agreement as to the overall advisability, we decided to do it as a preliminary kind of

exercise.

I agreed to cut and paste the comments that came to me. Of the 16 or 18 Committee members, five Committee members responded.

These include Dr. Auerbach -- I am sorry; Dr. Eisenberg, who simply said "no comment" because he was such a new member of the Committee. That was his first meeting, in fact.

Then substantive comments came from Ted Cairns, Jackie Warren, Jane Kinney, the Chairman of the Committee, and myself.

What I have done is simply cut and paste these comments and, as you can see, they are not too lengthy, they are general in nature, they generally run to criticism not on legal or technical grounds, but I would say criticism on internal policy about perhaps going too slowly or perhaps too painstakingly, although there are other comments which reflect other attitudes.

But we decided to deal with eight major issues which are stated on the first page: How OPTS was performing on testing requirements; Number 2, the PMN Procedures; Number 3, Regulation, Risk Assessment and Economics; the fourth issue had to deal with information gathering; the fifth issue, citizen participation; the sixth, cooperative efforts with other agencies and international efforts;

The seventh was specific cases of regulation as to asbestos and PCBs; the eighth, overall management. Well, the comments, as you can see, deal most heavily with the first three or four items and sort of tailed off after that.

Since you have just gotten this report this morning, it would probably be most useful at this stage if you simply took the report with you, thought about it, decided whether you wanted to add any comments or, as I have done in a few of the cases, simply endorse comments made by other people by adding my name next to what they essentially submitted and go through yet another iteration of this or recommend that the whole matter seems to be not leading to any useful convergence and should be dropped.

But I think probably some further thought should be given since only five people responded and since very few of the members are here today to discuss the report.

I would be happy to try to interpret some of these comments for you or go over them with you now if you want to spend the time.

CHAIRPERSON BENDIX: Does anyone on the Committee have any comments, any desires, with respect to how we should proceed this morning with regard to this matter that they would like to express?

MR. CAIRNS: All the comments are quite brief.

There are also a lot of them, if you add them all up. I don't think I have been able to digest them; I have only got to Page 5 since the report was handed out.

MR. BARAM: It was unintentional to be so late. It is just that the comments kept coming in.

MR. CAIRNS: I think we would do better, in view of the small attendance, to ask the Committee to go back and take a nice quiet Saturday afternoon where there are no football games and see if they have comments on the comments.

CHAIRPERSON BENDIX: In that case, we would ask Marsha Ramsey to send copies of this material to the members of the Committee who are not present today.

MR. BARAM: I would also suggest that this be kept within the Committee's confines because these all represent preliminary deliberations and discussions; these do not reflect any Committee consensus at all, so we should just keep this here for the Committee.

MR. CAIRNS: And of course it is so indicated.

MR. BARAM: Yes. Are there any other comments on this draft report? Do we all agree then with Ted's suggestion?

MR. MOONEY: I want to comment, and it is only an inadvertent oversight on my part that I failed to notice this was in the packet that was sent to me when I missed the last meeting.

I do want to comment these are very interesting to read. Some I agree with and strongly support. Others I think I take issue with, at least from my perspective, so I would like the opportunity to comment.

MR. BARAM: Fine.

CHAIRPERSON BENDIX: Marsha, I think that we would like to be sure that this material be sent to the members.

MS. RAMSEY: It already has been done.

CHAIRPERSON BENDIX: All right.

MR. BARAM: Perhaps a follow-up reminder note at some time.

CHAIRPERSON BENDIX: I would presume, then, we also wish to drop from tomorrow's agenda the 11:30 item on discussion and adopt resolutions.

MR. BARAM: Yes, definitely.

MS. RAMSEY: I didn't hear the discussion because I was on the telephone.

MR. BARAM: We are going to take this report back with us, Marsha, and discuss it at the next meeting to see where we are at the next meeting.

MR. MOONEY: Are we likely to have a different attendance tomorrow? Should we keep an entry on the agenda to at least recycle on what we have been kicking around here?

We don't know where the people are.

MS. RAMSEY: I don't know what happened with Janette Sherman, but Ted Radford should be here tomorrow.

MR. BARAM: That is still less than half the Committee.

CHAIRPERSON BENDIX: I don't think it is worth reopening the discussion for one additional person.

MR. MOONEY: Okay.

MR. BARAM: I am sure we will have time for questions. We will probably have time tomorrow.

CHAIRPERSON BENDIX: It appears that the various people who are due to come in at 11:00 and subsequently have schedules such that they couldn't come in earlier, and unless somebody present has something they would like to propose for discussion, we will recess the meeting for 11:00.

Does anyone have anything they would like to bring up? If there is anybody in the public who would like to make comments to those of us who are here at this time, we would be happy to take public comments, since we are ahead of schedule on our agenda.

Seeing no expression of such interest --

MR. MOONEY: Is there any meaningful expression we can have on Section 4 test rules?

MS. RAMSEY: Can you read the paper?

MR. MOONEY: Couldn't we turn, for example, to

Lou to update us on significant activities his organization has been involved with that bears on this?

MS. MOON: I would appreciate hearing that.

MR. MOONEY: Your suit is a significant suit and something feels funny to me about just adjourning until 11 o'clock, and I have got to believe there is something constructive we can do in the absence of Warren Muir until then.

DR. SLESIN: The NRCC suit is progressing. We have just received the papers from EPA just last week, an affidavit from Mr. Jellinek, and the test package.

We are still looking at that. There is really not much to say, other than we have a few weeks to respond to that and we are now in the process of reading those documents and preparing a response.

MR. CAIRNS: What was this: the same thing we got last --

DR. SLESIN: Yes, absolutely.

MR. MOONEY: Have people seen Jellinek's affidavit in response to the court's decision? That really lays out a fairly detailed program in what is going to happen under Section 4 as the Agency proposes it.

MR. CAIRNS: I have not seen it.

MR. MOONEY: In the next four years.

DR. SLESIN: I would not have anything official

to say at this time until we have had a chance to look at it.

MR. MOONEY: It probably puts you in an awkward position.

MR. CAIRNS: Madam Chairman, this affidavit from Jellinek must be a public document. It isn't 50 pages long, is it?

MR. SLESIN: Yes.

MR. MOONEY: It is 50 pages long or so. I have a copy of it.

MR. CAIRNS: I was thinking it might be distributed, but that is not practical.

MR. SLESIN: It is certainly worth reading.

MR. CAIRNS: It could be distributed later, but not something you could hand out now.

MR. MOONEY: Lou, can you comment on the original basis for this suit? Do people understand on what issue you took the Agency to court because it deals with much of the comment that is in here about how fast the Agency is or isn't progressing under Section 4 as addressed by NRDC's view that they certainly didn't, and they backed it up?

CHAIRPERSON BENDIX: Does anybody have any feelings about the need to have this on the record?

MS. MOON: I think it might be worthwhile for

people who weren't here to hear what this court suit was all about.

MR. MOONEY: I am simply bringing this up because if Warren walks in, it is a terribly critical part of the EPA's critical activities and what is going to happen over the next two or three years and, consequently, if we are not up to speed on it, I don't think we can discuss it very meaningfully.

MR. SLESIN: We are all acquainted with the time schedules in the Act for compliance with the ITC recommendations, or should I start further back?

ITC had nine months to issue a list of priority chemicals for testing. EPA then had one year to respond to that list.

Since then, there have been additional lists. The first list was issued in October 1977. EPA took the Federal Register in October of 1978 and listed its response as not being ready to make the decision called for in TSCA to either begin testing or state reasons not to begin testing.

Essentially, the reason was we have not done the necessary background work, and research is continuing. Essentially, the same approach was taken on the second ITC list in the following year.

Very little has happened in terms of initiating

testing under TSCA. There are two issues here. One is the law that says what the deadlines should be. That is, the one-year deadline for EPA and, beyond that, what was legally called for in that response by EPA.

That is, was the response as is given in the Federal Register one year later -- that is, we are not ready in accordance with the mandate of TSCA.

We, NRDC, took this issue to court after notifying EPA 60 days ahead of time that we would be doing so under the provisions of the Act.

And the basic point of the suit is to get EPA to meet this TSCA deadline. What comes out of that work really is the idea that you have a tremendous problem with a number of chemicals, the number of effects of each chemical, and you have to start working on this as soon as possible, that the 12-month deadline mandated by TSCA is as much a policy directive as a legal or scientific directive by Congress to the Agency.

By that, I mean you have a job to do in 12 months, and you can't do a perfect job, perhaps, but the problem is such that you have got to get started.

When EPA did not meet the deadline and it became clear that it would be a considerable amount of time before they would be able to initiate testing on these priority chemicals, we decided that perhaps a little general pressure

might work wonders.

MR. BARAM: This is all pursuant to what section of the statute?

DR. SLESIN: 4(e). EPA, as you have all seen the test rule package which numbers a great number of pages, and EPA has done a very precise job in putting together that information, and one could raise a question of how much work should have gone into putting together these test rules.

One particular issue is how much literature and how many abstracts should EPA have gone through to determine the necessity of testing under Section 4(a).

I would say it is my feeling that there is a problem here of exact science, taking over the policy directive of Congress. That is, Congress said we have a problem with toxic chemicals; we need to do something about it; but to make sure we do it in careful steps we will set up an Interagency Testing Committee to select those chemicals which are in most need of testing; i.e., in most need of getting some information about their potential harmful effects.

Congress went further and said we don't want this to get out of hand, so we will limit the number of chemicals that can be on this priority list to 50.

So 50 is not, we believe, a very large number, given the other statistics of, say, 50,000 chemicals on the

inventory out of the 4 million-odd that have been catalogued by CES.

What I am getting to is it has been a long time since TSCA has passed and EPA has yet to initiate testing on a single chemical.

And if one looks at the affidavit, one can see that it will be still quite a while before testing will be initiated on these chemicals.

And if you look then at the further time horizon -- that is, how long it will be before those test results -- let me back up a minute and say EPA's current proposal is-- for some of these chemicals is to go the ANPRN route.

Some of them will go to proposal; some of them will go to advanced notice. Then we will go to proposal, and then we will go to final, and then testing will begin; that is, if there is no litigation on some of these rules, which is always a high probability event.

Then we have years of testing, and if the tests show anything, we go through another possible Section 6 regs.

You see, we can go right into the 1990's very easily. What we are talking about is the first report on toxic substances came out in 1970. There were five or six years of debate on TSCA to 1976.

We are now getting to be mid-1980. We have yet

to test a chemical. If there are any bad actors here, you are into 1990 before you see effective regulation, and this is just not what we believe Congress had in mind when it set out this process.

Now we are not saying at all that we believe that EPA should be doing half the job in terms of the science, but we do think that there is very little in profit in EPA going through every abstract of every study done on a chemical because one of the guidelines is what information do I need to ascertain whether this chemical is a problem.

Perhaps legally you might ask what burden must I fulfill for the "will present standard" in Section 6 if that chemical turns out to be a problem.

And I would say, given the Agency's performance under asbestos in schools, PCBs, it "ain't" going to start regulating on a 1938 Czechoslovakian study with how well it was controlled, I don't think even if it was positive.

That is the point. If you look at the nature of the burden that EPA must meet to initiate rulemaking or to make a judgment on a chemical, it needs some pretty solid information, and I would consider this sort of a five-study problem; that is, you could call up many of the leading researchers in the field across the country and say, what do we know about this chemical; are you satisfied that we know enough about its mutagenicity or carcinogenicity,

et cetera, and go through these effects.

Going much beyond 1960 there may or may not be some good studies out there beyond 1960, but you could find that out without an expensive contract to review every single piece of literature, every abstract, every paper in the literature.

So there is a perfect science problem going on that I think is worth the Committee's attention to the extent -- let me say that Steve Jellinek was in New York on Monday speaking to the New York Academy of Sciences on problems of risk in carcinogens, and I think he gave an excellent speech to that audience which basically said no decision is a decision and we should bear that in mind and that if you worry too much about false positives or false negatives you are trading off among these.

I would say that EPA's record under Section 4, Section 6 and Section 8 in many ways shows what happens when you don't make a decision. That is, you have made a decision not to move ahead.

And I would say that from a policy point of view what NRDC is trying to do is to get this program moving, not wait for every single piece of information to be in to start some of this testing on the road as soon as possible.

One other issue in the suit which is much talked about in the affidavit which is the whole issue of ANPRNs

as a regulatory mechanism for public participation and public input into the regulatory decision-making.

We think that the -- when the ITC list comes down to EPA, that really is effectively a notice to all concerned parties that these chemicals will be the subject of intense scrutiny by the Agency under recommendation of the ITC.

Going to ANPRN route, it seems to me there is another built-in problem in the sense that you don't need that extra stage. Any comments could be listed when the ITC Report comes out.

The proposal stage is, I think, adequate for getting substantial dialogue going on it, and if there are revisions, these can be made in the final rules.

But we don't see a definite reasons to go ANPRN on every single chemical. Sometimes maybe there will be outstanding problems with a chemical. That means that certain policy issues will have to be resolved, but on the whole, I mean, going proposal and final, I would say, is quite sufficient, given you have the ITC Report on the public record at the outset.

MR. BARAM: Does the ANPRN usage stall or prevent citizen suits under Section 20? Because citizen suits against the Administrator for failure to act are limited after the Administrator is duly processing.

DR. SLESIN: That is a legal question which I

don't have the answer to.

MR. BARAM: Because it may have that purpose as well.

DR. SLESIN: EPA has certainly been breaking new grounds with the use ANPRNs, and I would suggest this is an indication of the tentativeness of the Agency in approaching some of these problems which other agencies have not had to turn to as much.

I think if the Agency makes a commitment to do something about the problems of toxic chemicals it will start going a bit more forcefully into this area.

MR. CAIRNS: You were talking about precise science or perfect science or something. I think I know what is bothering you, and it bothered me.

I read very carefully the one on methylchloride, and I somehow just don't feel that EPA has to write this scientific monograph as background to justify testimony.

On the other hand, you also can't or could not reasonably require testing if you had not read the literature to know whether or not it had been tested.

Now there are all sorts of reference services nowadays, and I would that EPA could quite reliably go through those with a much smaller amount of effort and conclude that a compound that has not had an adequate evaluation for carcinogenicity or teratogenicity simply

state the references to justify that and then require the rule.

Now is that the sort of thinking?

DR. SLESIN: Absolutely. It seems to me there is a whole timing issue on some of these rules, that you don't have to get all your ducks in water before you start moving them out. So you can stop worrying about that and start worrying about epidemiology.

MR. CAIRNS: I was wondering if somewhere in the back of your tone of voice there was a hint, perhaps, that you were advocating ignorance.

DR. SLESIN: A perfect science, but we cannot afford sloppy science.

MR. MOONEY: Just a couple of comments. I think there are some points of Lou's which I would be very much in agreement on the perfect science, and we have been into this at great length in the test standard proposals so far.

If you digest those and study what they are doing, they are extremely detailed. These are the generic standards proposed back in May of last year and July of last year, and we can look forward to environmental effects and environmental chemistry, physical property chemical standards, emerging in 1980.

We have had a serious concern about whether there is a need to go that far. So in that sense of the refining

of these things right down to the specification of feeding levels in the diet and many, many details regarding the conduct of tests, I think the Agency has used a lot of time that it would not have needed to use, the alternative being to rely on the judgment and professional experience of the people who have to do the work.

I know they have some counter arguments that they can't do that either, but I would point out that if there is a problem, you can't ignore the statute nor the way the statute has been constructed.

It does not make a testing rule an easy exercise for the Agency, and I don't think you can presume that the Congress didn't know what it was doing in putting the statute together.

It is too easy to read through it and see the requirements that have to go into a well-constructed testing rule. They are substantial.

And the Agency has to do its homework to put it together. I would agree I think too much old data is probably not productive to pull together as a factor into this analysis.

I would submit, for example, reaching back to 1950 in the Section 8(d) proposal is a waste of energy--going too far into history for data that by contemporary standards may be too old.

But ITC did not have access -- at the time it is developing its priority recommendation does not have access to all of the literature and, in fact, some very important contemporary literature, testing is not reflected in the literature.

Industrial research that is going on concurrently right now is not part of the literature that ITC can readily access, and it would seem to me to be a substantial waste of resources for the Agency to be promulgating test rules dealing with what are unquestionably going to be some very, very expensive testing requirements, if indeed there is work in progress that is fully satisfactory for purposes of filling the data gaps that the Agency determines exists with regard to a given chemical.

So that is the problem: finding the right middle ground where I think the Agency's testing recommendations are indeed based on solid perspective on what is going on.

CHAIRPERSON BENDIX: I was going to comment, Lou, that I believe that when the ITC Report is published in the Federal Register and is published with a request for public comments, I would expect that concerned industry groups that are aware of testing in process would communicate this fact,if they saw a compound they were working on on the ITC list would say, hey, you know, we are doing this stuff now; you don't need to promulgate a test rule on that

one.

MR. MOONEY: It was published early on and the comments filed voluntarily. That was not a Section 8(d) type rule; that was just an opportunity for comment.

And my recollection is that the extent of comment was pretty limited. I think that is a practice that will change.

This is an evolving thing and the rules of the game are not altogether clear to everybody. And I am sure a company that perhaps had a study in progress, not to a point of having anything conclusive, might well conclude that it wasn't appropriate or wasn't timely, and the Agency would undoubtedly be coming forward under AD, as indeed it did with the first ITC List, to get a full report of what factor is going on that might bear on the question of whether a testing rule is appropriate.

That process, I think, will change. I hope it will change.

CHAIRPERSON BENDIX: Lou.

DR. SLESIN: I think in your comments about second-guessing what Congress has in mind in terms of what there needs to be in terms of a testing rule, I think one shouldn't also second-guess the Congress at 12 months.

That is a policy statement by the Congress of the United States, saying we see this as a problem and we want

you to get moving on it.

I think the deadline has to be taken seriously.

MR. MOONEY: That is the basis of the whole suit: Just what did the Congress intend to happen. What event is it looking to see happen within the 12 months?

NRDC has advanced the position, and the court has supported that position, and until something changes, this is the way it comes out.

But there is, of course -- the interesting thing to me about the suit, there really is no test of what reason, no sufficiency of reasons spelled out.

Your contention is that they did indeed meet their 12-month requirement of publishing reasons. You contend that they weren't sufficient, and the court has ruled in your favor. And now we are looking to see what does constitute sufficient action on the Agency's part within that 12 months.

But it is very interesting that the Congress picked 12 months, recognizing that the same Congress also established the requirements for a Section 4 rule and established the rulemaking requirements under Section 8.

From what we all know about rulemaking, it is not a process that moves all that expeditiously.

DR. SLESIN: We certainly hope once the wheels have been greased that things will start moving, hopefully

there is a learning curve here, and that EPA will move ahead more quickly.

Let me follow up with a couple of other things. In terms of going back in the literature, I think in the affidavit, for instance, I think it points out before 1960 some of these reports were not retrievable by machine, through services like Toxline and other computer data systems.

And here again, I think that is a good way to cut it off in terms of if there are important studies out there before 1960 I think any researcher in the field will know or a team of researchers, if one could quiz by phone, will tell you the one or two studies that are worth looking at before then.

MR. CAIRNS: Even review articles of textbooks will pick up most of these.

DR. SLESIN: Exactly. In terms of the precision of the test rules, I think we are talking about slightly different things, and let me make one point of clarification. One is the protocols or standards, which I think you were addressing, and I was talking mainly about the background work to determine whether testing is necessary.

I think the standards, it is important they be uniform and well-thought-out so there is not a problem that when the results do come in "x" years after the rules

are promulgated that everybody will be working from a common base.

Now certainly some flexibility will be there, but how much is a difficult issue, also.

MR. BARAM: Are any of the substances currently regulated by other agencies or EPA under other statutes, such as FDA or OSHA regulating any of these substances now?

MR. MOONEY: On the ITC list?

MR. CAIRNS: I don't think so.

CHAIRPERSON BENDIX: I think that was part of the basis for selection.

MR. BARAM: I see, that they not be dealt with.

DR. SLESIN: Is that -- a good book by EPA that has all of the rules on all of the chemicals. I don't have that here.

MR. MOONEY: What I can't say for certain is whether any of these chemicals find a place, for instance, in an approved new drug or anywhere--food additives, indirect food additives--where they might be subject to regulation or as pesticides.

Presumably they don't, but I don't know that.

MR. CAIRNS: There are some regulated by TLVs under OSHA.

MR. MOONEY: I want to make one more point, Selina. On this business of getting your data base together,

you know, I am told it is not always the easiest thing. Ted, you may have better experience than I, but I am told it is not always the easiest thing to get published in reputable research literature negative data.

MR. CAIRNS: That is right.

MR. MOONEY: So what else is new? You tested it and it didn't produce anything. That really doesn't seem like interesting new science and, therefore, it doesn't get published.

I am sure there are some tests that have not been published for that reason. There are other tests that have not been published just because a firm has concluded that is proprietary information and it is not going to.

So I am simply making the point that the literature --

DR. SLESIN: I would agree with you totally, but I think EPA is not turning to industry enough in this particular exercise in the sense that there is good data out there that shows no good effect.

I would ask the industry to come forward with that data, and if they are relying on the studies that are inappropriate, say not to test and, therefore, to push it under regulation in Section 6.

I also count on industry to come forward with a critique of those studies. What we are saying is between those two calls there is a large area that says go ahead

and test and as you begin this process, you will have to resolve a great number of issues, but start the proposal so the debate can get under way, and if the decision not to test is because of studies believed to be there or because we don't know about the negative data, I think industry can then come in once the rules are proposed.

Tape 1 Side B

MR. BARAM: What was that book you cited?

CHAIRPERSON BENDIX: It was sent to us a couple of months ago. I think it has a white cover, and it lists each chemical and what its status is with respect to every agency.

MR. BARAM: Every agency.

MR. CAIRNS: Does anyone have a copy? I can't recall it.

MR. BARAM: I can't recall getting it either.

DR. SLESIN: It is down in Marilyn Bracken's shop.

MS. RAMSEY: It is not the inventory.

DR. SLESIN: It is much smaller.

MR. BARAM: I don't recall getting it.

MS. RAMSEY: I will see if I can find it, but it would help if anybody could remember a name. It is a list of chemicals and where they are in terms of regulations.

DR. SLESIN: In terms of which agency has

participated in any kind of regulatory process with respect to that chemical.

MR. MOONEY: I don't know how that could possibly be a complete list, though, because the chemicals that make up a new drug, subject to new drug application, are proprietary and part of the drug file, but not necessarily part of a public file, nor do I know that FDA has developed a listing of all such materials.

DR. SLESIN: I think you are expecting too much.

MR. MOONEY: I don't think what Mike is thinking this is is necessarily the full story.

DR. SLESIN: I think any time an agency has put out a proposed rule on a chemical, that will appear. Like if it is under the Clean Air Act, 112.

MR. MOONEY: Oh, if the agency has acted, okay.

DR. SLESIN: I don't know if it can be proposed or not, but certainly if there is a labeling requirement or whatever, but nothing as precise as decomposing a drug into its components.

CHAIRPERSON BENDIX: On the other hand, all the pesticides are going through the ARPR process.

MR. MOONEY: In the drug area, I would submit those are fact related chemicals because an agency has had a chance to review that file and take action, if they felt the need to, but there would not necessarily be a composite

list of all the materials that had gone through that process.

CHAIRPERSON BENDIX: I would like to place this discussion perhaps in a more general context. That is, first of all, I think we ought to start with the premise that OPTS staff are just as frustrated as anybody else about the slowness of getting the law implemented.

And I think we ought to understand that they all have a very genuine concern about making this work. I think one of the most constructive things that the members of this Committee could do would be to focus on this question of what could reasonably be left out and that one of the things we ought to be looking at in each issue that we discuss is can we make recommendations to staff about things that we think they don't have to do that would speed up the process and that if we can come up with some constructive suggestions, that this would be helpful.

I don't think that it is constructive to make very general statements about, gee, why can't you get more regulations done faster.

I think the kind of thing that we have been talking about in terms of how exhaustive does a literature search have to be is moving more in the direction of being specific enough to be helpful.

I would also suggest that now that some of us have received those specific Section 4 proposals -- and I

gather from those of you who have read them that you think they are perhaps unnecessarily thorough -- I wonder if it would be helpful if a number of people went through and did an editing job and sent it back to staff and said if I had been doing it, this is the amount of information I would have put in.

It might be helpful to EPA staff to see if there is some consensus on a very specific case about what was necessary and what wasn't.

MR. MOONEY: Selina, I would like to raise a procedural point.

MR. CAIRNS: Excuse me, Tom, on the same point. I don't think I am going to volunteer to do the editing job, but if I did, I would not use two pages on the physical properties of methylchloride under the section that is entitled "Identity."

I just see that as nothing to do with the testing rules. Everybody knows what methylchloride is. Now they should specify purity, which they did.

CHAIRPERSON BENDIX: Mr. Mooney.

MR. MOONEY: The question I am raising is whether -- where we make our contribution. Now you get into these testing rules in terms of the kinds of specifics that was brought up or back in the protocol details, and it seems to me we are getting into an area of science that

I read our charter to suggest as the province of the Science Advisory Board.

So I am trying to figure out where we play a role. Do we get into this thing from a procedural standpoint or is it our place to get into critiquing whether the protocols are really detailed or the literature appears to have been misinterpreted.

MS. RAMSEY: The Executive Secretary -- Helene, are you here still? I know Helene is the Executive Secretary for the Science Advisory Board, and I know they have spent a good bit of time on these test rules, and perhaps you could give us a reading on how far the Science Advisory Board has gotten and what role they are playing in these. Helene.

MS. GUTTMAN: Well, I can give you only a very brief rendition. First of all, the SAB Subcommittee on Toxic Substances only received the test rule package about a week ago.

Therefore, they have something like 10 days to review the test rule package and to have their first meeting on the topic this Friday.

Therefore, no one can expect every question to be answered at this time, but many of the problems which you brought up in terms of picking up the high points and giving the distillation of the salient features of what

the scientific problems are to accomplish all these things which I think everybody wants to do to get something not only adequate, but good out that will give both the public an opportunity to respond to and give a feeling of both comfort in terms of scientific adequacy as well as protection where needed will be achieved.

I can't tell you what will happen on Friday, but certainly everybody is welcome to come and hear it for the first time, as I will,on Friday morning when our committee convenes.

I might add that we were bumped out of our meeting room here in the mall, so if anyone here wants to attend that meeting, it will take place in HEW North, Room 4131 to 37, starting at 9 o'clock on Friday.

MS. RAMSEY: Will that be a full day meeting?

MS. GUTTMAN: It will be a full day. The main agenda item, with very few exceptions, for old business and some scheduling for the new things will be the Section 4 rule package.

However, it is quite clear, as you yourselves have already figured out, that the meeting will cover main points.

I am going to request that the committee study further and submit any further written comments as well as to members who are unable to attend the meeting on

Friday and are already preparing to submit written comments to me.

MS. RAMSEY: Thank you.

CHAIRMPERSON BENDIX: Mr. Slesin.

DR. SLESIN: We got a list the other day from you of all the new EPA committees, and noticeably absent was the membership of this particular subcommittee of the SAB.

CHAIRPERSON BENDIX: It is in there.

MS. GUTTMAN: It is a subcommittee of the Executive Committee, and Committee Management chose only to list the committees and not the subcommittees.

DR. SLESIN: Could you tell us then who was on that committee or just notify us in some way of the membership.

MS. GUTTMAN: All that material will be there on Friday. I don't want to take away from your schedule.

MS. RAMSEY: If you see that I get a list, I will make sure everybody gets it.

MS. GUTTMAN: You probably got it in the mail along with the agenda.

MS. RAMSEY: I don't think we got an agenda of the meeting.

DR. SLESIN: Could we also get all the comments of the SAB?

MS. GUTTMAN: The comments will be oral.

DR. SLESIN: Will there be any reports out of the SAB?

MS. GUTTMAN: There will be a set of summary minutes, as for every advisory committee. A more inclusive report is not timely at this point because of the preliminary nature of the Section 4 rules.

Since it is not a final EPA document, it has not gone through final EPA review. One of the more closer to final reviews will not be held until a week from Friday and, therefore, the comments and suggestions that the Board Subcommittee makes will be advisory only and will not be reflected with what the Agency's final position will be.

No doubt the Committee will be -- subcommittee will be given a copy of the final approved Agency document for their further review, but that will be the document which will also go to the public for comment.

So there is a little slippage in what we will see as opposed to what the final thing will be, and it might not be a perfect report because I would expect that possibly as a result of your committee's work, our committee's work, the deliberations of the steering committee and other internal advisory is that there will be some changes made between the documents that we see, which I believe is something like a version of a month ago and what

will finally come out for public comment.

So just as with your draft comments, to bring that out at this time will not be reflective of what our final thing will be and will serve more to confuse than elucidate.

DR. SLESIN: If you can get the minutes officially transmitted to you.

MS. GUTTMAN: The minutes are always transmitted to committee management, where they are available to everybody and the public.

DR. SLESIN: If we could get them to ATSAC.

CHAIRPERSON BENDIX: I would like to respond to Mr. Mooney's earlier point as to the difference between the responsibilities of the Science Advisory Committee and the ATSAC.

There is no question in my mind but that the Science Advisory Committee will be doing a much more in-depth analysis of the report and looking at questions of how data were evaluated and what was considered to be valid and useful for decision-making purposes.

I think there is an important role for this Committee, however. We are supposed to be dealing with overall policy, and the single most important problem that OPTS and perhaps all of EPA has, as far as I am personally concerned, is the question of how can these mandates in

the various statutes that are being implemented be implemented in a more expeditious fashion.

Anything that this Committee can do to suggest policy decisions which would aid in implementing these things as quickly as possible I think is perfectly within the purview of the Committee and appropriately a focus of our attention. Yes?

MS. MOON: I took the opportunity to look at the affividat, and it is an extremely concise summary and explanation.

As I was reading it, I could remember Steve said something about that three meetings ago and we picked up something four meetings ago, and what is interesting is you can read through and the bits and pieces are put into historical perspective and it is beginning to make sense.

I think it might be very worthwhile to have a copy of this. It is 45 pages long, if we drop out some of the addendums that were added, but it is very little verbage.

It gets right to the point in two or three sentences and explains.

MR. MOONEY: It is for a judge: it has to be simple.

CHAIRPERSON BENDIX: Do you think that your office problems will resolve to the point that it might be

possible to get copies of Steve's affidavit in connection with the NRDC suit for members of ATSAC?

MS. RAMSEY: For tomorrow, no.

CHAIRPERSON BENDIX: I don't mean for tomorrow. That would be unreasonable.

MS. RAMSEY: In the introduction of the test rules, it gives some explanation which may serve the same purpose in the preamble to the test rules.

You might want to take a look at that.

MS. MOON: That might be adequate for some people, but I think this a really good compilation. It is the best I have seen and far better than the other summaries I have seen coming out in terms of me being able to pick out why something was or was not done in an easy fashion.

It is laid out very clearly.

CHAIRPERSON BENDIX: I think we might take note of the fact that there are some members of the ATSAC, such as Mr. Mooney and, I presume, Mr. Slesin, who already have copies of the affidavit. I don't know.

MR. MOONEY: I have a copy.

CHAIRPERSON BENDIX: Maybe it is more difficult for you to start making exceptions.

DR. SLESIN: I would like to emphasize something you said, Selina, and that is, there are many other things that we as a committee could do under our mandate to try

and expedite this process.

I think one of the things that is very clear that should be done -- in fact, EPA has proposed to do this already -- is the AD Rule.

That is, under the AD Rule, EPA has proposed to make submissions under AD generic for all ITC chemicals. That is, every time the ITC List comes out, EPA does not have to issue another AD Rule. That simply says, okay, this triggers off -- the ITC List triggers off AD and you must start submitting any document you feel you should -- you feel appropriate or would bear on those chemicals.

So that would be a very easy way to make the process one more quickly.

CHAIRPERSON BENDIX: Does anyone have any further comments?

MS. MOON: I just want to say I am very glad that you and Tom Mooney did give us their feelings about this.

I had heard about this and, as you know, Arizona tends to out in the hinterland. We knew it was there, but not sure what the whole thing was about.

That is why I think it is valuable to come in and hear not only what is going on, but your specific perspectives as to why you think this is important is so important.

CHAIRPERSON BENDIX: Unless there is any other point that somebody wishes to make, I would like to call for a 15-minute recess, and we will reconvene here as a group at 11 o'clock for a discussion of the Section 4 test rules with Warren Muir.

(Whereupon, a recess was taken)

CHAIRPERSON BENDIX: I would like to call the meeting back to order even though some people haven't come back from the break yet.

I would like to raise a question about how people want to handle the afternoon session so that we can inform staff who needs to be here.

As I see it, we have two possibilities. In the 1:30 to 3:00 segment, we could ask a total group to discuss the EPA plans for chemical hazard warning labeling in industry and commerce and get a brief update on the status of 8(d), (e) and (c) rules or we could split up into two groups, the seven of us, meaning, presumably, groups of three and four, which would give us an opportunity also to find out about the status of the follow-up rules 8(a) and SNURs.

Unless there is one person on the staff who could briefly cover both of those, I am not sure how productive this would be or if we handled it just as an information item, perhaps it could be handled.

MR. CAIRNS: I think we should really meet as a committee. Too few to split up.

CHAIRPERSON BENDIX: Do people have any feeling about what they want to do about 8(a) and SNURs and 8(c), (d) and (e)?

I have the impression there is a general consensus that everybody wants to hear about the hazard warning labeling.

DR. SLESIN: Given that there is a proposed rule out about 8(a), it might be helpful to talk about that.

CHAIRPERSON BENDIX: Well, how do other people fend?

MR. MOONEY: Is DeKany scheduled at 1:30 on label?

MS. RAMSEY: Yes.

CHAIRPERSON BENDIX: DeKany is also going to replace Irv Auerbach. DeKany was to replace Irv Auerbach on the chemical hazard warning and he could also cover the 8(a) and SNURs, in which case the fact that both of these items are scheduled for 1:30 is not too much of a problem.

DR. SLESIN: Who is going to do 8(a): DeKany? I don't think that is his --

CHAIRPERSON BENDIX: We have both DeKany and and Blake listed.

MS. RAMSEY: Not 8(a).

CHAIRPERSON BENDIX: As the agenda was set up, it was DeKany and Biles to cover 8(a) and SNURs.

MS. RAMSEY: It wasn't under, necessarily, 8(a).

MR. MOONEY: Can we have them at 2:15? Why don't you have DeKany at 1:30 on the labeling question and the other come in at 2:15?

CHAIRPERSON BENDIX: That was my thought. Whatever he can cover. I am assuming for the public participation item as Item 1 there as being postponed until the next meeting, with 1 and 2 under Information Gathering, are off the agenda.

MR. MOONEY: Okay.

CHAIRPERSON BENDIX: In that case, our agenda, unless there is any further discussion this afternoon, will be at 1:30 we will discuss EPA plans for chemical hazard warning labeling in industry and commerce and at 2:15 or shortly thereafter we will be discussing various subsections 8 and possibly the SNURs.

MS. RAMSEY: Should I ask Mr. Kovalick to be prepared to cover the 8(a) topic during that time?

CHAIRPERSON BENDIX: That would be helpful if you could do that. At this time, I would like to turn the meeting over to Dr. Warren Muir and Mr. Steve Newburg-Rinn to talk about Section 4 test rules, and I am asking them to focus their presentation, since we have such a short

time, not on trying to tell us what is in this long document, but to focus on the areas where decisions are yet to be made where public input is being sought.

DR. MUIR: Selina, does everyone have a copy of this or is this the stack to be distributed?

CHAIRPERSON BENDIX: That is the stack to be distributed to everybody who needs a copy.

MR. BARAM: I could use a copy.

DR. MUIR: Steve has a brief amendment here.

MR. NEWBURG-RINN: A brief administrative matter on that. In the package that was sent out to you, we found that there were four pages of Appendix B on exposure that were inadvertently omitted.

I have replacement papers. And, in addition, on the support document for chlorinated benzene, Pages 40 through 42 -- you do have a 42, but the wrong 42, and I have the right one for you.

I hope that did not confuse you. Our apologies for that confusion.

DR. MUIR: Well, just by way of brief overview as to where we stand, this is the first of hopefully a continuing series of test rules that we will be proposing that is in the Agency's review process now and is at the Agency steering committee and will be reviewed by them next week.

Hopefully, we will move on to proposals no later than May or June, with the remaining agency clearances and so forth.

This particular test rule basically incorporates the various appropriate test standards that have been proposed previously in the health effects area and proposes that certain of those test standards be carried out on the particular chemicals in the individual rule.

In this case, chloromethane and the chlorinated benzenes: mono, di, tri, tetra, pentachlorabenzene, that the specified chemicals be tested by our proposed test standards.

Also, this package contains a notice of a tentative determination by the Agency not to go forward with a proposed rule to test acrylamide based upon its known neurotoxicity, which is well confirmed at quite low levels and our understanding of the nature of the testing that will be initiated by Dow Chemical Company to look at chronic and carcinogenicity and other chronic effects.

This particular test rule references test standards in the health effects area only. We are in the process and will be coming up with proposals in the very near future and are about ready to start a whole stream of test standards in the environmental fate and ecological effects areas, and as soon as we have a number of those that

can be referenced to proposed rules and we hope by the time of the next rule we will be able to cover both health and environmental effects in our proposed rulemaking.

The basic content of this particular package, for those of you who have not had an opportunity to digest it all completely, there is at the front a preamble which addresses both the major generic issues that we see raised by this proposal as well as the chemical specific ones and discusses the basic approach we plan on taking with the test rules of this type.

As an appendix, we have an appendix discussing exposure, the way in which we view the various sources of exposure information, how it factors into our analysis and decision-making.

We have the proposed rules themselves, again addressing chloromethane and chlorinated benzenes. We have technical support documents for chloromethane, chlorinated benzenes and acrylamide which basically lay out our evaluation and rationale for the various conclusions that we have come to.

There is a notice indicating our tenative conclusion not to go forward with the proposed testing of acrylamide, and there is a discussion of exemptions, policies and procedures as a separate piece to this package. So those are basically the component parts.

In getting from the statute to this particular document, we have slogged through an enormous number of issues, many of them generic rather than chemical-specific.

We have slogged through a number of issues which are not contained in this particular document because they are n ot pertinent to the particular chemicals we have gotten to and because we really need to have some idea of where -- what the downstream ramifications of any policy we might take now might be.

So we have had to take a look ahead. We have found this particular job to be far more complex than we would have ever imagined, just taking a look, first glance, at the statute and thinking about going forward with testing recommendations on high priority chemicals recommended by the ITC.

Hopefully, that will be apparent from your reading through. You can see a lot of the very complex kinds of interactions and so forth that we find once we start scratching the surface of this whole thing.

Just by way of trying to focus a little bit the discussion in the preamble, pages 99 through 118 are a series of questions and issues that we particularly solicit public comment on in the proposal.

I am not going to go through all of those. Many of those are chemical specific, but how they may apply to

chloromethane. We are going to bump into some circumstances in the future and so forth.

So there are a series of questions there and issues that we are particularly soliciting comments on and for which there has been a lot of comment and consideration within the Agency.

Among the issues that I might call particular attention to that we see in this package, first and foremost, is the amount of detail and the amount of energy necessary to develop such proposed rules.

I will say that there are some offices and so forth in the Agency which suggest that perhaps we ought to do some more analysis and be somewhat more -- provide somewhat more rationale for what it is -- for the conclusions that we come to, provide more evaluation for studies that were cited and so forth.

There is, we recognize, a very great concern when you take a look at the aggregate of the amount of work it has taken to get the whole thing out to begin with.

I might say that Steve Jellinek's affidavit to the court in the NRDC lawsuit clearly pointed out our overall concern and frustration of the amount of hard work and the amount of energy and transaction cost there is on the part of the Agency to go forward in ways with testing requirements and in some instances approaching or maybe even

exceeding the cost to the Agency of the cost of the impact of the regulation upon the industry, which to us is not very good public policy.

There is a question or issue as to whether or not to reduce the economic impact of the regulation whether we ought to go through sequential rulemaking requiring a first level of tests first.

Maybe an effect which might be more likely to come out adverse or something first and then after having the data and going foward with subsequent rules for subsequent effects.

A major issue which is likely to come up in the context of the public discussion on this particular rule is the use of categories.

There has been much comment on the Agency testing reports which recommended categories to the Agency. There was a lot of concern,particularly on the part of a number of industry commenters that categories were not appropriate for the ITC to recommend and they recommend the Agency limit their uses as much as possible.

In this rule, we propose -- we are basically making our findings on the category of chlorinated benzenes. We are proposing testing of chlorinated benzenes.

We expect when we get the information in to have the data on the group of chlorinated benzenes and

hopefully to be able to make some judgments about chlorinated benzenes.

In this particular test rule, we feel that we would have the basis for making findings on every one of the chlorinated benzenes which exist in the group.

There are 11 such chlorinated benzenes. All of them are on the inventory, but we have chosen a sampling approach which would require testing of six chlorinated benzenes because we think that is a more official use of the limited toxicological resource out there and the financial resource of the industry, and we think the data on the six will provide an ample basis for us at the end of making ample conclusions on the group as a whole.

I think the various ways, the various aspects of our approaching categories, making findings on categories, sampling categories and so forth will be an important issue that is contained in this proposal and will be one that during the public comment period I am sure will be focused on considerably.

Another significant issue in here is the whole concept of driving effect. We have discussed that briefly, and that raises the whole question if there is a particular effect which is of important concern, sufficient for regulatory purposes, should we be going forward with a testing rule to evaluate the other effects or should we

try to hone in on the effect either for testing or for regulatory purposes.

That hasn't presented itself too squarely in this particular case. It was one which was considered in the instance of acrylamide where we have in our opinion well-characterized neurotoxicity of acrylamide, but the Agency also had concern about carcinogenicity and other chronic effects for which ongoing testing is going on and that is the basis for our not going forward with testing recommendations.

But in considering acrylamides, we realize that there is an important issue of that type which we must be facing; that is, do we go forward with testing on the most important effect or if there is a basis for some regulation on a particular effect,do we go forward with testing at all on the basis of that.

Next is the question of who to test. The statute provides that the Agency shall require manufacturers or processors -- they are supposed to carry out testing depending on whether the chemical -- whether the concern arises out of manufacturing, processing, distribution use or some combination.

And in the instance where use or processing raises concerns, processors would be subject to the rule under the regular requirements of the section.

And we had the question of the extent to which we should specifically define processors under Section 4 or whether we should go forward with just the statutory definitions for the processors under Section 4.

Another issue which we have encountered is the whole issue of study plans. In part, this is a test standard issue that was raised in the context of our chronic test standards where we had requested that study plans be submitted to the Agency and be submitted 90 days in advance of the carrying out of the study.

In this proposed rule, we recommend for the -- propose that for the other tests that study plans be submitted to us no later than the initiation of the test.

We did not, until we got into the rule, realize the importance of that, how important it would be to have study plans for purposes of running the exemption process and verifying that testing is going on.

And really, we have only -- as a result of this rule, have bumped into the whole study plan issue. It is an important one. I assume it is an important feature for the purpose of the Agency being able to know what kind of testing is going on subject to the rule and to be able to monitor the compliance of the various people subject to the rule, too.

Those are a series of issues that are contained.

There are many, many more. You may very well have a whole series of issues that are not listed in the pages I have cited.

We have a number that are contained here. Why don't I leave it at that and field questions that you have.

CHAIRPERSON BENDIX: Thank you very much. I appreciate what a difficult job it was to condense your presentation, and I think you did a good job of it.

Would anyone like to comment on some of these issues that Warren has raised? I think one of particular importance is this question of the handling of category and sampling within categories, if someone would like to comment on that.

I know Ted has.

DR. CAIRNS: At every meeting I think this Committee has had, I worry a great deal about using the results of two or three compounds in a category to believe that the other members of that category are safe.

I think we are just bound to fall into traps. I think in the chlorobenzenes I feel better than I do about many others.

But there are just so many examples of the next higher homologue, the next lower homologue, or an isomer being basically different than the rest of the category.

I am sorry; I have said this before, and I think Warren is fully aware of it.

CHAIRPERSON BENDIX: Lou.

DR. SLESIN: I think it might be useful to look at the decisions on the chlorinated benzenes and explain perhaps specifically how you came out with the ones you did--six out of -- what is it -- 11.

For instance, I know that you picked also paradichlorobenzene, which one would expect to have similarities. I guess the reason it is here is that it is produced in small quantities.

But I wonder if you could go through some of the thinking that you went through in terms of this is the first time such a selection has been made and would be extremely valuable.

DR. MUIR: There are a number of factors that have to be weighed in the sampling. One is when you go forward with a category under sampling one is making the presumption, in the end when you have the data in, the data is going to fall together in such a fashion that you are going to be able to make some kind of overall conclusion.

There is, of course, the possibility that data when it actually comes in will end up in such a hodge-podge fashion that it will be clear that the group, in terms of the information you got in, didn't hold together very well,

that the group is a reasonable proposal of the group, but at the end when you have the data in hand it starts to fall apart.

Because there is that possibility, we tried to strike the best compromise or try as much as possible to get high exposure to chemicals into the group, into the sample, in the event that we cannot in the end make a more summary conclusion about the group so that if we need to take the chemicals one on one and the end with the data on hand, it will be the basis for dealing with the most important public health environmental concerns.

So exposure factors are important in our sampling approach. In terms of selecting this particular sample, the metabolism people and the pharmacokinetisist,toxicologists in the office and so forth very carefully looked at the group and wanted to get what they considered a representative sampling of the various substructural classes that exist there, also factoring in the whole question of exposure, and come up with a sample that they thought, with the data in hand and presuming that it comes in in a consistent fashion, would allow them to make judgments across the group.

Now in the instance of choosing the orthopara vs. meta exposure factor into that, there are constituents with metho, in relationship to each other, and their feeling was

that with the combination of the sampling we have of the dyeing tetras and these two particular dye chemicals, dichloro compounds, we would have the basis for judging.

CHAIRPERSON BENDIX: Yes, Mr. Mooney.

MR. MOONEY: Warren, how do these dovetail with the test standards finalized? These make reference to the proposals in May and July.

DR. MUIR: We are proposing in this rule that these chemicals be tested by the method in our proposed test standards, except that there are certain test modifications that are proposed here which are of a chemical specific nature and this proposal solicits comments on any other test modifications which ought to occur as a result of a particular aspect of the particular subject chemical.

So we are proposing those test methods be the tests that will be performed here in terms of our generic test standards and the schedule they are on. The comment period closed in October.

Comments are being digested by both the Office of Testing Evaluation and Office of Pesticide Programs in an effort to come up with a common proposed -- common methodology between the two offices in the health area.

We would expect to have those final probably, I would estimate, not in one package, but probably it will come out in two or three pieces, with the acutes and so forth

coming a little faster than the others, and probably those in the Federal Register this summer.

I will say that it isn't the most pressing priority from our programs perspective because it is not on the critical path for getting testing done, and we feel we need to get the test standards into place before we go final with these test rules, but we are devoting our energies to developing test rules rather than test standards where there is a trade-off.

Tape 2 Side A

MR. MOONEY: Could I fairly presume then the test standards, as proposed, are eventually what we are going to see as finalized?

DR. MUIR: I think there will be some changes.

MR. MOONEY: These chemical-specific rules, though, you anticipate will not have gotten off the ground. There will be time to factor that in to any development of testing plans.

DR. MUIR: The test standards will be final prior to release of final test rules.

DR. SLESIN: I have not had a chance to read all the pages you gave us, but can you explain to me, like in Table 1 of the chlorinated benzenes, 59(a) of the proposed test rules for chlorinated benzenes.

DR. MUIR: 59(a) of the Technical Support Document, I am not sure I understand the difference between

capital "D" and dash as to positions as to proposed testing deferred, not at this time.

DR. MUIR: Let me explain that. The "X," obviously, we are proposing the proposal as contained in here, and the instance where there is a dash we are not proposing testing at this time because of either ongoing testing or preexisting testing.

The National Toxicology Program has got the chemical under test and, presuming that is going to come in with sound results, we basically made a determination not to propose.

But for some reason should that ongoing study fall through, presumably, we would reserve the right to go forward in the future.

In the instance of neurotoxicity, metabolism, and behavioral teratogenicity, those are effects for which we do not have any test standards.

Therefore, there wasn't a basis for having a test that we could propose in this particular proposal. So that is what these refer to. We are going to be working on additional test standards in the health area in both the neurotoxicity area and behavioral teratogenicity and also for the metabolism area.

In the case of mutagenicity, what we are doing there is, in order to be more expedient with respect to these

chemicals, there are a number of short-term tests which we think are good to the bottom tier test in the mutagenicity area. They are rapid and inexpensive, and rather than going through the whole rulemaking process on that, to come up with decisions and decision rules and everything with respect to any advance mutagenicity testing, we are going to go ahead and just do that testing.

It is very inexpensive and rapid, and we can get the results in probably before we get this proposal out. So we will defer a decision on that as to whether or not we need to require the advance mutagenicity test.

DR. SLESIN: Does that mean that your office, ORD, is going to do that?

DR. MUIR: Yes, we will do that in that instance.

DR. SLESIN: You won't subcontract that out?

DR. MUIR: We may. We presumably will be. Our office doesn't have a laboratory, so if our office ends up doing it, it will be under contract.

But probably is ORD would do it, it would be one of their contractors, too. There are a number of contractors both of the offices have which could perform such things.

DR. SLESIN: Who will pay for that?

DR. MUIR: We will. It is cheaper for us to do the studies than to go through rulemaking.

DR. SLESIN: So the way you define it, I thought epidemiology should be a "D" rather than a dash since there is no standard there.

DR. MUIR: The problem with epidemiology is we haven't been able to identify a cohort that would serve as the basis for writing a requirement.

That is an important area. It has turned out in our efforts to try to develop epidemiological test standards and so forth that there is really no easy generic way of doing that, and actually the real determinant in the epidemiological area of any type of study is our ability to get suitable cohorts for study.

So we are looking into various ways in which we can use 8(a) authorities and so forth to get us information down to where epidemiological studies are most appropriate, and then there has to be a decision as to whether Section 4 is the right vehicle for carrying it out.

We might want to get the right information under Section 8. So at this point in time, we are not proposing to go ahead with epidemiology.

MR. BARAM: I would like a perspective because I haven't read your document or the affidavit, but how many chemicals now has the ITC come forth with?

DR. MUIR: Thirty-eight recommendations. Approximately half are groups and half individual chemicals.

MR. BARAM: This represents a proposed rule on 6.

DR. MUIR: No, in terms of the recommendations, they have recommended acrylamide. They have recommended chloromethane, which they had two recommendations which covered chlorobenzene, so this covers four of the ITC recommendations.

That leaves 34 to go, and there is a report coming up in April which undoubtedly will have a number of more chemicals in groups recommended to us.

Our affidavit would indicate that based upon this amount of analysis and allowing ourselves the ability to review premanufacture notices and so forth in the office, that it will basically take us until 1984 to get proposals out on all of the 38 chemicals.

MR. BARAM: I see.

DR. MUIR: It is 1984 for proposal.

MR. NEWBURG-RINN: It may actually be 1985.

DR. MUIR: The point is it is a long time and there is more piling up, and we are not getting to other chemicals which may be important under Section 4 as well.

MR. BARAM: So what action does the Agency intend to take?

DR. MUIR: We have indicated we are doing a fundamental rethinking about how to approach Section 4 both

from a chemical-specific point of view and from a generic one as well.

The obvious conclusion is that it is taking too much to get too little, and we just don't think it is good public policy.

MR. BARAM: So this may be the first and last time that you have taken this particular approach then; is that right?

DR. MUIR: Maybe so, except that we have got a substantial investment in the next few.

MR. BARAM: Can you tell us what directions you might take?

DR. MUIR: We are considering -- well, much of the analysis, much of the energy in this goes into the analysis of the sort of finding that existing information is inadequate and testing is necessary.

There is a lot of analysis and 50 years' worth of literature. We will certainly look into ways through -- I don't even know exactly how, but the way in which the Agency can take on less of the burden of having to do all of that evaluation.

Maybe we will lay out certain criteria. Maybe using such criteria, make certain presumed conclusions and so forth.

This represents about as much analysis as we

feel we would need to do to regulate these chemicals were they a hazard and, in fact, in many respects, it is more than that because you only need to have one important effect to regulate a chemical, and here we are looking at the multiplicity of effects.

So I think we recognize -- well, we are not happy, the step-back overview of the whole thing.

CHAIRPERSON BENDIX: Mr. Mooney.

MR. MOONEY: Warren, a series of questions or inquiries with regard to some material on Pages 12 and 13.

DR. MUIR: The Preamble.

MR. MOONEY: Yes. Test standards under Section 4 will be consistent with internationally and nationally redefined guidelines approved by, et cetera. How do you do that when you have everything moving at the same time?

OECD is a long way from finalized. IRLG has yet to get out proposals on very many of these human effect areas.

You have got a few out as drafts and more to come, but your test standards are way ahead of them.

DR. MUIR: Our test standards are way ahead of them, but we are to review and revise them in some respects, and we are to review and revise annually, per Section 4, and to the extent that they are basically scientific conclusions of IRLG, would cause us to reconsider a particular aspect,

that will be part of our review process and be part of our proposed revisions.

So we pick them up the next year.

MR. MOONEY: Would you broaden that statement to reflect consistency with FIFRA guidelines as well.

DR. MUIR: I don't think that there is any -- with the exception of --

MR. MOONEY: I am just highlighting another.

DR. MUIR: With the exception of any particular aspect of FIFRA testing or TSCA testing, which are really statute and pesticide and so forth specific, our two offices will be fully consistent.

MR. MOONEY: So those will also be consistent. Let me explore what consistency means a little bit because I have a perception that you don't consider inconsistent when you say will be consistent; however, because of statutory reasons, we may be more specific. And you still consider that to be --

DR. MUIR: I still consider that to be consistent. That is right. And to meet your point head on, this has been the number one issue associated with our test standard has been the whole question of specificity and, to date, because of the way in which our statute is structured, we do not see how we can propose as a testing requirement which is the specification of what people should do, a series

of guidelines and principles on testing as the requirement as to what people shall do.

We do expect that our test standards should be consistent. Where things say appropriate species or at least 60 days in duration or more than one or whatever, that any specification that we do specify be consistent with those and, therefore, any of our test standards should fully satisfy IRLG, OECD and pesticide guidelines.

But, in our view, there may very well need to be, with respect to certain aspects of the test, there may need to be additional specification because it will be laid out as the requirement as to what people should do.

Under the statute, they don't have to do anything more than what we tell them they have to do.

DR. MUIR: Most of the guidelines contain a considerable amount of judgment which is to be employed by the experimenter and the evaluator, and I emphasize both the experimenter and the evaluator, and in the instance -- in our instance, both the experimenter and the evaluator have no other standard to judge it by but the standard we lay out, and that is why there needs to be some additional specification.

So you can anticipate our test standards will be more specific in certain instances than IRLG or OECD and in some --

MR. MOONEY: Let's move to the middle of the paragraph where you do indicate that you may choose to be more specific because of, I gather, statutory considerations.

We have had a lot of difficulty understanding where we are coming from in our differing views on an issue like that, and I would just like to know for, as an example -- and pick another one if there is another discussion point that helps to clarify it better -- why, for example, in a GLP area, which really is part and parcel of all of this as well, is it necessary for the Agency to require board-eligible or board-certified pathologists when the Food and Drug does not?

I don't understand the consistency of those positions. Now we could pick other areas, but I just single that one out to illustrate what to me is a difference, and yet the Agency continues to say it is being consistent with ILRG and OECD, and I don't grasp how that is a form of consistency.

DR. MUIR: There are no IRLG GLPs, number one. Number two is, with respect to OECD at this point in terms of draft, the only thing that has developed so far is a draft which discusses very broad principles associated with GLPs and not GLPs themselves to address the GLP issue.

There are a number of instances where in our test standards there are some specifications there which

bear upon qualifications or how records shall be kept and so on and so forth, for which we have had a lot of comment, and we are going to carefully review that comment and see whether or not we think it is necessary to assure the quality of the test.

If it is, we will have to go forward. And if it isn't, we won't.

CHAIRPERSON BENDIX: I am sorry, Mr. Mooney, but I think we really need to go on to the next item on the agenda.

DR. MUIR: I will be happy to talk to you more about it separately.

MR. MOONEY: I am sure we will, which is what --

CHAIRPERSON BENDIX: Marilyn Bracken is here to talk to us about OECD and efforts to involve public interest groups in these activities.

Thank you very much, Dr. Muir.

DR. SLESIN: Warren, before you go, I would like to raise an issue for later discussion. I am very interested in your thinking about the sampling, what I started to discuss about selecting out some of the compounds from the larger category.

How willing will your team and general counsel be if you get a positive result for one of the sample compounds? Will you be willing to go ahead? And if you issue

a Section 6 rule, will you be willing to go ahead and regulate or propose regulation on those that you didn't actually test?

DR. MUIR: Let me give you a simple answer. It is our presumption that we in a sample get a consistent set of results.

And I say consistent--they don't all have to come out the same. There may be just a logical trend in the data that would indicate concern. It is our presumption that that would provide us data upon which to make Section 6 judgment.

If that were not the case, there would be no basis for not testing the other chemicals that are not contained in the sample.

CHAIRPERSON BENDIX: I am not going to make any introduction, so we can proceed.

DR. BRACKEN: Okay. My understanding is what you really wanted to hear was how we were going to involve public interest groups in OECD and other international activities.

So I will take, as a presumption, you generally know what we are doing with respect to OECD and some other organizations.

CHAIRPERSON BENDIX: Let me ask, would you group prefer to have a few minutes' review of what is being done

with OECD?

I don't know how familiar the members of this group are with these activities.

DR. BRACKEN: Why don't I give a few minutes. I think most of you know that several years ago there was a meeting in Stockholm of the administrators of various governments regarding the environment and the issue of chemicals and the idea that since we have so many new pieces of legislation being developed internationally, it impacted on chemicals and particularly notification programs with respect to new chemicals, that we had this unique ;eriod of time to begin to look at harmonizing the implementation of our various statutes and that it would make sense, as much as possible and as closely as we could, to work together and develop consistent guidelines, consistent protocol standards, and implementation aspects of our law.

There were several priority areas that were recommended where we should begin. At the time, TSCA had passed and the Sixth Amendment to the European Commissions was just about to be put before the Commission, and that since has been passed. so we had two major pieces of legislation we were dealing with.

The Japanese already had some legislation, as did the Swiss and some other countries, but we did feel it was a unique period of time and that we were trying,

essentially, to avoid the development of non-barrier trade barriers, different approaches to implementing our laws.

The first effort that we undertook, which in fact had already been started in the chemical group in the OECD, was to develop test guidance, and they were being developed in five areas.

That is, short physical chemical properties, short and long-term toxicity, et cetera. There was another group developed to look at step systems or the taking of the various protocols and putting them into a tiered approach for testing new chemicals.

There was a two-year program set up to develop the five guidelines, the reports from the expert groups on the five guidelines.

Expert groups were created under a lead country approach, and as a matter of fact, the groups were due December 31, 1979.

We have now received the guidelines from the different groups. They are not totally complete in all cases in that that was a major undertaking for these international groups, but we have got well over 200 guidelines, when you take the fact that physical chemicals, we had quite a number of them in that particular area, but there has been amazing and consensus on what should be involved in these guidelines, and we had very good support by the

countries and on each of the expert groups we generally had a BIAC or Business and Industry Member City.

They will be received in the U. S., we hope, and in fact I have several already, but we will put a notice in the Federal Register indicating the availability of the guidelines as developed by the expert groups.

And I expect that to be in about two weeks. We intend to put these guidelines in the regional offices and in our own public reading room around the cities and convenient places, but I call your attention to the fact that it is stack like this.

So we won't be copying extensively because it is just too burdensome, so we are trying to put them around the country so people can go in and look at them.

We will take -- we meaning the OECD Chemicals Group -- will take comments from countries on these guidelines, and since they were developed by the best experts, we think, in the various countries, we don't expect to find extensive comments on them.

But comments will be coming -- we, EPA, will handle the EPA comments, and they will be forwarded from this country to an editing group that has been developed by the Chemicals Group, and that editing group has membership by the six chairmen of the five expert groups.

The editing group is chaired by Canada, and there

is a representative from EPA and from the European Commission and the Swiss are sitting on the editing group.

This group will really just do that: edit. They will not make substantive changes to the guidelines since they have already reached agreement within the expert groups.

But if there are substantive changes that will be recommended, they will be given to an updating mechanism which we expect to create because we don't expect the guidelines to exist forevermore.

We want to have an updating group that will deal with the state of the art changes. So we have an editing group that will deal with editorial type comments and a few areas developed in the guidelines and then create an updating mechanism which we will put in place to deal with changes to the guidelines in the future as the state of the art changes.

So that is the story with respect to the guidelines, The other area the OECD is working with is the development of principles for laboratory practice, and we now have, as Warren was mentioning, a document that is a very generic document and addresses generic principles of GLPs.

We are working on some development of some more specifics to that document, and then the second part of that

activity is to look at the means for enforcing those GLPs internationally.

The third activity is the activity that involves confidentiality or exchange of confidential information between countries involved in regulatory aspects of chemical substances.

That has just gotten under way. They have had two meetings to date. It is again an expert group approach under the lead country of France.

The U. S. has representation on that group from the Department of Commerce, EPA, CEQ, and an industry member.

And I will talk about public interest group involvement in a minute. Let me review the other activities. We also have an international activity under the lead country of the German Government to develop a glossary of key terms.

We have been finding in our conversations that we use terms differently, so this is the idea of developing. We are starting primarily with legal terms; that is, what does a chemical substance mean under each statute, how do you define these kinds of terms.

So we will be developing this glossary initially in two languages: the language of the OECD, French and English, but then they will be translated back to languages of other countries.

After we deal with the legal terms, those terms typically in the statute, we will deal with more scientific terms, and then we will be working closely with the OECD expert groups on the scientific terms.

We have activities under way in economics in looking at the potential barriers and how different notification programs in different countries might impact economically on small business innovation and so forth.

So that is another area of activity that is not a lead country approach. That was a project handed to staff from the Secretary.

And at this point, we have just developed a few documents that are being reviewed for the first time on impact and innovation.

Those materials are available if people want to take a look at them. I think I covered the major activities of the OECD.

Let me just mention that we have made extremely good progress in these areas, and we plan to have a high level meeting in May, at which you will have the chemicals group meeting in what we call high level.

They will be represented by, in our case, EPA or the U. S. will be represented by Doug Costle. There will be an equivalent level person from the other countries, and they will come to discuss and possibly reach agreement

in certain areas.

That will be the substance of the OECD test guidelines in principle. Certain areas we will be looking for agreement in is the acceptance of the generic document.

Another area of agreement which has been generated as a result of the sub-systems group, and that is a minimum market base set, and this is countries would agree that this base set would be applicable to the testing of all new chemical substances.

Now, of course, if EPA or the U. S., I should say, decides to take agreement in that area, that would, of course, mean that we as an interim could say these would be used as test guidance for all chemicals.

If we went any further than that, we would need a legislative change or something. But what we are doing at this point is this will be a discussion, and whether or not there will be agreement reached, remains to be seen.

The other area there will be discussion and perhaps agreement on is what we call mutual acceptance for test data.

What we are saying is that countries would agree that if studies weren't conducted according to the OECD test guidelines that data would be accepted for purposes of risk assessment in one country and another country; that is, no country could claim --

So that is another area that we hope to reach agreement on at the high level meeting. There has been some concern that we had no mechanism for public interest groups or what we call NGOs, Non-Government or Non-Industry kinds of organizations to participate in the activities of the chemicals groups and the expert groups.

The reason that industry has been able to participate for some time is that there is what we call the Business and Industry Advisory Committee, which is a recognized committee of the OECD.

It is an international activity and there is a USBIAC, and the U. S. and other countries as well have had an industry member on their expert delegations through this BIAC committee.

There is no equivalent for environmental groups. There is something called TUIC, which is the Trade Union Advisory Committee, but this group has not been active in chemicals.

In order to bring in and to give the public interest groups and other organizations an opportunity to be involved in our international activities, we have tried to have briefing sessions as the first way of getting people involved, as long as they understood what we were dealing with, the areas we were working in. That was the first step.

We had a meeting at the State Department and invited a number of organizations and briefed them on where we were, what we were doing, and plans for the high level meeting.

We suggested at the time -- and since then a letter has gone out from me to all the participants at that meeting -- that we would to, in the interim till they can get themselves some sort of equivalent organization with respect to OECD, like BIAC, that we at least get their participation in expert groups through some coordinated approach.

What we have suggested, and the Conservation Foundation has agreed to organize the first meeting, we feel we have a focal point for those groups to deal with.

It is much easier for us, so we have suggested that these public interest groups get together, and under the immediate direction of the Conservation Foundation--since they have volunteered, they will call the first meeting--they will organize themselves to provide a focal point for us to talk and deal with and then we will try to get one expert selected by that group to participate in the individual expert groups.

That is how we will deal with that. We have also suggested that we form some sort of advisory panel of these groups to EPA that we can meet with on a regular

basis, and we have also -- we will try to get them involved in this plan for the OECD updating mechanism.

We anticipate having industry representation on that group, and we will look forward to having -- essentially, we have suggested several things.

We will continue to have these meetings, we have suggested that they perhaps organize themselves into an advisory panel meeting on a regular basis. They also created organizations somehow coordinated at the moment through the Conservation Foundation, and they can select their own chairman that we can deal with, and perhaps through some funding grant mechanism we can provide for some representation at the expert group meetings.

So that is our immediate plan. We have also suggested that the labor union groups try and get the trade union or the TUIC group revitalized through the OECD.

That, of course, will be up to Labor to try to get moving. We have also suggested that they look into getting themselves something like BIAC, but that is not as simple as it sounds because there are not the same kinds of organizations in many other countries like we have in this country.

So it probably will not be quite so easy, although there has been offer made by an environmental group in Germany to take some -- they have indicated some

interest and indicated they would work for this group and try and see about establishing some kind of mechanism.

That covers it. Pat, do you want to add to it? This is "Pep" Fuller.

MR. FULLER: No, I think you have summarized the major features, Marilyn. I think we are quite open to suggestions as to how environmental groups can participate more actively, and I think the question of how they now play a role is really up to them at this stage.

We put forward a number of suggestions and we are going to be in a listening mode for their response.

CHAIRPERSON BENDIX: Mr. Slesin.

DR. SLESIN: If I understand you correctly, that means that you are now willing to have environmental and public interest groups on these expert committees.

It is just a matter of us getting our house in order.

DR. BRACKEN: Yes, to appoint a person. And I want to make some important caveats. One is that the membership on these groups is up to the lead country chairman.

Now I have never had a lead country chairman turn us down on a member in an expert group. We make a recommendation when a BIAC expert is suggested to us.

I make a recommendation to the chairman of

that particular group and suggest -- describe the qualifications because these are true expert groups, and when we have industry represented, we don't have industry from Allied as an expert sitting on that committee, so we are looking for qualified experts.

The chairman has always accepted it, but the groups are kept very small, so we would keep the representation to one person.

We also need a commitment of continuity. These groups are usually in existence for about two years, and it is very disruptive to keep changing the membership, so we would need the continuity and commitment from the person.

Also, it is important to point out that the meetings are often held around the world, so there is a commitment of travel.

And in the case of industry, they have to pay their own way, and of course the Government pays their own way.

And I know that is pretty much of a burden on the public interest groups. We are looking at some kind of a grant mechanism, some kind of way we can try to help the public interest groups cover that, but we are just starting on that, and we have to work with this group.

DR. SLESIN: One of the most important subgroups is the Step Sequence Group, which I think is meeting at the

end of April in New York.

Do you think with the Foundation's help that things will be arranged such that somebody can attend that?

DR. BRACKEN: I think the Chairman would be quite open to that, but it is up to the group to get themselves together to make recommendations to us.

I think that will be able to be worked out, yes. And I also want to point out that some of the expert groups have finished their business. So we will not be meeting except on special call by the chairman.

Some of the groups have a lot more to do. For example, the toxicology group has a lot more to do in terms of development of guidelines because that was way behind to begin with.

There is not that much in that area in terms of established guidelines. Some of the long-term, short-term group will only be meeting to address some issues they haven't had a chance to address, like mutagencity and neurotoxicity.

So they will only be having a few meetings. We don't anticipate all of the groups to continue. Step systems, though, will be expanding, and we will be looking at other areas as they go into the other tiers around.

So that is a very good group to get involved with.

MR. BARAM: Marilyn, I raised this point at other meetings, and I always find this strange why this doesn't relate to the World Health Organization.

I can understand OECD's involvement on confidentiality and other business economic related aspects of chemical regulations, but on the subject of the technical areas, WHO is all set up.

I work with both organizations and I find them miles apart, and I find OECD probably the poorest forum for dealing with these technical issues.

DR. BRACKEN: I guess one of the major reasons that we put the major emphasis on OECD is that they already have a chemical group, they had a budget, there was a mechanism to enhance that budget, they had the testing program well under way, and WHO participates in the experts group.

There is representation by WHO in the chemicals group, number one, and on all the expert groups, so they are in -- the mechanism was there.

Also, the WHO deals with longer term problems. They haven't been able to move as quickly in some areas as the chemicals group, so the idea of the chemicals group might be able to turn something around a little quicker. For example, the general principles of the GOP area was a concern.

This is a group that has traditionally had to

move a little faster, had the 24 major country participation, where WHO had been involved in risk assessment and longer term activities.

So we still look to WHO to deal with that, and we have other activities involving them.

MR. BARAM: They are the only international organization thathas really come out with any documents is the WHO.

I guess the question of philosophy of the organizations, different philosophy, I think.

DR. BRACKEN: We are looking to WHO to provide a lot of guidance in risk assessment and individual chemical assessment.

We are also looking to getting WHO very actively involved in the updating mechanism because we feel they can make significant contributions in that area, the review aspects of what are the best test guidelines, but they have been very much involved in the test areas.

CHAIRPERSON BENDIX: Any other comments?

DR. SUTTON: At the moment, it seems that the OECD test guidelines seem to leave a lot of room for flexibility in the precise applications of test procedures, whereas the test standards and rules that are being proposed and developed here are really quite specific, and it would seem possible that we would end up with a national focus here

which is very specific as to how the tests were done and international ones, that leaves a lot more room for flexibility, and yet you are looking for some mechanism by which each other will accept those tests.

What kind of thinking have you done about the import situation where somebody is coming in with a set of materials, tested it according to a flexible OECD guideline procedure and quite acceptable there but not matching any test rules that we have?

DR. BRACKEN: First of all, when you really take a look at the OECD Test Guidelines, they aremore specific than you would expect.

I think when we have done some comparisons -- and I think there are some others who could speak to that -- when we have done comparisons of our test standards with the OECD Test Guidelines, they are not that far apart: they are totally consistent.

They might be, in some cases, more specific. That is a problem we have to deal with because if our thinking is, as far as new chemicals and for those chemicals where we do not have a Section 4 test rule, if a test is conducted along with OECD Test Guidelines, they should be well done and they should be acceptable for purposes of risk assessment.

There may be cases where if we have a session for test rule out that we will have to ask for more specific

requirements, for the reasons Warren stated before.

But we are hoping to have the test guidance specific enough in general that we can get very good test results generated from them.

But as I say, there may be cases where we have a Section 4 test rule that we may have to have more specific in order to meet our own requirements.

Those are the areas we have to look at carefully as we review the test guidance. We haven't seen the whole set of test guidance together as a package.

Our expert group members have seen the individual packages, but as we get the whole set together, we will be looking at carefully how they do match.

We will be looking to make that comparison to see, in fact, how specific they will be, how they will meet our requirements.

MR. FULLER: If I can just add, the work that has gone forward in the Step Systems Group, you mentioned, has identified a minimum set of data and that data, if it is agreed on by member states, would really be more comprehensive than anything we are currently getting now so that when we talk of new chemicals and we talk of importation of those kinds of chemicals, we think there is a real opportunity there to have a very meaningful set of information that would be available on imports and that would be the same set that

currently, as Marilyn said, it couldn't be mandatory under existing law, but voluntary in the United States, and that would be an addition to the knowledge base we have.

CHAIRPERSON BENDIX: Thank you very much. Unless people want to have less than an hour for lunch, I think we are going to have to adjourn.

I suspect our reporter might be much in need of a break by now, too.

MR. MOONEY: Dr. Bracken, I hope one of the terms your glossary group will work on will be guidance and guidelines because it is frustrating and I think it is important we do talk a common language.

We talk guidelines under FIFRA which are in no way guidelines to mandatory requirements. We talk guidelines under Section 5 of TSCA where it is voluntary concept just because there is no statutory authority.

So we have got to get those terms straight. This consistency, the picture you paint, when I look at what has gone on within the U. S., with only four or five agencies as parties to IRLG, with the differences that have emerged within EPA with regard to testing effects standards under FIFRA as opposed to TSCA, I would find it remarkable indeed that these OECD groups could come out that close together.

We haven't seen them so I can't deal substantively with that issue, but I would find it very surprising that

there is that level of uniformity.

And this brings me back to the point that I couldn't tell when you had arrived behind me, but it was the point I was belaboring with Warren Muir.

We have some strange concepts of conformity, of harmony, and somehow there seems to be a sense that two things are in harmony when one is general and the other is highly specific.

And I don't understand that, and I wonder from your perspective of having seen both what is emerging in that big stack from OECD and what is in existence on the books as proposals under TSCA in this country whether that is what is at work here.

A funny concept of consistency and conformity where somehow highly detailed is viewed as being in conformity with something that is rather general or performance oriented, the GLP area for example.

I would find it remarkable indeed if the OECD group could come up with something that matches EPA's current thinking as reflected in the Human Health Proposals of last May.

Tape 2 Side B

DR. BRACKEN: As I said, the OECD has not a specific document at all. The document as it exists now is "Principals and Management Practices." It doesn't speak to specifics.

It will, we hope, in some areas speak to more specifics, but in general at this point it is a very general document.

But when we say consistent, I guess what we are talking about is in the case of the Section 4 test rule we might -- well, in the guidance, for example, it might say two species and it might identify the species, for example. That might be an example that we would say in the Section 4 test guidance or test standards that two species are required and name the species.

I am not sure this is a good example, but it is the kind of thing we are talking about. The specificity is more in terms of duration of the test than numbers of species. It is that level of detail rather than sort of general guidance you would tend to give a researcher.

MR. FULLER: I was going to add one thing. I think when we talk about consistency internationally, it is also useful to make a distinction between the large number of new chemicals that are going to be in international trade which we think we have so far evolved a rather good set of minimum packages of data for those new chemicals to make a distinction between that and existing chemicals and to say to our knowledge there are only three countries in the world that are currently talking about dealing with existing chemicals and testing.

The United States and the Japanese are already testing and the Germans have built into their law, which is not yet German law, the fact that they plan to have the ability to test existing chemicals.

So I think it is important to make that break because what you are talking to in specificity really goes to those existing chemicals and there is not a broad scale intent we have heard yet on the part of many nations to even test them at all.

So if you look at the new chemicals, what we think we have is a good package that we think we will be able to have agreement on and the 24 nations are saying yes, this is a useful set of data for new chemicals that come in. They are imported into our countries for us to use in making a risk assessment.

MR. MOONEY: Are you suggesting that the package of requirements in the Sixth Amendment, with which I would presume the German law and all others will need to conform in the next year and a half or two years, are sufficient for risk assessment purposes?

MR. FULLER: I am not suggesting that; I am suggesting that what is being evolved within OECD is a set that we hope all nations will feel form a reasonable basis for making assessment on new chemicals.

They certainly represent much more than we have had

to date in the United States. As I say, they wouldn't be mandatory in the States because we don't have that authority.

However, the OECD document is not a carbon copy of the Sixth Amendment, and the EC has indicated its intent, if international agreement is reached, to take steps to modify the Sixth Amendment accordingly.

DR. BRACKEN: What we are suggesting as far as the new chemical is concerned is that the recommended minimum base set that is coming out of the Step Systems Group is that: a minimum base set that you would do for most chemicals, but that does not preclude the country from asking for more test data if they feel it is necessary, depending on the chemical or, in some cases, even less if it is a chemical for which there is some reason to believe we don't need to do the whole minimum.

We are saying that is truly a minimum base set.

MR. MOONEY: This would suggest you are looking down the road to modification of TSCA, Section 5, to accommodate to something like this.

DR. BRACKEN: What we are saying, as an interim, certainly, we could recommend the minimum base set as guidance under TSCA, and that is all we have the authority to do at the moment under TSCA.

But it does say that if we accept and reach agreement that we will, in fact, require this for all new

chemicals as mandatory, yes, we would have to modify TSCA in some way.

That could be modified as a legislative amendment or it could be modified through some sort of international agreement where you had an international convention and countries reaching agreement, which would then require Senate ratification.

Those could be two possible ways. You are right: if we say for all new chemicals this is a mandated base set --

MR. MOONEY: The Sixth Amendment does have a quantitative exclusion at the low end. Would this mean then that the Sixth Amendment countries conforming in this OECD proposition would have to reengineer their own statute or does the OECD Step Sequence Group take a position on a quantitative threshold?

DR. BRACKEN: It doesn't, to my recollection. But it does have some language in there that allows for flexibility.

So I think that exemption as it is now presented in the Sixth Amendment would probably be allowable under the wording that exists in the Step Systems Group.

But it may mean in time -- as you know, the Sixth Amendment makes a recommendation for additional testing as you reach certain production ranges.

That has not been a recommendation that has been accepted by the Step Systems Group yet, but as they proceed to make recommendations about higher tiers of testing, they may disagree with that trigger, and if the Sixth Amendment countries subject to that agree to that, they would have to go back for some kind of change to the Sixth Amendment, too.

So there is a possibility there will be changes in several countries.

MR. MOONEY: So sub-systems at this point hasn't really progressed beyond the base set numbers.

DR. BRACKEN: That is right. What they have said is they anticipate a constraint behind it, but they haven't gotten that far.

They have listed data elements involved in the base set, and as they receive reports, they will attach a set to that and then they will be looking at higher tier testing in the future.

MR. MOONEY: Is there an economic component to the Step Systems Group? Is anyone trying to put some cost perspective on the package?

DR. BRACKEN: Originally that was one of the charges to the individual expert groups, but in some cases the groups got to it and in some cases they didn't, so as they put together these packages, the Step Systems will be addressing cost.

DR. EISENBERG: I, too, share some of the concerns Tom Mooney expressed about the use of the word "consistency." We talked about guidelines internationally because I had the same difficulty with some of the Federal agencies--with EPA and FDA.

I think we might be better off if we use the term "they are not inconsistent with" rather than being consistent with because what you are saying there is that when you are saying consistency you are giving the impression they are quite similar and they are dealing with the same subjects, where in some cases some might be very specific and others are quite flexible and general.

If you call them consistent, I don't think that is really the case. I think what the case is is that they are not inconsistent with each other.

MR. MOONEY: Let me illustrate my point. The FDA's GLPs and EPA's GLPs have been represented as being consistent, and yet, as a case in point, EPA has taken the FDA GLP requirement to observe the animals twice a day and it has translated that into a requirement to observe the animals every 12 hours.

Those are two concepts, and yet one could be argued as being consistent with the other. Every 12 hours is, after all, twice a day, but the practical implications of the difference are tremendously important in terms of

research, and it is that kind of thing that is troublesome, I think, as these things evolve.

On one hand, one could easily look at these and conclude these are consistent, and they indeed at a practical level are not.

So we will view the stack with great interest.

MR. BARAM: I think we are talking about conceptual consistency. It is just that each country has different needs. Legal requirements, technical findings that have to be made here in the United States might require more findings in other countries.

So we are talking conceptual consistencies, economic inconsistency, and perhaps practice consistencies.

MR. MOONEY: I agree, and yet we come down to the literal language of the Agency's requirements, so at that point the conceptual aspect becomes less important to the practitioner than the precise language that is down on paper.

DR. BRACKEN: Those are exactly the kinds of comments we would like to have because I think it is our objective as we edit the OECD guidelines that we, in fact, are not inconsistent, if that is better language.

MR. BARAM: Would you ever get beyond conceptual levels and agreement among the countries? It is hard for me to imagine that you would get down to practical

consistencies.

MR. MOONEY: I doubt if the Europeans will look kindly at your pathology requirement that they be American board certified.

(Laughter)

DR. BRACKEN: They haven't, to be perfectly honest, and chances are -- I don't remember the wording; maybe Bob can speak to that, he has been one of our experts -- that it would say something to the effect that "or equivalent."

So there will be some equivalent to that. It probably wouldn't get quite that specific. I don't even know how the guidelines speak to that, but it would be at a higher level in a hierarchy than seeing U. S. Board Certified because clearly that couldn't be the case if you are dealing with testing in another country.

MR. FULLER: It did get their attention, though.

(Laughter)

CHAIRPERSON BENDIX: Any further comments? The meeting is adjourned until 1:30.

(Whereupon, at 12:45 p.m., the meeting was recessed, to reconvene at 1:40 p.m., this same day, March 19, 1980)

A F T E R N O O N S E S S I O N

1:40 p.m.

CHAIRPERSON BENDIX: If the members of the Committee who are scattered through the room would come up front, we would like to convene the meeting.

I am going to be passing around the amended sheets for the Section 4 regs that were discussed this morning for those of you who don't already have them.

Mr. DeKany is now going to talk to us about EPA's plan for chemical hazard warning labeling in industry and commerce.

MR. DE KANY: Thank you. I wonder if you would refresh my memory. Basically, the labeling program with which we are involved is really a joint partnership between EPA and OSHA, and basically what we have done is split the responsibilities for the labeling program along these two lines.

EPA has taken over the responsibility of protocol labeling; namely, how do you label, what sort of information you put on the label, label size, regulation pertaining to which types of containers might be labeled and so on.

OSHA has taken on the responsibility of determining the scope of the labeling rule. Basically, which types of chemicals should be labeled, labeling in the

workplace, any records keeping or information on chemicals that relate to the workplace and so on.

And I will be getting into the specifics of each agency's responsibility. Basically, let me start by giving you a rather broad summary of the features of our proposal at this point on the labeling of chemical hazards.

We have broken up our rulemaking activity in two basic parts, one dealing with the labeling of key hazards, and the other dealing with chronic hazards, and both activities fall in different pathways.

Let me summarize how we propose to handle acute warning. Basically, we think the industry has done a great deal of effort in this area. In particular, the American National Standards Institute has devised an excellent labeling system, and that becomes the framework upon which we are building upon the procedures for labeling acute hazards.

This system basically treats 13 categories of health and safety hazards. The health hazards include things such as toxicity, corrosiveness of chemicals, those that cause irritation to eyes, skin, and so on.

The safety categories within the standard would include such parameters like flammability, combustibility, strong oxidizers, reactive materials, compressed gases and so on.

MR. BARAM: These are all bounded by the workplace.

MR. DE KANY: This is the classification, basically the part of ANCI.

MR. BARAM: It will apply only to the workplace.

MR. DE KANY: I will get to that in a minute. Basically, what I am talking about now is what sort of acute hazards does the ANCI standard address?

Some are health related, some are safety related, so we have, by and large, adopted that classification of acute hazard.

As far as the exclusions of the labeling requirements are concerned, we would, of course, exclude those things excluded by TSCA, including pesticides, food, drugs, cosmetics, firearms, and so on.

We would also at this stage propose to exclude anything of the nature of articles because articles tend to be complex mixtures of chemicals. So this particular phrase we would not propose that the labels apply to articles.

We would exempt from the label requirement R&D chemicals because there are millions of them, and we are, however, thinking in terms of a generic R&D label which would be common to all R&D chemicals to be handled by professional chemists or something like that, but would not propose to have the ANCI system apply to that.

We would also exclude consumer products because,

in this case, the Consumer Product Safety Commission has elected to do that.

They are doing it now, of course. I am not going down the whole list, but we will also exclude PCBs because we have an active labeling requirement there, so it doesn't make any sense to include PCBs in this.

Containers: As far as we are concerned, EPA labeling requirement would pertain to barrels, drums, bottles, boxes, basically the commercial containers for the commerce and chemicals.

We would exclude stationary stores, equipment and reaction vessels. Those kinds of items are definitely part of the workplace, and of course OSHA is currently investigating the need for labeling in that line.

We would also exclude large boat carriers, again primarily because these are adequately and currently regulated by DOT.

We are requiring a manufacturer importer of a chemical who is distributing in commerce to first of all determine the hazard of that chemical, and if the hazard falls within the category as defined by ANCI to adopt basically the provisions of the ANCI label.

And we also require that a recipient of a -- commercial recipient of a labeled container must not remove the hazard warning label from labeled containers unless the

item is repackaged or relabeled.

And if you repackage or relabel it, he has to at least carry forth the hazards and hazard warnings. The reason for that, obviously, is that the prime thrust of our labeling program is directed toward commercial use. Workers who are handling chemical drums and so on are aware of the hazards contained in those drums.

Of course those who are in the transport end of it also to be knowledgeable of the things they are getting on board aircraft, trucks and the like.

How does a manufacturer determine whether a chemical is hazardous or not? Well, we have done a considerable amount of thinking about that.

We thought we would at first precisely identify protocols for determining whether a chemical is hazardous. By protocols, I mean requiring, for example, a search of, let's say, chem tracks or something like that.

Then we suddenly realize there are a great many references in this area and, frankly, if we have specified specific sources of hazard information, we may limit the liability of a manufacturer.

Therefore, we decided to provide flexibility and make sure that he exercises his knowledge of the area. In other words, we are requiring that the manufacturer make a reasonable effort to locate existing hazard data in

his own files and to take advantage of available literature.

This then, of course, puts a fair amount of responsibility on his shoulders because I think those of us in the chemical profession could easily agree upon the kinds of data that is available and what a reasonable manufacturer would do to investigate hazards.

If the manufacturer produces a mixture of chemicals and he does not find any hazard information on the mixture itself, we would allow him to use his judgment and determine what the hazard of the mixture would be from consideration of the hazards of the individual components in the chemical.

MR. BARAM: Could you step back a little bit on that liability provision?

MR. DE KANY: I was simply saying that in a situation, looking at the issue should we basically put down a minimum requirement for research, that was one option. We would identify what sources of literature--for instance, chem tracks or the journals.

The other approach would be to tell a manufacturer you are responsible for determining hazards in chemicals; you take advantage of the literature.

If you take the former position, the kinds of that one are if we spell out things you should look for, then it may relieve the manufacturer from the liability.

MR. BARAM: You meant responsibility. It could be liability.

MR. DE KANY: Sure, because he said I searched all the things EPA told me to search and I preferred the minimum -- I followed the minimum requirements of the regulation; therefore, I am not responsible for missing something in the journal.

I can see from the faces I am getting kind of boring, but if you want me to stop, you see, what I am doing is going through ANCI, and many of you may be familiar.

So if I am covering areas that you feel you would rather skip, please tell me. As far as the label, the elements of the label are concerned, the ANCI system provides a single word something like danger, warning or caution, and this is prescribed for each of the 13 hazard categories, and there are instructions or triggers as to which term to use, which single one to use--danger, warning or caution.

There are three tiers, essentially, of hazards in each of these categories. It also requires a statement of the hazard: for example, corrosive: causes severe burns or highly toxic: may be fatal if inhaled.

These kinds of wordings or statements of hazard are in ANCI. However, we would allow the manufacturer to change his words, use something equivalent if it made more

sense.

There are also precautionary instructions required on the ANCI label; that is, wear a respirator; do not expose chemicals to open flames and other instructions such as first aid, instructions in the event of fire, spill or leak, storage handling instructions.

These precuationary measures are discussed in the ANCI standard in our regulations. However, they are also left up to the judgment of the manufacturer as to which of these precautionary measures seem to be most appropriate.

Also, the name and address of the manufacturer and importer is required, and if it has been repackaged, the name and address of the last repackager.

This is important because often poison centers do not know who to get ahold of. Medical people can also write for data sheets. So that is the reason.

MR. BARAM: You won't have chemical composition or name on the container of what the chemical is inside, but would you have a coding requirement? Because if you called certain manufacturers, they wouldn't know what you were talking about because there are so many different kinds of chemicals out and containers that might be marked danger or warning or caution.

MR. DE KANY: We certainly expect there will be an identifying name on the label. When I get to the OSHA

part of it, there will be certain requirements for revealing chemical identity.

We would urge manufacturers to use the chemical identity. If specific identity is confidential, a generic identity would be desirable.

We would set the use of guidelines as a trademark. The date of the mixture, the date of the chemical or mixture preparation is also required on the label, and the reason for this is often particular trademark chemicals may from time to time be changed in formula.

They may use one solvent today and have to switch two and three months later. So the date of the chemical preparation is also required, and that will enable the manufacturer to pin down the exact formula as to when it was manufactured.

Also, a statement as to whether or not a material safety data sheet is required or available would be on the label.

There are things like display requirements, and obviously we have regulatory language in there that says it must be written in English. It should be durable, visible, et cetera.

These are some of the administrative details of the label itself. I won't bore you with all of those.

MR. BARAM: What is a Data Safety Sheet?

MR. DE KANY: That is also a very common item in industry. A Material Data Safety Sheet is a summary of the information a manufacturer has regarding the health and safety considerations of his chemical.

It would give the specific identity, if it were not confidential. Usually it is given. It would give important physical chemical properties. It would give health and safety data.

Many manufacturers even go so far as to label chronic data. I have seen many who say caution: this chemical is found to be carcinogenic in animal tests.

That practice varies between manufacturers, but a Material Safety Data Sheet is a very, very important tool to those in the chemical industry who are professionals, who are using chemicals and handling chemicals at a stairway of learning about a chemical and its properties from the manufacturer.

As far as the display requirements are concerned, the only thing of interest to you is we will not allow terms such as nontoxic or safe to be used.

Basically, that would be very difficult for anybody to determine for sure whether a chemical is safe or nontoxic, and I am sure you as consumers have seen many, many labels on consumer products saying nontoxic.

And that could be very misleading, particularly if

the manufacturer is not sophisticated in understanding what is toxic.

As far as updating labels, we will require that a manufacturer update a chemical label whenever he learns of any new hazard data, or at least every three years he should update his label, he should make an attempt every three years.

If a chemical was judged to be nonhazardous solely because there was no information available, the manufacturer would have to determine annually, at least annually, make an attempt to search the literature again to make sure if there is new literature regarding hazards.

If the manufacturer, in any event, finds new information on hazard, he would have to correct and update his label within 180 days of finding new information.

We also have a fair amount of recording -- record keeping requirements. The reason for this is a study that the regulation is enforceable.

If a manufacturer puts out a chemical without a hazard warning and if information comes to our attention that indeed this chemical is hazardous, we would then go back to the manufacturer and require him to produce the various records that might be kept.

At a minimum, he should be able to show us he has made a good faith attempt to research the available

literature, and he would also have to make available to us the reasons for any judgments he might have made regarding the interpretation of that data.

So the record-keeping part of it is a very important aspect of enforceability of the label provision.

DR. SUTTON: I have a question. If the material is judged not to be hazardous, a label is still required?

MR. DE KANY: Would not be required.

DR. SUTTON: What is the signal word? You can't say it isn't hazardous.

MR. DE KANY: We are talking about acute hazard, 13 categories. If you find there are no data to suggest that any of these 13 categories are not present, then you don't have to label it.

ANCI, I think, is fairly definitive. When you are talking things about flammability, there are numerical values. If you talk about oral toxicity, ANCI has the figures in terms of milligrams per kilogram of animal --

DR. SUTTON: I am just trying to understand the flow here. The chemical is evaluated, you have good experience with it, you have done appropriate toxicity testing, and it does not fit any of the 13 hazardous categories and, therefore, you don't put a precautionary warning label on the product.

MR. DE KANY: Bear in mind again I am still

talking about categories of acute hazard.

DR. SUTTON: That is what I am talking about. I think that is what I am trying to talk about. Then once a year are you supposed to do --

MR. DE KANY: Once a year there is a responsibility placed upon a manufacturer to at least annually readdress the label.

Let's take a scenario where you are producing a new chemical and you go to literature. There is no data on flammability.

DR. SUTTON: I asked you about a situation where there is data. We have developed the data, done the testing for acute hazard and have come to the conclusion that there isn't. Do you once a year do a literature search then?

MR. DE KANY: Well, yes. In the sense of determining whether or not there is new evidence. What I am talking about is a case where there is no data.

If you have done all the testing, if you have tested for flammability, obviously there is no requirement to search the literature for flammability.

Let's take oral toxicity. You have searched the literature and you found none, and you have not tested your chemical. Therefore, we can't require you to post an oral toxicity on the label, but you would then be obligated at

least annually to search the literature for oral toxicity for things like -- frankly, we would advise a manufacturer to do it annually, anyway, in case of new hazards that may come up.

DR. SUTTON: I am not sure I yet understand all of the interfaces here, but I think I see your problem. Clearly you are not requiring testing in order to label. In other words, you are saying use the best data available and produce a label, and you don't want to provide testing to do that.

So to make sure that that is reasonably updated, you have asked for periodic reviews.

MR. DE KANY: That is right.

DR. SUTTON: How specific is that going to be? Not very, I hope. The point I am getting to --

MR. DE KANY: I know what you are getting to. Let's suppose you have done all your testing, okay? You have found that your chemical does not fit into any of the 13 categories.

You are not then required to label. Now whether or not you are going to reexamine the literature is really your game, your risk, because no one from EPA is going to look over your shoulder.

But let's suppose that someone else has tested your chemical and you found a negative, let's say, in a

test and they find a positive.

EPA would then come back to you and say are you aware of the fact that there is new evidence to suggest that conflicts with your flammability data or oral toxicity data exist.

We would then ask you why didn't you take cognizance of this new information or did you examine this new information.

You would technically be in violation if you say, no, I didn't search the labeling literature. Frankly, I think it is really a non-issue because it is fairly simple.

First of all, you wouldn't test your chemical if there was literature available anyway. The sequence of events would flow as follows: you would probably search literature first, then if there was missing data, test yourself.

So when you were asked to reexamine the literature every year, you wouldn't have to pour over the literature already investigated; you would simply take 1981 literature and review it.

So I don't think it is a real issue. I wouldn't expect you to go back over the past literature once more. It is just a current awareness kind of program.

CHAIRPERSON BENDIX: Mr. DeKany, are there any

outstanding issues with respect to this regulation, any things that are not yet settled that the members of this Committee might usefully --

MR. MOONEY: How much time do you have, John?

MR. DE KANY: I will take off my coat. It is getting warm here.

CHAIRPERSON BENDIX: You have been presenting most of this as pretty well settled. Where do you see the points of flexibility?

MR. DE KANY: I think as far as the acute hazards part of it, there really shouldn't be any controversy associated with it, at least as far as industry is concerned, because basically we have adopted an industry developed system.

It has been developed and endorsed by most of the leading chemical companies in our industry. The real controversy is going to come on the next part, which we refer to as our cancer hazard warning label.

DR. SUTTON: If you don't mind, I would just like to pursue my point a little bit. I don't want to be troublesome or cause a lot of difficulty, nor do I think this is the most important issue, but it does illustrate a troublesome kind of feature.

Any time you go from what amounts to a voluntary and sensible kind of system, the one that is specified

precisely in our regulation, you get into difficulty, and this is a minor difficulty, but it is one that is obviously going to face those people who have to comply with the regulation, just as simple a one as the issue of reviewing the literature once every year.

What literature are we talking about? Where is it? Is it worldwide? How do you really go about addressing worldwide literature of everything that is written on 4,000 chemicals a year?

It gets to be a significant issue for some people that can't be tossed off lightly. I don't want to try to solve that issue right now, but I want to make a point that it is not as simple as it may seem at first glance.

MR. DE KANY: I would probably agree with you to some degree. However, frankly, what our attention is to here is a simple one: you can't review in 1980 the literature in 1981.

Basically, what we would expect a manufacturer to do in 1981 is precisely what he did in 1980. So the review requirement is to make sure that you don't do this in 1980 and then not review it until 1999.

What we are talking about is simply reviewing the current year's journals. In fact, our position has been somewhat simplified.

We feel you are the best judge, and by you I mean

the chemical industry, of deciding which journals are most relevant for your particular chemical.

DR. SUTTON: If the reliability is missing data that is now available, if it is not relying on your information, reviewing every biological and toxicological article published worldwide, that is another issue.

And you have converted one kind of liability of doing a good performance job into a specification liability that you can monitor once a year, and that is a very different duty.

MR. BARAM: Are you going to specify one year update?

MR. DE KANY: For those who do not label, for those chemicals that bear no hazard warning label, nine times out of 10 it is because the manufacturer has not tested it, so he hasn't found anything in the literature and he hasn't tested, so the chances are quite good that in a period of a year someone else may have investigated that chemical.

Obviously, a manufacturer who has done all the testing is obviously in very good shape. We are not intending to hurt a person like that, but by and large, based on the notices we received to date, we are not getting acute hazard, let alone chronic hazard.

MR. BARAM: Was that part of the ANCI STM requirement?

MR. DE KANY: The mechanism deals with technical details of the classification, the words to use on a label. Obviously, to adopt it in ANCI, we have had to put together administrative rules, and the kinds of things I am talking about are administrative rules.

MR. MOONEY: John, I have got three questions, before we get to the question of what are some of the issues. Let me post them for you.

First, as a general comment, as a general issue, why, given OSHA's authority in the workplace and DOT's authority covering the shipment of chemicals, what is the rationale for EPA's involvement in what is in the main going to be largely a workplace and shipment oriented labeling group?

MR. DE KANY: This is directed to all the industrial users of chemicals. There is no question in my mind, based upon, again, notice, review, experience in Section 5, that there are some companies making new chemicals who didn't even know the feedstock material. They bought a generic compound and we had to go back and find out what that generic substance was that he was using to make a new chemical.

What we want to make sure is that all the downstream processes are given the opportunity to at least be aware of any knowledge requiring acute hazards and

carcinogenicity.

This is what we intend to do: to make sure the purchasing agent down to the engineer who designs a process flow sheet down to the worker has every opportunity to understand that this chemical causes skin irritation.

It is as simple as that.

MR. MOONEY: The second question. I am glad I am asking simple questions. The second one: I don't find any discussion of the concept of unreasonable risk in your preamble. Perhaps I have missed it, but you are citing Section 6(a) authority which deals with the requirement for finding some unreasonable risk, not just hazard, but some unreasonable risk is going to be addressed by the control mechanism that you are proposing.

What you are doing is dealing generically -- so I guess I am raising the question of in what way have you addressed the unreasonableness in Section 6(a) terms.

MR. DE KANY: Of course, our regulation and our technical support documents will express that. The bottom line is we think any manufacturer who possesses information on acute hazards would create an unreasonable risk if he didn't advise users of that hazard.

Is it reasonable to expect a fireman responding to a fire at a plastics company being faced with unmarked, unlabeled drums, not know whether one is generating

hydrocyanide gas, not knowing whether he should make his men wear respirators, not knowing whether or not there is danger of an explosion from heat?

I can give you anecdote after anecdote; namely, fire fighting. The firemen have been killed and mutilated and hurt because they didn't know what chemicals they were dealing with.

DR. CAIRNS: I think Dr. Mooney has a point: everything you mentioned really dealt with unreasonable risk.

There are lots of hazards that I judge not to be unreasonable. I think plain ordinary table salt, if you just dissolve it and want to stick your finger in it for a few hours, you are going to have a lot of irritation: it dehydrates your finger. I don't think that is unreasonable.

MR. MOONEY: I would pose a question on that irritation. The way this is worded I would question that any chemical will "pass" language.

So we will end up labeling everything.

MR. DE KANY: Not really because we are adopting the criterion, the triggers for labeling that have been generated by yourselves.

On one hand, you tell me don't label because we have adopted ANCI and every one of us religiously adheres, and how you tell me it is unreasonable.

MR. MOONEY: I am sorry; I am raising the question of unreasonable risk in purely legalistic TSCA terms, and you are saying there will be support documents that address that and we will have to take a look at them.

MR. DE KANY: We will weigh the cost of labeling.

MR. BARAM: This will be done for OSHA also.

MR. DE KANY: Under this regulation, we will have to balance the cost of labeling, the cost of searching the literature, all the administrative requirements, against the benefits of labeling and show that the risk of not labeling offset the costs of labeling.

MR. MOONEY: Okay. My final general question.

MR. DE KANY: We do have a contract report being generated which will address those kinds of issues.

MR. BARAM: Couldn't all of this have been done by OSHA itself, which wouldn't have to deal with the term "unreasonable risk."

OSHA has other language in its statute and OSHA could come up with the regs also.

MR. DE KANY: I don't know the answer because I am not that familiar with the authorities.

MR. MOONEY: I am raising the question in that sense if OSHA has not taken action, doesn't that in fact diminish your argument that an unreasonable risk is present?

MR. DE KANY: No, because they felt TSCA was

a better vehicle for requiring the labeling.

MR. BARAM: Your data base is much broader than theirs.

MR. DE KANY: This goes beyond just the workplace; we are dealing with items in commerce.

DR. EISENBERG: If your concern were, to some degree, the situations you described--firemen or emergency personnel, a transportation accident or something like that--I notice that what is specifically excluded is cargo containers, shipping containers, anything other than barrels, drums and things like that, so if someone were shipping it in a tank car, it would be excluded from the labeling, regardless.

Tape 3 Side A

MR. DE KANY: We are dealing with totally different labeling needs. We are dealing with large tank trucks. The details like the size of the label, the information it conveys, obviously you can't take a petroleum tanker and say caution, benzene, breathing gasoline is dangerous to health.

That is not the hazard of transportation. You have a great big flame symbol and basically contents flammable, explosive.

So there is a different need for hazard information in large cargo carriers. Tankers, even liquid chemical tankers, are labeled.

There are some very good, both domestically and

internationally developed, systems for handling hazards in transportatation.

MR. MOONEY: DOT goes considerably beyond tank cars. I see considerable potential for overlap.

MR. DE KANY: That is why we are saying we don't require it for shipment. In other words, if the DOT label is on your container, it is not required to be duplicated.

In other words, that is what the situation is with the tanker. You would not have to put an EPA label on a tank truck or an outer shipping box.

Let's say you may have 100 jars of chemical substance within a great big shipping carton. The shipping carton would bear the DOT label, the individual labels themselves, just the way it is done now for those that voluntarily label.

MR. MOONEY: My last point is there are deviations from the ANCI voluntary program in the standards or tests. Does your support document address those as why you have chosen to differ?

MR. DE KANY: Yes. We are also at this point proposing or will propose for comment the adoption of the European labeling system which, in some respects, might be more useful than the ANCI labels.

They have developed a thorough system of symbol. We have one symbol, a skull and crossbones, but they have a symbol for flammability, a symbol for skin burns, and so

forth.

Things like that will be contained in our proposal. We have asked for public comment, does it make sense for us to adopt the European community international symbol language; should we adopt the language proposed by the U. N.

Those kinds of issues will be brought up in the preamble in the proposed regulation itself. Obviously, the reasons for considering the European community is for harmonization.

We will still be faced with two systems of labeling for those who import and export.

CHAIRPERSON BENDIX: Are there any other questions on this portion?

MR. BARAM: John was going to talk briefly about the cancer labeling.

CHAIRPERSON BENDIX: That is going to have to be very brief because we have two more people to hear from before 3 o'clock.

MR. DE KANY: We would propose that any chemical substance designated as a carcinogen would be subjected. By that we mean the Administrator would put out a published list of carcinogens.

This list likely would be obtained from the Cancer Assessment Group in EPA, from NCI Reports, and from OSHA lists, but there would be a very specific list of chemical substances

which, by tests, have been shown to be carcinogenic.

In that event, that mixture for chemical substance would have to be labeled with a cancer warning, and this likely, of course, would be very controversial.

I have been asked to keep it short, but obviously no one would like to label their product with a cancer warning, for obvious reasons.

Secondly, there may be great concerns and anxieties about how a chemical gets on the Administrator's list.

These will be some very important issues. The issue as to how do you handle a mixture when a carcinogen is present in a part per million level, our suggestion on that is there be a .01 threshold for a carcinogen unless a manufacturer deliberately added a carcinogen.

In other words, if there was a carcinogen present as a by-product, we would not require it to be posted unless it is more than one percent.

On the other hand, if it is something the manufacturer deliberately adds --

MR. BARAM: There is no list -- EPA list now, is there?

MR. DE KANY: There is a NIOSH ACAG list. We will propose in a proposal we will present that list. It will be proposed the chemicals will be listed and the source

of these chemicals through CAG, IRI, NCI and so on.

DR. EISENBERG: That doesn't seem to make any sense from a health effects standpoint at all. Why would you be concerned whether it is added intentionally or unintentionally.

If the tenth of one percent is serious or something that one should be concerned about, why is it relevant whether it is intentional or unintentional?

MR. DE KANY: Because we could not put a threshold if it were not for the cost implications. It is probably fairly arbitrary.

People begin to argue about the .01 percent.

DR. EISENBERG: I am not questioning the tenth of one percent; I am arguing whether it is intentionally or unintentionally.

MR. DE KANY: There is no analytical cost if you add it intentionally. It is simply to lessen the burdens of analytical costs.

DR. CAIRNS: Suppose you did the analysis and you found it was less than than the tenth of one percent. You wouldn't have to put it on the list if it was unintentional.

You should drop the second part of your proposed rule because what you are telling us, I think, is that two different things can come out, two different chemicals, each with the same amount of carcinogen in them.

In one case it would be reported. In the other

it wouldn't, and I don't think that makes sense.

MR. DE KANY: I am not happy. I would rather remove the .01 entirely.

MR. MOONEY: You will still have to meet the unreasonable risk test for carcinogenicity.

DR. EISENBERG: What happens if I do analyze and I do determine it is there but I am not adding it intentionally as a product?

In other words, I don't need it there. It happens to be a by-product of the process. If I could avoid it, I would, but for one reason or other I don't, and it happens to be there incidentally.

MR. DE KANY: Do you want an answer?

DR. EISENBERG: Sure.

MR. DE KANY: You should label it.

DR. CAIRNS: But that is not what your proposed rule is.

MR. DE KANY: I am sitting here as a person concerned about public health, as a professional, and if you know there is a carcinogen in there, you should disregard what EPA's regulation is there.

DR. EISENBERG: Why don't you say that in the regulation?

MR. DE KANY: We will put it in the preamble, but the point is the industry is coming in and arguing not about

.01, but the industry is arguing vigorously it ought to be one percent.

DR. EISENBERG: Whatever level you determine, we will still have the second question: whether, in fact, it is intentional or unintentional.

MR. DE KANY: It certainly is something worthy to think about. If a manufacturer analyzes it and it is known to him, he should post it.

That would be one suggested part of the proposal. But, strictly speaking, the .01 was put there to alleviate the burden of extremely expensive analytical costs.

It is very liberal: a thousand parts per million. It is very liberal. But that is the main reason for it. Now, frankly, I don't think I should have to sit here and tell you what should I do if I know there is carcinogen in there.

You have to look at it as a responsible manufacturer.

MR. MOONEY: You shouldn't have to. I think you will have to meet the test of establishing a tenth or a hundredth or one percent or whatever you are talking about constitutes an unreasonable risk.

MR. DE KANY: Why do I have to do that?

MR. MOONEY: You are making the rule.

MR. DE KANY: We will do it for .01. I feel comfortable with that.

DR. CAIRNS: You have to demonstrate an unreasonable risk, not just say that you think it is okay.

MR. MOONEY: .01 percent or any other level, per se, does not necessarily constitute an unreasonable risk is all I am saying.

MR. DE KANY: On what basis do you make that statement? Would you share with me a technical analysis or is it simply your opinion against my opinion at this point?

MR. MOONEY: Probably the latter.

MR. DE KANY: We would weigh the benefits. I asked you how much would the words "caution, suspect carcinogen" cost you.

Do you put a label on a product? How much does a multi-colored corporate logo cost you versus the cost of three words saying, "caution, suspect carcinogen"?

MR. MOONEY: I don't think the economics are terribly important.

MR. DE KANY: The buyer may avoid it like the plague when he has got somebody else selling something that is not a carcinogen.

We should be equitable, we should require all competitive comments are evaluated on the same basis.

CHAIRPERSON BENDIX: I am sorry; we are going to have to call it quits on this point because we have got other things we have to discuss.

I don't know how the rest of you feel, but I would like to make a request that on our agenda for the next meeting that we set some kind of a minimum time, like 45 minutes or, better yet, an hour for each agenda item so we don't end up with this feeling of not being able to finish discussion.

MR. BARAM: Could John tell us where the status of this is right now, what is the next step, how is this going to proceed--just a time frame.

MR. DE KANY: I think this dialogue is helpful for me. The point is, we haven't even posted yet. I think I should point out that everyone in this room knows what we are up to. They have got copies of the drafts. We will be talking to manufacturers.

It is our aim to get a proposed notice out. I always eat my words on dates, but April, May, thereabouts.

MR. BARAM: With OSHA.

MR. DE KANY: Yes. And then we will go over these issues once again, and I think what I am hearing is that the burden of unreasonable risk is upon our shoulders, and I agree.

MR. BARAM: As long as you are going into it with OSHA, you have got OSHA's statutory authority,also.

MR. DE KANY: Their part of it will be dealing with how to label process vessels, et cetera, fairly detailed

record-keeping requirements in the workplace: names of specifically chemical substances manufactured in the workplace will have to be kept and posted in certain places in a workplace.

They are basically aiming at providing workers with access to chemical identity and hazards at reasonable places in a company.

MR. MOONEY: When you talk about OSHA lists, are you talking about Category 1, Category 2 listings under their new cancer policy?

MR. DE KANY: The manufacturer will have to keep the names of all chemical substances manufactured in a workplace by identity and hazard and make it available to workers, if they so desire.

The limitation on this will be, however, that it will only cover the chemical identities in our inventory and in the registry of toxicological effects.

There are about 50,000 substances thereabouts in our inventory and 33,000 in the register. Roughly speaking, it will cover maybe 60- to 70,000 chemicals.

The requirement is there: is there access of chemical identity and hazard to the worker.

MR. BARAM: Do you see a need for other Section 6 rules? Do you think there will be less need to regulate on Section 6 on a lot of these chemicals?

Is that one of the benefits that might come about?

MR. DE KANY: This won't, of course, relieve resource requirements to us to individually tag chemicals like we had to in the PCB case.

We take advantage of what is an internationally recognized system. It was developed by our industry. The main issues are administrative rules of how to apply this system of labeling to the industry.

Obviously, there is some difference of opinion there.

CHAIRPERSON BENDIX: Thank you very much, Mr. DeKany. I believe Blake Biles is here and wants to very briefly present something to the ATSAC.

MS. RAMSEY: Is Mr. Robert Bohen here from 3M?

MR. BILES: All I want to do is tell you what is here, particularly because if you mail it, it will become public document, and I wanted to get it in the hands of those of you who are here, and I don't want to hear a week later everybody saw it before we did.

What I have done is pull together a couple of materials, with one exception that I will mention in a second.

The cover memo that goes with it, you need to make two or three edits on those. There are some additions

that are not represented in the cover memo.

What I have pulled together is listed in the cover memo. As most of you are probably aware, we received a letter from Senator Muskie asking questions about -- enclosed is a copy of the memo in response to Senator Muskie.

The caveat is that this still has not been signed by the Administrator, but I am going to provide it to the Committee in the hope that it does not change before it is signed.

That is Attachment A, and that is there. The second is listed on the cover memo: provision of a number of the 5D2 Federal Register Notices. Those are not attached.

You have those in your other larger packet. Those are a big group of things, and they are not in the clip here. The third and fourth things listed on the cover memo are attached: the test marketing exemption materials, and the other materials are some responses that we have sent to companies who have submitted -- provided submittals to us that we deemed incomplete and therefore returned.

And what we provided here are a couple of the letters that we sent back to the company specifying grounds that the submittals were incomplete.

There are three or four other things that I just want to identify for you, and of course at a separate meeting I will be glad to talk to you about it.

Most of these are in the public record. First, we have attached two or three of the 5C extension review period notices, including one that is not Federal Register print, but that is basically typed like this.

It is one that was signed last week, and it is in the Register or will be in this week. It is extending the review period on one of the PMNs we have in the process.

Second, towards the last, is a coalition of status of PMNs. This is an update of one that is being sent to Senator Muskie.

This is a more recent one: March 12th. These are some of the tables we have developed--over 80 by now--and sort of the status of them, the types of information received, basic indexing of types of information by company size and so forth.

Those are the other materials, and the finally the very last is an example or a copy of one of the 5D3 Notices, which is a section in the Act which requires us to publish monthly. That is all. I am prepared to talk about anything, of course, but that is all I felt the need, given your time limits, to present, an explanation of what they were.

The one thing I mentioned in the cover memo that is not here, as I have indicated previously, we would be quite willing to meet and discuss with you. It is just that it is my judgment that we do not want to run off 30

copies of them.

As I mentioned in the cover memo, this does not include internal documents to be generated during our review of notices, assessment reports and so forth.

Any time in the future we would be glad to sit down with a committee of ATSAC, Section 5 Group, and provide you with some of those to talk at as examples of our assessment process.

I think it is inappropriate for us to take them as examples of company submittals, but these kinds of documents I gave you don't give you a total picture of our assessment because it doesn't represent the internal documents.

We will be glad to share some of those with you to the extent they don't contain confidential business information.

My preference for doing that would be to do it with meeting with the subcommittee and walk you through some of the examples of the documents generated and not focus on the specifics.

That is the thing that is missing, and we would be willing to meet with you at any time to talk about this.

CHAIRPERSON BENDIX: Thank you very much. I think now Mr. Kovalick has been waiting very patiently, and I think he has another meeting at 3 o'clock. He now gets his chance.

MR. KOVALICK: Well, our adjusted agenda. I was going to talk to you about two topics. One was in work group format, public participation and Section 8 record-keeping and reporting rules.

Marsha tells me that I should confine myself to Section 8 record-keeping reporting rules and the status report on where we are, primarily, on 8(c), 8(a) and 8(d), if that is correct.

CHAIRPERSON BENDIX: I think that is a good deal to cover in the next 20 minutes.

MR. KOVALICK: All right.

CHAIRPERSON BENDIX: Particularly since the Committee will probably have questions.

MR. KOVALICK: I am not going to give you this paper unless you want it, but I did hand out two meetings ago a chart that looks like this.

It has the status of our rules, and I won't give you another one unless you would like them. It is the same one. It hasn't changed substantially.

At any rate, since we last met, we did publish in the Federal Register on February 29th the 8(a) Level A rule that I think I briefly discussed.

This is the proposed basic information gathering rule to gather preliminary assessment information, and we are now in the public comment period.

As is usually the case when we propose rules, we haven't gotten too many official comments because they usually come in the last day.

We are planning at least one if not two public meetings, and we anticipate at least one of those not to be in Washington, which I am pleased to report.

We are working with our Industry Assistance Office to make those arrangements. So the comment period closes May 6th and both of those public meetings then would be held before May 6th, before the end of the comment period.

That is the status of that, and we would anticipate having comments come in in the early part of May. That will take us 60 to 90 days to wrestle with all of them and hopefully have a final rule ready to wind its way through EPA in June or July, to be published by the end of the fiscal year, which will be in September.

We are getting ready, then, to put into place our first major rule that serves the risk assessment process which you have discussed at one time or another with Warren Muir, and this is one of the primary uses of these, and this information is to help that process.

I might add that the other levels, 8(a), the levels, more detailed levels of information, that would be more than a 12-question questionnaire are under way.

We have been meeting throughout EPA in the water

and air programs and been meeting with NIOSH, OSHA and other agencies to discuss their needs, and we are manifestly, therefore, intent upon building into Level B and C rules the kind of information that they can use in the spirit of TSCA and not duplicating what others have gotten, but provide them access to information that we alone can gather.

So we are looking forward to having Level B proposal in late summer, probably around the same time we finalize Level A.

The 8(d), the submission requirement to submit lists and copies of health and safety studies, was proposed when you met last December 31st.

The comment period for that rule closed February 29th and we have recently published an extension of the comment period, primarily for two reasons, one of which we have a number of requests from different individuals and companies to extend the comment period for a variety of reasons, including a number of things for TSCA. That is out on the table now.

The second reason is that the public record for 8(d) was not entirely in order and everything wasn't in it during the entire comment period.

So we have rectified that and it is now in order, and it is now available for anyone who wishes to review it. So that 30 days didn't come on the date we started, so it is

30 days after the publication date, which will lead us towards the beginning of April for closing comments on Section 8(d), and we also have been holding, as the Federal Register Notice announced, a number, by request, of public meetings. Individual or trade associations or others can call up and say we would like to talk with people who are working on the rule.

And we have scheduled two or three days worth of those so far. They are on the record, and the transcripts appear in the public record.

That is for a more personal exchange rather than a more postured issuing of public statements. The 8(c) rule,which I believe I talked about a little bit and got into some detail last time, was the requirement, the statutory requirement, for record-keeping of allegations, significant adverse effects to both workers and consumers, and a probable proposal for reporting of those allegations is now in Mr. Jellinek's office.

We have completed one of the major milestones in doing that kind of rule. It is called the Reports Impact Analysis, the burden of those required to comply.

And that was an extensive effort because in a thoughtful reading of TSCA you realize that the standard industrial classification code, the SIC codes -- we normally think of when we think of TSCA those in chemicals and the

chemical portion of the pharmaceuticals.

SICs 2829 are far and away not the only SIC codes affected by this rule. Anyone who manufactures or processes chemicals -- that means the applications of chemicals like paints and so forth.

So the number of SIC codes starts back with mining and metallurgy and almost comes up into interstate wholesaling.

We have to figure out how many processes there are in that crowd. It is a fairly heavy effort, and we have to do some research in the Bureau of Labor Statistics.

This is done now and so we begin our approximately four to six-week process to get to the Steering Committee -- Henry Beal is going to go through all this -- the process to get it to the Administrator's desk, and then we will have a proposal again for comment coming out, and I hope by the end of April.

And this is a rule that I am particularly interested in that we have non-Washington public hearings on. If there is any useful input we can get from those whom we affect when writing a rule that affects consumers and employees and their ability to make allegations, this is it.

So we are most intent about having a balance of non-Washington as well as Washington-based public meetings. I have used about half my time, and I will stop.

CHAIRPERSON BENDIX: Thank you very much. Any questions or comments?

MR. BARAM: A quick question. This 8(c) rule you are talking about, the allegations rule, those records are kept by the different manufacturers themselves?

MR. KOVALICK: Yes.

MR. BARAM: How did OSHA's medical record contention of rulemaking come out because that would be an important parallel development?

MR. KOVALICK: If we are talking about the same thing, the last I knew, that was in their Solicitor's office. I believe we are talking about a requirement to keep medical records by the name of the individual.

We are talking about keeping an allegation by the name of the chemical.

MR. BARAM: I see.

MR. KOVALICK: The problem we have, as you can imagine, on first keeping the records, when we say, do you have any allegations, if you write a letter on cast number so and so, it would mean looking through or having a computerized set of employee medical records.

It is not fair to the vast majority because the vast majority of people do not have that kind of system. It is not what you would call overlap and duplication. We can't make those mesh and still have undue burden.

I don't think that requirement is out, but I could be corrected, I am sure. Dr. Sherman would know.

DR. CAIRNS: I notice the agenda mentioned also AD reports. I am still interested. Perhaps there is some in that package we got this morning. Is there?

What I was particularly in is what impact these have had, what action has been taken which resulted in improving health and safety.

MR. KOVALICK: Yes.

DR. CAIRNS: Perhaps if that is in here, I will read it.

MR. KOVALICK: I am not sure what is in there, Marsha.

MS. RAMSEY: All that is in there is a compilation of some of the AD notices that we have gotten after those that were used for a compendium that is supposed to be coming out next month.

MR. KOVALICK: We are going to be publishing a compendium of all the status reports, a page or two-page status report that they write up and an AE Notice is submitted. That is going to be notices available in the Federal Register.

What you have in your packet is a log listing of notices received since the date they went to press. In other words, it is the more current issues.

Those two answers don't address your question, which is the fact that we have, if you look at the statistics of some 300 AE Notices, a number of them seem to be obvious to us--the Assessment Division, NIOSH or OSHA probably many of them, 120 or so, and we have been discussing whether we need to, as a matter of fact, last week, execute some kind of more formal agreement with particularly NIOSH or OSHA and haven't reached a conclusion on that because -- a couple of reasons.

One is we have an Assessment Division that keeps an inventory or a stack of the forms NIOSH makes available to any employee or employer where they can request a NIOSH special survey, hazard survey, which they are required to conduct, if requested.

If, as a matter of routine, we get a AE Notice that seems to reflect occupational problems, we will send the submitter a form so they know they have this right to pursue their own follow-up.

The other reason that it may not seem obvious is that we have a number of things we are asking other agencies to do for us.

We are asking them to search their files for 8(a) and 8(d) information. We are asking them to search their files. We are asking them to cooperate with us in developing asbestos information, labeling information, so

when we go over with our men on the side, they have to implement the Occupational Safety and Health Act or the Consumer Safety Act.

So we do have to make a judgment about which of our major responsibilities are going to be the subject of formalized Memorandum of Understanding.

I forgot the PMN Program. That is up in the toss, and 8(e) has not come to that threshold yet. So the NIOSH solution seems to be a pretty good one for about half of the notices that seem to be occupationally related.

The Consumer Product Safety Commission also has a hot line, and they do log in and track consumer complaints. Those that seem to be a consumer product have another avenue.

It is not immediately obvious that we need to develop a bureaucratic and in the public administration sense arrangement where we get a report back from them every month on the ones they take in with their system and the ones they don't.

DR. CAIRNS: What I was really reaching for was what has happened that is positively good as a result of over 318 notices, not the mechanics but the actual results.

MR. MOONEY: To say it another way, how many has the Agency meet the 8(a) test. Unfortunately, I am not the evaluator of the 8(e) Notices; I only look at the small percent: the so-called emergencies, and I sign those letters

that go back to the submitter as to whether they are a true 8(e) emergency.

DR. CAIRNS: Have some of them been true 8(e) emergencies?

MR. KOVALICK: They were reportable. They should have been reported as a water spill. The person probably did that and reported it to us and we are advising them by error so much dye and you should have called, and they usually do.

The ones I see, the ones I evaluate, we haven't seen that many. The ones -- I can't think of an example, but there are some odd ones, such as an explosion, a chemical spewed all over the neighborhood, where the spill doesn't obviously apply.

I can't think of one offhand, but the chemical dissipates in 15 minutes, and so the reporting mechanism we have means you have to send in a letter within 15 days.

So it is isn't an emergency response section we have under TSCA. That is still vested in the emergency response side of EPA.

Emergency 8(e)'s, which are 10 or 12 out of 300-plus, are kind of a fish out of water relative to the ones who say, we have completed a rat study and it has these effects or we have an interim result.

For example, the results on formaldehyde reported

by a firm. Those you should have Joe Mirinda come in and discuss.

Generically, I know they are funneled into leads for their assessment process to write the ship chemical hazard profile, and some become evidence to support a test rule where we already have information on a chemical.

So there are those connections.

MR. MOONEY: Again, maybe what you are saying says that you are not the right person to address the question to, but then have you drawn any conclusions about what all this tells the Agency about 8(e) and its guidance?

MR. KOVALICK: My conclusion on the vast majority of them is that they are finding them a valuable set of leads for the risk assessment process and for knowledge about additional chemicals that should enter that process.

We always have a cue of chemicals ready to go into the risk assessment.When an 8(e) notice comes in that has serious information, it can cause a chemical to move to the top of the cue which wouldn't ordinarily be there.

MR. MOONEY: That is what I would anticipate. I haven't seen anything come out at the end of that height yet, but I guess --

MR. KOVALICK: That perhaps bears discussion of how long that process takes. I think you had a meeting with Warren in a small attempt to look at the available

literature.

It will be a three to five-month process to look at the actual risk where they actually evaluate studies available.

Given that 12- to 14-month horizon, it is not surprising you may not be able to see a whole slew of 8(e)'s coming out the other side.

MR. MOONEY: The 12- to 18-month horizon makes 15 days seem rather precipitous, doesn't it, in terms of a company's reporting in the first place?

MR. KOVALICK: Those are the emergency ones.

MR. MOONEY: 8(e) bears on the whole spectrum of reports, not just those that are just emergency.

MR. KOVALICK: Yes.

MR. MOONEY: The 15 days seems at odds to me with the process, the response process, that then takes 12 to 18 months.

MR. KOVALICK: Oh. Dr. Muir should probably talk -- that is the standard process. The process, for example, making a 4(f) judgment. We have to make a regulatory decision with 180 days, so each moment of that time becomes very valuable.

If we get information that there is indication of widespread injury or harm from a carcinogen, mutagen, teratogen, we have to make a decision within 180 days, and a

half a year is not that long, given what you hear about a process.

MR. BEAL: Is that my introduction? I won't leave.

MR. KOVALICK: Don't leave.

CHAIRPERSON BENDIX: Any more questions of Mr. Kovalick?

MR. MOONEY: I don't know if you see where I am headed with that line of questioning that 8(e) guidance with its various ambiguities created a lot of uncertainty within the industrial community, particularly immediate response requirement in our 180 days, and now we see nothing happening.

MR. KOVALICK: You have an ability to find out what the process is, perhaps more than the average person, so you may want to inquire about those 8(d)'s that have entered the risk assessment, either the rapid one or the slower one.

But the fact that the notice comes in quickly doesn't make it any easier for us to conduct the work. Well, I hope next time I will be able to report that we are ready to start our discussion on 8(c), too.

CHAIRPERSON BENDIX: We hope so, too. Thank you very much. We seem to have lost a few of our Committee members. I suggest we take advantage of a moment to stretch.

Tape 3
Side B

(Whereupon, a recess was taken)

CHAIRPERSON BENDIX: I would like to reconvene the meeting, please. We will hear now from Mr. Henry Beal, Director of Standards and Regulations Evaluation Division, on EPA internal procedures for rulemaking, and I would like to point out to everybody, in view of some of the points being made in our discussion this morning, that this is the key question of where the time goes, and anything that we can learn from Mr. Beal about the internal procedures for rulemaking should help us to deal with the question of what might be done to expedite the process.

MR. BEAL: Thank you very much. I will try to speak loud enough so the folks in the back can hear, but I would like to stand up here so I can use the chart which the folks at the table may be able to read.

There is some fairly small printing on some of the slides, but for those who can't read it, I will be talking to the points, anyway, so you will be able to pick up the substance.

EPA's rulemaking process is designed to help its senior managers make decisions in an environment of considerable uncertainty and in an organizational structure that is a highly complicated and in which we have to work to draw on a wide variety of disciplines to help us solve environmental problems.

The process that we have designed to do that has been fairly widely regarded in the Government as models of how one ought to go about it.

There are many questions left as to how well we all work within these processes, but the designs themselves have been regarded rather well.

Among those who have regarded them well is the White House, who used EPA's process as the basis for its Executive Order 12044 on improving Government regulations, an order that came out a couple of years ago and applied to the other executive agencies and asked them to set up rulemaking processes that met certain characteristics, which characteristics consist in general of ensuring that senior managers in each of the Government agencies exercise effective oversight over the decisions.

Decisions are not made by junior staff people and then whirled through some pro forma signature routing, but in fact our senior managers focus in on what is important that we provide for meaningful public participation, that we ensure that we have identified the alternatives available to us, and that we analyze those alternatives so we know what we are getting when we choose one or the other of them.

Another feature is that we want a systematic review of the regulations that we have written and that we do write, that we have some sort of an evaluation plan to ask

ourselves how are we doing after we have done it.

And, finally, that we write these regulations clearly, that they be in plain English and understandable to the people who have to obey them.

We do this in an environment of some considerable complexity. EPA has 12 statutes that it administers. That is more than any other of the regulatory agencies, and they are highly complex pieces of legislation often requiring decisions, as you folks here are more familiar than me,of what science is able to tell us about both the nature of health problems and the risks they impose and at the edge of our technological capacity to solve them.

EPA responded to Executive Order 12044, which asked us to develop this process largely by just shaping up and improving on and hopefully making a little more efficient and effective the process we already have, since it was the same process that 12044 enacted.

What we have now in place as our system is a four-stage process for handling regulations that we regard as significant.Because there is such a substantial number of these significant regulations in the works at any time, it really isn't reasonable to expect our senior managers to be able to deal with all of them to the same degree of attention.

So one of the primary characteristics we wanted

to build into the system was some way of prioritizing what it was we were doing and then to manage the system in a way that reflected those priorities. Yes, sir?

MR. BARAM: Can you tell us what significant means, how you measure significant?

MR. BEAL: I will be there soon. Finally, that we do improve our Outreach Program, that we find some way of bringing into the decision-making process people outside the Agency, both here and pay attention to their views more successfully than we had been doing or indeed are doing now.

So those are the three features we were paying particular attention to when we went through a redesign in regards to 12044.

We had a lot of significant regulations. It seems like a lot to me. We have 190 in process right now, and this little pie chart shows how they are broken up about our various programs.

For those of you who want a list of these things, they were just published. We just published a list of them in the Federal Register a week ago--either last Friday or the Friday before that.

It lists all the regulations, it gives a brief description of them, it tells their status and contact points, if you want more information about them. A useful document.

Briefly summarizing: 190 significant ones, a bulk of

them, no surprise, in the water and air pollution. Toxic substances is not as large but growing, as you would expect.

Some of these are a little misleading. Believe it or not, solid waste shows three regs in the works. Those are, however, parts of the RECRA, the Hazardous Waste Management Program, and they are truly a titanic effort.

So this is numbers only. We do classify those in a couple of ways. First of all, and as we go through it in steps based on when we know enough to make judgments of this sort, and the first judgment we want to make is, is it, in fact, a significant regulation.

And the way we go about doing that is by the process of exclusion. We say what isn't significant, and what is left over we call significant.

The effect of making this decision, this particular decision, is chiefly a procedural effect. If we say that our regulation is significant, that means it goes through the process I am about to describe.

If we say -- the obvious alternative to being called significant, it should be insignificant, and people had general objections nonsignificant to those kinds of words.

So we decided not to do that and call it specialized. And actually that is a little bit more accurate because what we mean by that is it goes through a

special development process.

These regulations, which number in the thousands, go through separate processes, and some of them are very strange kinds of regulations.

We would not normally think of them as regulations. They could change a tolerance level on a pesticide, for example, so the regulation consists of a number.

We change the number from this to that. It is generally regarded as a fairly minor kind of an action. It is a specialized process that goes through its own process.

A state implementation plan, for example, which must be approved by the Federal Government, published as a Federal regulation, and goes through its own processes, and it is labeled specialized.

So we have gone through the kinds of things that we do here in the Agency that are of a rulemaking nature, and we have separated out those that have their own set of processes or that are unimportant for other reasons.

DR. EISENBERG: What is your criteria for determining whether it is significant or specialized?

MR. BEAL: By separate, a specialized regulation is one that has its own statutorily required review procedures and, therefore, doesn't have to go through the process I am about to describe or it is change that is mandated by statute and over which the Agency has no discretion whether to act

or not or to decide or not.

A decision, for example, to set necessary mobile source emission reductions at 90 percent of the 1970 level. That decision alone, if that was the entire regulatory decision, could be called a specialized decision because we have no choice.

It is not a matter that we have to debate.

MR. BARAM: But, Mr. Beal, in all candor, what is the measure of significance?

MR. BEAL: We don't measure significance.

MR. BARAM: What does the Executive Order provide as a guidance?

MR. BEAL: It simply says all significant regulations must go through a process, and it leaves to each agency to decide that.

We tried the more positive approach first, as you might expect: what would make a regulation significant--it has a certain kind of health impact, it has a certain kind of cost, it affects certain critical industries, it impacts certain areas disproportionately to other areas and thus produces political problems, a whole bunch of things.

DR. EISENBERG: If I can get back to the example you gave as an example: the one you termed specialized was one, perhaps, where you changed the tolerance level of a

pesticide from one value to another value and you said it was only about three lines long.

But the point is, a tolerance level could be very important from a health standpoint, from a cost standpoint could be very, very significant, but yet what basis does the Agency have to determine which kind of route they are going to go?

MR. BEAL: Because that kind of a decision has, as a matter of history, the statute under which it operates, a separate decision-making process, which we said it does not have to be subject to the same set of procedures as these other decisions which lack that decision-making process.

So that is what I am saying. The specialized does not mean unimportant; it means there is a special set of procedures already in place that we determined were adequate for ensuring that the decision was reviewed by the right people and of acceptable quality.

MS. MOON: Like the state implementation plans, it is not that they are insignificant.

DR. EISENBERG: I can appreciate when you are talking about a tolerance for a pesticide, when you are talking about kepone tolerances in fish or PCB tolerances in fish. If you are permitting a certain concentration in fish right now and all of a sudden you come back and you

now lower the tolerance to 50 percent of what it was before, that action may be significant.

You may be wiping out the market.

MR. BEAL: What you are saying is there are some specialized decisions.

DR. EISENBERG: I am just taking the case you gave,

MR. BEAL: There are a couple of thousand tolerance actions per year on that order. That is a tremendous volume. What I am about to describe--if you tried to put that volume of decisions through the process, it would collapse it.

DR. EISENBERG: Are you basically saying it is a judgment value that is placed by EPA on an item and it is that judgment value that determines which course you follow?

MR. BEAL: That is right. And the dividing line tends to be whether or not -- two sorts: either there is a procedure in place which we think can accommodate and deal with those issues you raised already there or it really is a minor kind of thing over which we have little discretion and has little impact.

The next one is trickier, and from our point of view has more effect, at least on the way the Agency manages its business, and that is, out of these significant regulations, of which I said there were 190 in the works, we take another cut of them and the labels we use for dividing up

significant regulations are major and routine.

These labels don't particularly -- the choice of the words doesn't mean anything, but what we intend by these labels is to say that there is a subset of our significant regulations to which it is clearly important that the senior managers pay attention and we will put regulations into this category largely until we have absorbed the time that our senior managers can give to these things.

If they could spend all of their time working on regulations, which they cannot, we might call all of them major. They cannot, so we have to start treating some differently.

And the chief difference is when they are major, people who write them must give more attention than otherwise to keeping the senior managers informed of what they are doing, what issues they are considering, and give them more opportunities to influence the outcome.

MR. MOONEY: What do you do if the schedule is already full of majors and along comes something that really is major by any criteria? Do you --

MR. BEAL: Bounce something?

MR. MOONEY: Yes, bounce something.

MR. BEAL: There is nothing hard and fast about the line. I think the next chart does show how it has been divided so far, and it ebbs and it flows. If something

clearly major came along, we would definitely add it to the list.

Whether something else bounced out, it is not black and white like that. We would probably leave it in except by attrition, this percentage.

MR. BARAM: Do you have criteria for someone making the evaluation of whether something is major or routine?

MR. BEAL: There are some marked criteria, but for the most part, the criteria remain subjective. So we are talking about a relative judgment here.

Out of the 190, which are the most important to the Agency, and so among the hard criteria are cost -- will it cost a hundred million dollars a year or more -- we chose that number because that number came from the Executive Order.

MR. BARAM: That is in the Executive Order, and it is an important criteria.

MR. BEAL: We use that to determine whether a regulation should be called major or not. There are many things we call major that do not cost $100 million and might not have any cost.

The air cancer policy, for example, it is a policy statement; it has no economic, direct economic consequences. The decisions we make later on as a result of this policy

will clearly have cost, but we don't know what those are yet.

Nonetheless, it is a major action.

MR. BARAM: What other criteria are there that you could reduce, like if we have $100 million for cost, you have health criteria like number of risk, risk exposures reduced?

MR. BEAL: Impacts on health are the first of the criteria we will look at: will this action have the likelihood; will it address a significant -- a substantial health problem.

MR. BARAM: You see, a few days ago in the New York Times Alfred Kahn was quoted as saying, "We are grinding down on the health safety environmental regulations," and to many people this is part of that process of grinding down.

MR. BEAL: Which is part of it.

MR. BARAM: This process of segmentation of regulations. I am just saying to many people that is the major concern, that there seems to be dual criteria.

Congress has established the statutory framework for the Agency to go out and deal with certain issues under TSCA, whereas the President has a routing system under Executive Order 12044 which is supposed to grind down on health safety environment regulations.

So it is this conflict that is a lot of concern to us between the economic prioritization and the health

safety prioritization.

MR. BEAL: If you are saying people with evil motives, wherever they are, might say, I want to spend my time destroying only important regulations, you have to tell me which are the important ones.

MR. MOONEY: You can't tell what the tread line is there. This may be an increase.

MR. BEAL: This is purely -- as far as EPA is concerned, this is purely a management device. I try to keep this fairly constant, simply because what I am trying to do is find a way to feed information to our senior managers at a pace and in a way that they can deal with it.

I cannot treat 190 regulations as if they were all equally important because if I do that, they will just freak out. They have no way of dealing with that.

So I have to find some way of telling what is important and what is not so important so they can budget their time.

That is the reason for this division. Things happen as a result of this choice other than purely management nature; that is, the obligations on the people who write regulations as well as the people who make the final decisions about them are affected by this choice, these particular numbers.

If you are interested in a particular program and

want to know how many regulations within each of our program areas have we put this label on, feel free to come up afterwards, but I don't think we will benefit by going through that right now.

There is it. All of those regulations, whether major or routine, go through the process I am about to talk about, and I will point out where they are different, where major makes it different.

I mentioned a four-stage process. What I am going to do now is just point out the four steps and go into them in a little bit more detail in the slides that follow.

Starting up, that sounds simple enough, and of course, starting, you didn't see me make that a step. But we have bureaucratized it. Before you can start up writing a regulation here, the Assistant Administrator who wants to do that has to notify the other senior managers and has to tell them what he is doing and why he has decided to do this and has to invite them to participate.

The first thing these people who participate do is they write a development plan or work plan, and I will tell you what that is. It just lays out what we are going to do, when we are going to do it, and how fast.

That development plan gets reviewed by the senior managers, and it does make a difference whether it is major or routine.

Then these folks, assuming all that gets approved, go out and write the regulation. Writing a proposed regulation is the next step. It goes out for public comment, and here you have the formal interactions with the public.

Formal is the ones required by laws. That takes place. Here you get the comments back. We respond to them, we work on them, and the same group that has been working on it all along puts together the final rule, which then goes through a review process.

It is largely in these review processes that it makes a difference, whether you call them major or significant.

MR. BARAM: Are there significant time differences? If you have routed it through major or routine, what is the time lag difference?

MR. BEAL: There does not appear to be any statistically significant difference, depending on the label. Some regulations that are major do not have really difficult technical problems.

The chief time lag in these regulations occurs right in here, Base 2, between these two steps: between the development plan and the proposed. And that is because most of the time there you are figuring out you have got to get the health data or the environmental data, you have to analyze it, you have to figure out what your solutions

are, you have to analyze them.

Those activities are enormously time consuming and expensive, and apparently from just examination of what in fact has happened, the regulations we call significant will face difficulties in assembling that data and analyzing it.

That will end up taking them as long as the regulation that has major policy issues.

DR. EISENBERG: Can you explain to me the philosophy here in EPA whether in fact the intent is to have the best, to have as many of your ducks in line before you go to proposed rulemaking or to go with perhaps 89 percent into the proposed rulemaking and then to depend, to some extent, on comments of interested parties and other information gleaned from there before you go into the final rulemaking?

MR. BEAL: I would say in general we try to know everything that is knowable and reasonable, expenditure and resources, before we start.

DR. EISENBERG: That may be one of the reasons why it takes so long to go to the final rulemaking. It might be more beneficial to go to the proposed 80 to 90 percent than to rely, on some degree, to those who will be affected and other interested parties to bring forth information at that point.

MR. BEAL: I have two reactions to that. One is that would tend to largely -- one is the timing and one

is kind of a politics thing.

Let me talk about the politics one. Maybe as part of involving a wider array of people in this decision-making process we should not go so far in our analysis and you would feel more confident that we had not made up our minds, really, and done everything we had to do if that were the case.

That is one set of issues. I would think that, though, is separate from the question of whether doing all of that before we propose or after we propose will affect how speedily we get to the final step.

I don't think it would make any significant difference.If we did not do the analysis before we proposed it, we would end up doing it after we proposed it. We would have to do it.

DR, EISENBERG: The difference is in one case you are relying upon your own resources to do the analysis, and in the other case you would be also getting data from other people, industry and outside sources.

MR. BEAL: Certainly all that is true.

MS. MOON: I am sorry; I didn't follow the latter case. Where are you saying you would be getting input from outside sources?

DR. EISENBERG: If EPA relies entirely upon their own -- in other words, if they don't go to the proposed

rulemaking until they feel confident they have everything they need and all the data is there and everything has been generated by them before they go to the proposed rulemaking -- in other words, before they come out with the proposed regs on the street, they want to know they have got everything there is to know.

MS. MOON: There is a lot, in my experience, going on between phase two and phase three. That is the sort of thing you are talking about.

DR. EISENBERG: Then only certain people are privy to that. It is not out on the street for everyone to take a look at.

There may be some in-house work and private counsel between friends in certain industry groups, but it is not on the street.

MR. BARAM: It would be helpful, Henry, if you pointed out the nature of the consultation that goes on between two and three and how it differs between three and four.

CHAIRPERSON BENDIX: Let me make one comment before you do that, and that is, one of the problems that I run into, Max, is there is a certain amount of work you have to do before you promulgate something; otherwise your agency loses public credibility.

DR. EISENBERG: I am not questioning that at all.

It is just at which point. It is the same questions we were having all along on the Section 4 portion.

MR. BEAL: The question about how much you have to know is the question that as a general matter plagues us in everything that we do, and there are some obviously significant differences of opinion outside of EPA about how much that should be.

MS. MOON: At what point would EPA be going to important Congressmen or to the President, depending on the impact of a significant reg, for input to see how they are going?

For instance, the ozone standard. We knew it was going to be a political baseball: where did we start broadening the game to include a lot of players; was the tie-up at the last management review; was the tie-up at the first management review.

MR. BEAL: It usually happens before--right in here--at least after a draft is read, when a draft of this proposal is completed and organized and we have some pretty good idea about what we want to publish.

At that point, as a general matter, we would let people in other Government institutions, know what we were going to do.

Now there are a zillion exceptions to that, and it depends on how important it is. If a regulation is going

to affect some other Government agency or if it deals with an issue that we knew the Congress was very much concerned about when it wrote the legislation, we will be in touch with those other agencies and up in the Hill way earlier.

MR. BARAM: Can you tell us the fate of some of the TSCA proposed regs: where are they now? If you could reference TSCA from time to time, it would help bring things to our major concern.

MR. BEAL: The Section 4 rules, the first three of them are coming to -- thank you for asking. They are coming to the Steering Committee process as a proposal a week from this Friday, the 28th, which means that the proposal is written, the supporting documents are written, the documents that convey these to senior managers are written, and it is ready to start through the Agency's review process, which consists of three parts: the Steering Committee, which I chair, which is why I am invited here to talk about it; the Steering Committee is composed of representatives of the Assistant Administrators, and we have a couple of functions, an issue resolution function when there are issues in this package that have not been satisfied, and a quality control function.

MR. BARAM: Where does this all take place, vis-a-vis the earlier chart: the three levels of review?

MR. BEAL: After each of these steps, there is a

review. Whatever it is that is being written has been written, and now we need to get it out of the Agency. We need to get our senior managers to agree that this is what they want to do, and they need some process to be sure that what they are getting is a quality product.

As you might suspect, they do not, in fact, read every page of this stuff. The idea is can you get them to pay attention to the important issues.

So at the TSCA 4 Regulation you are right here. They have written a proposed rule. They generally think it is okay. He wants to send it to the Administrator for signature, and we start through this review process.

MS. MOON: So that is where the political football starts: between 3 and 4; it isn't after 4 where we start having political decisions.

MR. BEAL: It is right in here, that is right.

MR. BARAM: Well, of course, the cases -- you said there were zillions of exceptions, and I think the cases we read about in the paper are the exceptions and that is where the political starts: between 2 and 3.

Between 3 and 4, you have an official notice of comment period. We are really talking about 2 and 3, the area of tremendous discretion and interagency pressures.

MR. BEAL: This chart is a little funny looking, so maybe it isn't right here. The charts looks right, but it

is misleading because you have it wrong, you are on the wrong place on the chart, so I will have to fix that.

We are in agreement on the substance -- forget the chart -- that the other players, other players within the Government, can and are involved in our decisions before we publish the thing in the Federal Register as a proposal.

And many of them we owe as a courtesy and the people on the Hill whose bill we are trying to implement we owe as a courtesy: here is what we are doing.

Other agencies who are going to be affected are concerned about it. Some of the White House staff is concerned about it.

MR. BARAM: Henry, most of the discussion of the Committee before you came here today has been focused on economic versus health trade-off.

Maybe you could confine your discussion to that.

MR. BEAL: Let me hit this review process. You have the major nature of it. This group of civil servants looks at the stuff and does something about it, sends it on to the senior managers.

The senior managers in EPA consist of the Assistant Administrators, and there are six, the Regional Administrators, and there are 10, and a few Office Directors, like the Director of the Office of Legislation, who is our chief liaison to the Congress, and the General Counsel.

These folks get the package for their review, and at each of these stages the idea is we are trying to build a consensus about what it is we are doing.

The reason for this multiple consensus building in all these different groups is the way EPA is organized--we have specialties all over the place. We have to find some way of bringing them together and bringing attention to bear on the decision.

Finally, it goes -- we can skip over this. Here are the main offices that write regulations--no surprise--Air, Water, Toxics and Enforcement.

And here are the statutes that they administer. The rest of the charts just go into more details of what happens in each of these phases.

The starting up is purely internal. Way early when starts something starts up, you will know about it because we print the agenda in the Federal regulations.

The development plan is actually a really interesting part of this, and it is one that I would like to see become a more public element of our rulemaking because it is here that people are asking and are supposed to write down what alternatives are we going to examine and what are the issues we think are important.

The rest of it is like a normal work plate: how fast am I going to do it; am I going to do it by contract,

in-house, blah, blah.

There is another feature I should skip over. This is the place where you identify who from outside the Agency you are going to involve, what is your plan for involving members of the public. That is supposed to be in this document.

Then there is a whole bunch of other things.

MS. MOON: Where is economics?

MR. BEAL: You have to say in here -- the only reason I am whipping along is to get to the part you apparently really wanted to focus on.

We have to identify in here issues and alternatives. You also have to indicate what analyses are you going to perform.

There is a lot of policies around some of them. Say you have to have an urban community impact for certain regulations and environmental impact analysis and economic impact, a resources impact, and there is a couple of others for which not all regulations do not need. So you have to show which ones you need. You don't do it here.

You just say you are going to do it.

DR. EISENBERG: How widespread distribution-wise is the development plan?

MR. BEAL: Strictly in the Agency. I think this is a good opportunity, a good kind of a thing, to circulate

around.

A potential public analogue of this could be the Advanced Notice of Rulemaking. There is a lot of it that is purely internal.

CHAIRPERSON BENDIX: Another potential analogue to this is the NEPA process.

MR. BEAL: I will take a look at it.

MR. BARAM: It is very similar--essentially going to the public and holding a few hearings to scope out what the impact statement should include.

It is a useful analogue.

MR. BEAL: If you folks want to recommend that to Steve Jellinek, if that is the limit of your concerns--if you want to direct it generally to the Agency--I personally would be very much supportive.

This development plan goes through all this. This is just a summary of what is in the development plan, and sometimes we publish an Advanced Notice of Proposed Rulemaking and sometimes we don't.

I think what we want to do is build this up and make this a real part of the rulemaking process and then routine it as a way of making a commitment to do something and involve others.

DR. SLESIN: How many other agencies use the ANPRM?

MR. BEAL: It is available as a tool, but how many actually use it, I don't know. I certainly know that they know it happens. How often it happens, I don't know.

DR. SLESIN: Does anyone use it to the degree this Agency does?

MR. BEAL: I couldn't answer that.

MR. MOONEY: There are certainly instances where agencies have called informal rulemaking, so I couldn't use formal, but have certainly released draft documents.

The OSHA cancer policy certainly first appeared as a readily available document in draft form before it was formalized in the Register.

I don't think OSHA called it an ANPRM document or position. It was that kind of a process, but it served the purpose of identifying issues.

DR. SLESIN: That is certainly the exception.

MR. MOONEY: It probably is.

CHAIRPERSON BENDIX: I think the answer --

MR. BARAM: With regard to the ARPRN again, under TSCA and under the Clean Air Act and Water Act there is citizen provision that someone can sue the Administrator for failure to take action, unless the Administrator has launched some sort of action.

Is an ANPRM some kind of a preclusion of citizen suits, do you know? If you publish an ANPRM, is that useful

as a defense or a motion to dismiss a citizen's suit against the Administrator?

MR. BEAL: I wouldn't make a legal judgment about it myself. I guess the General Counsel has left, so I have nobody to rescue me.

On the substantive matter, it is a point of law that somebody can figure out, I guess, but does this indicate that we have started rulemaking and then we are committed. We have committed resources to working on something and then we are under way with something. It certainly does that.

Whether that precludes anything, I have no idea. It means that we are at work, and that is what I know about it.

Now we are to the part of the process that you wanted to get to, and that is writing the proposed rule, which we call a decision package.

Now it consists of a bunch of things that go around to the decision-makers. Actually, we have been through most of this already.

This is the thing that has to contain all of the analyses that we were committed to doing before. It has to explicitly address the issues we said we were going to address.

It has to show alternatives we examined. It has

to explain why we chose what we chose. If we are recommending something in several of our regulations, we will just identify alternatives or we will come to really hard issues in one regulation and will say proposals saying we don't know what to do.

But here are the things we looked at. We would like comments.

MR. BARAM: I think we are particularly interested in the economic analysis that was on the preceding page.

MR. BEAL: This is the stuff in the decision package, and it is going to include supporting materials. That is what the economic analysis will be in in the supporting materials.

It has to be summarized here.

MR. BARAM: Is that done in-house or contracted out?

MR. BEAL: Almost always contracted out.

MR. BARAM: What do they usually cost, for curiosity?

MR. BEAL: The range is very considerable, from something like $50,000 to a million or more.

MR. BARAM: How do you handle this urban and community impact analysis that is done in-house?

MR. BEAL: We are struggling to do that ourselves, largely because that is a new requirement and it is not clear

what it is.

CHAIRPERSON BENDIX: What was the cost: $50,000 to $2 million?

MR. BEAL: Yes. The other analyses are also typically contracted out, and the result of these different analyses is when you combine together the idea is that you have some conception of what you are going to get for the various alternatives and what the cost on the various actors will be, including us.

One of the things that we really have to worry about is can we do whatever it is that we are proposing to do; does the Agency have the resources to do it; do the states have the resources to do it.

So with the states we are concerned about implementability as well as its theoretical attractions. And it is in this stage that the various players outside of the Agency at the senior levels have typically tried to influence the decisions. That was early on.

For the most part, we are trying to bring some rigor to that as well. People who want to influence the regulation, that is perfectly all right, and anybody who wants to do that, in fact, is why we are published. If you have a view, tell us about it.

What people object to when they object to these things is that it is done in secret and that you don't know

what Senator "X" has said to the Administrator or whether the President phoned in the night and told him what the decision was--any of those suspicions that come to mind.

And for the most part, I think everyone is pretty well in agreement that these attempts by various people, whoever and wherever, to influence the decision will be made on the record.

That is certainly true about people like the Regulation Analysis Review Group and the people who staff it or the Council of Wage and Price Stability. When they were first set up the first few times, they dealt very informally. They would develop their position and then they would phone over or come over and let you know.

Now they still do that, but they also do that on the record.

MR. BARAM: Who doesn't do it on the record, just out of curiousity? I guess the Council of Economic Advisors.

MR. BEAL: I can't say it doesn't happen.

MR. BARAM: I am just wondering is any of this hampering TSCA, in your opinion?

MR. BEAL: No.

MR. BARAM: Nothing has come out on the Section 6 in 3-1/2 years, and there seems to be technical evidence of legal authority for a lot of actions, and we are constantly concerned about this constipation in OTS.

MR. BEAL: It could be true. I have no way of knowing who called Steve Jellinek or Doug Costle. They wouldn't tell me if it happened, and I don't sit up there and listen.

So that could happen, yes. It probably does. Of course these people talk to each other and express their views. Is that improper or unfair? I don't think so. Communications have to happen.

The Administrator, however he reaches a decision, has to have a plausible rationale for it, and he has to express it.

And in regard to Section 6, I just haven't heard boo about anybody outside of EPA trying to prevent Section 6 action, and I personally know the people who work on it. I can't imagine that having any influence. What do you say --

You can influence it at the end. You can say about a package that got to a decision-maker, change the number or something, but if you are saying don't do it, how are you going to stop -- what does Steve Jellinek say: well, I have these 200 people down here, I have somehow got to prevent them from writing this package they are all hired to write and somehow do that in a discreet way so nobody knows that I have done that. That is impossible.

There are no signals going out to the people in

the Section 6 area saying don't produce, and make it go slow, and make sure that everything gummed up for as long as possible.

We have problems with TSCA because of the nature of the issues these people are trying to solve. And I have not seen any great bolts of wisdom from anybody about how to shoot through all of this and come out with great answers.

Maybe here, maybe this is where it is coming from. That would be great.

MS. MOON: Let me ask another question. I am still trying to get at the heart of something. Where in this long process do we begin to see the lack of enthusiasm on EPA's part as an advocate?

What we see at the public hearing is EPA more or less taking in all of the information and trying to sit as judge, evaluating whose argument is better than whose argument.

If the public's argument is not there or the public health or the public interest or something or other, we hear these long tales of woe: oh, you have to call out your troops to balance the industrial side or the union side or whatever.

I think the public perceives or would like to perceive EPA as being the advocate for the protection of public health in the environment, yet when it comes to the

public hearing stage, we seem to see this judge, who is willing to commit himself, no longer advocating and saying, all you folks out there argue amongst each other and we will put it in the political bag and come out with a political decision.

How long is EPA an advocate in this long process? At what point is it neutralized? We know in the beginning when you want a regulation, someone will say we really need it, it is detrimental to public health.

And going from that to the point where we are so unemotional about the whole thing, something happens between the enthusiasm and this very lackadaisical let's see how many letters you can turn out.

MR. BEAL: I don't think advocacy for the objective yes that there is not a problem with, and I don't think you can say about the people here that their enthusiasm to reach the objective wanes.

Where we do -- so maybe it does happen sometimes, too, but generally as an Agency I don't think that that is true.

I think the people here, to a remarkable extent up and down through the Agency, are here because they have a commitment to a set of objectives.

It is very unlike other Government agencies. It is not universally true. I think, to a very large extent,

that is true, and I shouldn't sell it. If you are looking for a job, you can't have a job now: there is a freeze. But this is a terrific place to work, for that reason.

But what happens when you take that commitment to an objective and you say and now how do we get from where we are to that place and what is the best way of doing that.

All of a sudden you have opened up a zillion decisions. Now there is a highly complex series of things that have to happen to do that.

In all of those steps you have people you are going to affect who you have to motivate in some way to help you reach that objective--other Government agencies, people who you were going to regulate, politicians of all sorts and all levels, citizens whose continued support is absolutely critical to keeping an interest in these objectives out in the public consciousness.

Balancing all of those interests is indeed a concern of ours. We have to be sure that what we are doing is going to work, and that means work in the short term and work in the long term and work in the local political processes and the state political processes and the national political processes.

And if you are not sensitive about what all is happening there, in the long run you are going to cause

yourself a lot of trouble.

Yes, there is a balancing that goes on. I don't think we try to hide it. We do want to balance these things. We want to make balanced reasonable decisions, and for what purpose?

And it is that purpose we are committed to, and that is a clean environment in relation to TSCA and individual decisions.

MR. MOONEY: I would like to say something in response. I have been involved in a number of these TSCA rulemakings, and it is funny I have never felt that is the way it is.

The picture you describe is not the way I felt that it was in any of the meetings we had with the Agency. At an early stage, in some instances, I think back to the inventory, the PMN rules, where you were really in that stage in the evolution of the proposed rules, the issues are being worked and the drafting is taking place.

I have seen perhaps an agency openness or lack of defined position on an issue because it is learning stage.

But when the proposed rules have hit the register and there have been open hearings during that review period, I have felt that the Agency stands very fast behind what it has proposed and that it does, in fact, take an advocacy

position of what it has put in that rule, and it is not saying if you people will all get together and figure out who has got the most votes, that is the way it will come out.

I really do sense a rather strong advocacy position on the part of the Agency on what they are putting into that package.

MR. BARAM: I think we would really find useful some more explicit discussion of the trade-off: what is an acceptable trade-off.

Given your experience at looking at economic and health evaluations, what is it, why does it come to be the appropriate kind of trade-off from your perspective?

MR. BEAL: Do you have a specific TSCA decision?

MR. BARAM: We could take the ozone standard, the ambient lead standard or another standard that is analogous to a TSCA type of decision in some kinds of respects.

MS. MOON: The ozone standard I think is not less of a problem than a lot of the things we are facing in TSCA, yet that whole standard, it was so difficult. It was a political football, I don't know. I just got fed up with the whole process.

MR. BARAM: Yes, I think the early processes discredited a lot of the results, unfortunately.

MS. MOON: It was viewed by so many people as simply a political decision where we lost our advocate.

MR. BARAM: Let's say trade-offs had to be made. That is the way the statutes are written. Every decision is a trade-off. Can one spell out general rules as to how thse trade-offs are going to be made ahead of time or is the trade-off going to be made ad hoc in each case?

MR. BEAL: Well, there are different -- there are different schools of thought about whether it is even plausible thinking about developing a decision rule.

There is a formula in which you pluck the variables and, whammo, you know the answer. From my point of view, that would be wonderful. It would save a lot of wear and tear, but I don't think it is practical.

On the other hand, there are a variety of analytic devices you can use to help you make an informed decision.

Among those are the risk assessment methodologies. How do you tell a decision-maker what the nature of a health or environmental risk is from exposure to certain things?

There is a lot of work that can be done to prove how you tell people what is at stake. In some areas, the ozone standard was one. We tried some fairly inventive things, and they showed a great deal of promise, I think,

for the way we can make decisions in the future.

There are a variety of economic things for those regulations that are either required or allow you to consider economics.

You can look at marginal costs and determine as you move from one degree of control to another what happens to the marginal costs of the firms that have to install those controls.

All it does is tell you certain things about how that cost pattern looks. It doesn't tell you what cost is acceptable.

On the other hand, there have evolved over time some basic perceptions in the economic community on how to interpret one of those curves.

You can compare costs and risks between decisions. How much cost were you willing to accept in the earlier decisions you made? What kinds of risks were enough to motivate you to act in earlier decisions?

MR. BARAM: Is that information available?

MR. BEAL: Sure.

MR. BARAM: On what distributions of cost and benefits have been acceptable to the Agency?

MR. BEAL: Have we ever compiled the whole thing? No. We have a project under way to do that, but it is not done.

The individual decisions are there.

MR. MOONEY: I was thinking the Agency did a study on the Section 5 that had Arthur D. Little. Am I correct?

MR. BEAL: Probably.

MR. MOONEY I got into at least one estimated judgment as to what it was going to cost to put together a PMN, what the impact would be of new chemicals, and we could probably challenge every assumption, if you had a mind to, because it was a judgment call.

MR. BARAM: What is your own personal impression? Are they going to regularize this or should we follow the ad hoc approach? The ad hoc approach is where you can be flexible.

At the same time, you can abuse the whole process of analysis. Anything cost benefit can be a numbers game. So what do you think is a better deal for the long run?

MR. BEAL: I don't think a decision rule is practical because of the uncertainty in the individual components that make it up.

But what you can do -- pardon me -- what we could do and you could look at to help you judge whether we are doing anything sensible is to identify the important decisions in each of our regulations, identify a variety of effects of various sorts, and array them so you can

see what they were and what we looked at.

And if we have enough data, we can identify the degree of certainty with which we know those things. I think we should do definitely a lot more in that area.

Our statistical work is a mixed bag, and our reliance on them to help us inform decision-makers about how good these numbers are that we tell them about just hasn't been very effective.

We can do a lot better there. And just array a bunch of things, but I would be interested in hearing from you what you think, what impacts you think ought to make up the decision: should we look at costs and, if so, what kinds of costs should we look at and the cost to whom.

MR. MOONEY: You have to look at cost.

MR. BEAL: In some cases we do, but not all.

MR. MOONEY: That is part of it, an unreasonable risk determination.

MS. MOON: I can't resist being Janette Sherman, and how many times have we heard her say we are always analyzing the cost of regulating, but when are we going to analyze the cost of not regulating.

Has this variable yet been pumped into the decision making?

MR. BEAL: There have been some efforts to do it.

While it is true the economic estimates are often highly uncertain, the efforts to quantify in economic terms the benefits of regulation or, alternatively, the cost of not regulating the methods are in a much more viable state of development.

We have a major project under way right now spending $7 million to try to do that, but we are a long way.

CHAIRPERSON BENDIX: Can you tell us something more about that? What is that project and who is doing that?

MR. BEAL: I am not -- I would if I knew, but I don't know, so I can't. You should talk -- get Franz to come to your next meeting.

MS. RAMSEY: I think tomorrow probably the panel discussion will throw some light on the issue.

DR. SUTTON: I would like to hear your views, Michael. You spent a lot of time on this. Not as long as you could do, but as brief as you can do.

MR. BARAM: Three things: I did that study at the Administrative Conference years ago on how agencies were using cost benefit analysis and how the White House was doing their thing, and it came out with really three findings. First of all, the cost benefit analysis process is a numbers game.

Most of analysts I spoke to in the agencies called it pushing the numbers to justify outcomes that they felt they had to justify.

Maybe that isn't the situation in EPA now. Years ago or as of last year that was the situation, that was the perception: people were constantly scrambling around to find the appropriate value for human life, what should the discount be.

I was at a meeting yesterday where someone was asked the question, since industry is always asking the Agency to do cost-benefit analysis, tell me, do you use cost-benefit analysis in making your own internal company decisions.

He said, no, we can't use the stuff, it is too indefinite. It is not helpful. The whole cost-benefit approach has been very arbitrary, somewhat abused, in the sense that it has become a numbers game, and that is why a lot of my concern as a result of that study focused on coming onto general decision rules.

If we are going to make trade-offs, let's break the billet and come out with one discount rate or one value of human life, if we want to go that route.

The second point is that there are procedural violations. Supposedly, the President and the economic advisors, including the Council of Economic Advisors, their

Regulatory Analysis Review Group and the OMB fashioned the legal argument that these treaties to the Agency should be channeled properly through procedures, through the notice of comment period only, not off the record, no ex parte communications, as have been conducted in the ozone case and a number of other cases.

So that was the second big finding, in a sense: that there were lots of procedural abuses, violations of separation of powers.

In other words, on Mr. Beal's charts, these communications between the President's office or some officers and the President and EPA should be confined to the Notice of Comment Period and, therefore, part of the public record and, therefore, available to everybody.

The third point was that there were better ways to consider economics, that the cost-benefit route was basically telling us how much health environmental quality we should have, if the benefits exceeded the costs, the number of lives to be saved exceeded the cost to industry, or something of a crude nature like that.

It seemed to me under TSCA, under the Clean Air Act and other statutes, the Agency has an affirmative duty to stick out a health goal, get rid of asbestos in schools or get rid of asbestos exposure--a clear-cut carcinogenic hazard. Stake out that objective and then do a

cost-effectiveness kind of approach, do the most cost-effective way to get the data.

You see, there is a difference between the cost-benefit and the cost-effectiveness route. The cost-benefit route determines what your health goal is and then helps you adopt the means to achieving a health goal, whereas the cost-effectiveness rule, in my opinion, is a limitation to the economic factors to choosing the cheapest route to achieving the health goal,which is chosen on health grounds.

MR. BEAL: Why in your scheme, Mr. --

MR. BARAM: To answer your question, Bill, those were the three findings, more or less.

DR. SUTTON: I listened very intently and with considerable respect because I know you spent a lot of time and thought on this, but I still got a little lost because you seem, on the one hand, to say, Michael, that you really can't do by the numbers determination by a formula and come out with a good decision, and I don't disagree with that for a minute.

In fact, I agree with that. I don't think we are anywhere near that stage where you can plug these decisions into a formula.

On the other hand, I really can't imagine a decision-making process that doesn't in some way try to take into account what is going to be achieved in terms of

benefit for the achievement and what are the adverse impacts, whether they be economic or otherwise, and in the course of getting those achievements, and you couldn't construct some ridiculous situation, but the facts are there is a broad spectrum of those things.

Not every health goal is curable.

MR. BARAM: I would expect the agencies wouldn't misuse their resources and choose health goals that have little benefit.

If you solve or achieve them, you would have a limited benefit. Take a big one. If you have the well-established hazards like asbestos in places, in general, there is no doubt about the technical evidence about the causal exposure and harm, and the real question is cost of the cheapest way to solve these particular problems.

It seems to me the Agency should be able to set those health goals on a health basis; health impact basis, and not on some balancing between health and economics.

So, unquestionably, there are some of those. There are also many that they must deal with which say go regulate this, this and this, and you haven't -- and you don't have a mechanism of determining how much of a health risk it is.

MR. BARAM: That is an unfortunate lack. It

would seem to me it would be a better use of EPA's money instead of spending a million dollars to develop quantification techniques, it would be a much better expenditure of money if they came up with a health ranking scheme: what are the real health goals we should be focusing on and the most cost effective way; are those health hazards that are irreversible significant by any measure?

In other words, where is the public health ranking or index that should be used in helping the Agency select their health goals, so then the cost-effective approach could be taken.

It seems to me that is the proper framework that is needed here.

CHAIRPERSON BENDIX: We are pretty close to the end of the time that had originally been allotted for this meeting.

I would like to suggest that since our reporter is weary of reporting what we talk about, that we adjourn the formal meeting.

If people want to continue informally discussing until our 5 o'clock meeting --

(Whereupon, at 4:25 p.m., the meeting was recessed, to reconvene on March 20, 1980)

REPORTER'S CERTIFICATE

DOCKET NUMBER:

CASE TITLE: Administrator's Toxic Substances Advisory Committees

HEARING DATE: March 19, 1980

LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence herein are contained fully and accurately in the notes taken by me at the hearing in the above case before the United States Environmental Protection Agency and that this is a true and correct transcript of the same.

Date: March 31, 1980

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