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ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

ADMINISTRATOR'S TOXIC SUBSTANCES ADVISORY COMMITTEE

VOLUME II

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ENVIRONMENTAL PROTECTION AGENCY

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ADMINISTRATOR'S TOXIC SUBSTANCES ADVISORY COMMITTEE

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

Thursday,
March 20, 1980

9:00 a.m.

APPEARANCES:

Dr. Selina Bendix, Chairperson

Professor Michael S. Baram
Dr. Theodore L. Cairns
Dr. Max Eisenberg
Ms. Becky F. Moon
Mr. Thomas W. Mooney
Dr. Edward P. Radford
Dr. Louis E. Slesin
Dr. William L. Sutton

Ms. Marsha Ramsey, Executive Secretary

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CHAIRPERSON DR. SELINA BENDIX: At this time, I would like to call the meeting to order.

This morning, we are going to have a panel of economists looking at the problems of economic analysis of the impacts of regulating or not regulating toxic substances.

The panel will be chaired by Dr. Edwin Clark, Associate Assistant Administrator for the Office of Pesticides and Toxic Substances.

Next, to my right, is Dr. David Harrison, Associate Professor of Economics at Harvard, now in the Council of Economic Advisors in the Executive Branch.

Next to him is Dr. Nick Ashford, Assistant Director for the Center for Policy and Alternatives at MIT.

Dr. Clark?

ECONOMIC ANALYSIS: HOW ARE THE RISKS, COSTS AND BENEFITS DETERMINED AND WEIGHED PRIOR TO MAKING CHEMICAL TESTING AND CONTROL DECISIONS?

DR. CLARK: I volunteered to start this panel to talk a little bit about what EPA and the Office of Pesticides and Toxic Substances is presently doing in terms of economic analyses; and then let Nick talk for a little bit about some of the problems involved, particularly on the benefit side.

And then let David talk about what the regulatory analysis review group, which is run by the Council of Economic Advisors - what they would like to see done in terms of

these analyses.

I also have a representative here from our Office of Regulatory Analysis who will answer any specific questions about what we're doing.

Sammy, maybe you should come up and sit in front here so that people can get at you quickly.

Judy Nelson could not make it.

TSCA, as you are all aware, is what is called a balancing statute. It requires some sort of balancing of risks and cause or risks and benefits. These terms are often confused, particularly when one talks about benefit-risk weighing and benefit-cost weighing, or analyses, because the benefits in the benefit-risk comparison are actually the costs in the benefit-cost analysis.

So this is going to be very confusing for a while, but maybe most of you know this already.

Essentially, what we do is, on one side, we look at the risk associated with the continued use of a substance. This is a risk to public health and to the environment. These analyses are based primarily on animal tests, epidemiological studies, exposure estimates, et cetera.

And we compare those risks with the costs of controlling the substance.

Now, the costs of controlling the substance are, to some extent, the benefits of controlling the substance and this

is where the confusion comes in when we use these terms, but what we're doing is essentially comparing the risk that will result from the substance's continued use to the costs associated with controlling the substance.

The risk side, at this point, is primarily a scientific process, making scientific estimates of the risks as I say based upon the epidemiological studies, whatever evidence there is like that we can find, and these are compared then to a cost which is developed through the regulatory analysis.

Typically, these cost estimates of the regulatory analysis start with an estimate of the compliance expenditures that will be associated with a particular regulation. This while process was developed in EPA with the more traditional programs: the air pollution control, the water pollution control programs.

We have, for the most part, taken this methodology developed for these regulations and tried to transfer it over into the area of toxic substances control. It is not directly transferable, as I will discuss a little bit at the end.

We have different sorts of problems and we are in a process of trying to develop appropriate methodologies to deal with these problems, but let's start with the way, then, we are transferring it.

You're saying, "Okay, we're going to regulate. We're going to issue a regulation." Let's take an example, toxic

substances.

This regulation might be a labelling regulation. We will estimate as a cost, versus the cost of just putting the labels on the cans, how much is on the containers. How much is this going to cost, outlays and expenditures by the firms?

Primarily, we go into this usually by hiring a contractor who is familiar with the industry. This contractor may or may not - depending on the knowledge available to it, the information available to it - may or may not go out and interview firms to find out what they think the cost will be, but will nevertheless try to come up with an independent estimates of these costs.

We also have to look at the benefits that the substance will provide. Now, labelling is not a good example of this. Our pesticide regulation would be a better example or if we were to regulate something like asbestos that would be a good example.

But the benefits that the substance provides our society that will not exist if we restrict its use, now these benefits are limited by the cost of substitutes for them, for that substance.

For instance, if we regulate asbestos and we can estimate that the use of asbestos -- I am not putting forth a hypothetical analysis. I wouldn't say that we've done this one.

Say we decided to regulate asbestos and one of the uses of asbestos was to control a fire in buildings - keep buildings from burning down - then we could estimate the increased incidence of buildings burning down if there were no asbestos, and then we could then put a cost on the loss to our society from the increased number of buildings that would burn.

That would be the maximum cost associated with that regulation; however, there would probably be substitutes for asbestos in the control of fire. So the limit on the compliance of these costs would be the cost of using a substitute.

So these are two types of costs that we will estimate directly: the actual expenditures by the firm, and the benefits of the substance in use.

Once we have these cost estimates, we then try to look at how they will impact our economy and the industry being regulated. We will try to look at the likelihood of firms closing because of this.

We will look at price increases in the industry and estimate those, the impact on inflation so to speak. Particularly under TSCA, we look at the impact on small firms. This is a particular requirement, to look at that under TSCA, whether small firms will be particular hard-hit.

And, under TSCA, we have this requirement to look at the impact on inflation. That is one of the areas where we have substantial difficulties because we don't understand very

much about the inflation process.

We will get all these costs together and this will provide some basis of our regulatory analysis which is on the cost side of these -- Well, the benefit side, whichever way you look at it. It's

It's a benefit on the benefit-cost analysis side, or it's a cost on the benefit-cost analysis side. That, of course, is not the basis of our regulatory analysis under TSCA, but it is not all we're doing in terms of economic analysis.

We are spending a fair amount of time looking at economic incentives associated with regulating toxic substances. You were given a report this morning which summarized a retreat that the senior officer from TSCA had last summer.

One of the conclusions that came out from that retreat is that we had to emphasize and analyze very carefully the potential for providing economic incentives to the industry to essentially do what TSCA wants them to do.

So that is one of the areas that we are involved in.

Another area is looking at the whole question of innovation, a very difficult question. What is innovation? How to we effect it? How can we reduce these effects? And things like that.

They got involved in a number of other policy-type analyses.

That very briefly summarizes that side, and I'll let Nick go on and talk about some of the problems of estimating some of these economic analyses.

Nick?

DR. ASHFORD: Should I talk about 15 minutes or so?

I think that the prime motivation for requiring economic or regulatory analysis is accountability of the agency for regulating toxic substances: the accountability in terms of whether it has been regulating a particular hazard to the extent that the Act - in this case TSCA - requires; and, secondly, whether it's choosing the right kind of hazards to regulate in a world where many more hazards are regulatable than can be regulated.

I think the debate over cost-benefit finds different prejudices that people feel about the accountability of this agency and other agencies. I think those that tend to demand - I say "tend", it's not a hundred percent corrolation - tend to demand rigorous analysis come to this area with a prejudice that the agency doesn't know what it's doing and is not using public funds wisely.

Those that tend to resist that kind of analysis say that the analysis costs money, delay regulation, and could be better spent - they, too, are cost-effective conscious, but it could be better spent moving on with regulations rather than try to tune a system that doesn't fine tune.

I think there are some methodological problems in cost-benefit problems that you could exercise to provide fine-tuned guidance as to how to regulate a particular substance or what to regulate just is not possible.

I am not going to pound my fist on the table and say, "You can't value a human life." It's immoral and all the other arguments with which I have sympathy or empathy. But talk about the fact, when you really sit down to do the analysis, you run into such immense problems of two kinds that it really becomes an analysts' game and a reflection of the analysts' prejudices.

The two problems are: one, that the data just isn't very good; and, number two, that there are methodological difficulties which, in order to overcome, require that you make certain assumptions, and those assumptions are can take such forms that the analyses can really come out any way you want them to.

I will try to be specific without being too technical. Let me work a word about costs and then, because Toby pretty well covered it, move to the issue of benefits.

The issue of costs is difficult because the data in terms of compliance costs mainly derives from the sector that is likely to be regulated. I'm not being too unkind, I think, if I say you would think there was a certain upward bias in those estimates.

But more to the point, bias aside, is that in any of these estimates - and I have looked at hundreds, virtually, of the so-called economic impact statements that have been performed by agencies over the last few years - you don't find economies of scale taken into account in the total cost.

You don't find the issue of a learning curve, which is the ability of an industry to comply more effectively as they learn how to control a particular hazard.

Most importantly, you don't take into account the technology-forcing aspect of a particular regulation that gives rise to a different kind of technology of three kinds: new kinds of direct-control technology, which is what the control business is about; and, secondly, process redesign technology; and, thirdly, the coming to market and development of substitute products.

Now, mind you, we're talking about costs as being in a transition period when virtually no costs were being expended by the firms to control many kinds of pollution to a time when it would be built into the plant design and product design.

We're in a transition period, and we're making up for lost time and the money we spend is going to be very different than what it will be the next time around.

Yet the economic impact assessment tends to focus on that transition period and the estimation of those costs with

all the problems that emerge.

Now, before I go to the benefit side, let me make some more points.

One is: Whenever you compare costs and benefits for a particular regulation and approach, you can never do that in the abstract. You would have to ask: What would have happened with vinyl chloride? What would have happened with lead had EPA or any other agency not taken its particular action?

And the pharmaceutical regulation is a case in point. It turns out that most of the money that may have been expended to demonstrate safety would have been expended anyway by the firm; and when you ask what the costs of a particular regulation, you have to say costs again what? Against what would have occurred with fear of products liabilities suits?

When you compare the EPA and the ambi-inhalant standard, you have to ask: If there were no standard, what kind of costs would have been expended by the firm in complying with the OSHA lead standard which required process redesign?

So it's not fair to do an economic impact on the ambient air and then do one for the OSHA lead standard, and then add those two things together. Not only is that wrong, you have to create a baseline that is sensible.

The second point is that the real effect of these regulations is to force and develop new development, and the beneficiaries of the regulation.

If we were faced with a model that most pollution in the toxics area was really trying to remove the last five percent of the toxics, we are now in the point of diminishing returns. One would say you have to draw the line somewhere.

But the truth of the matter is, very little is regulated that ought to be regulated on scientific grounds and that, for a long time - a decade or more - we will likely be able to redesign project technology, generate new products which will benefits the firms substantially and lead to lower citizen and work protection.

We are on the lower part of the curve, not the point of diminishing returns for most of the toxics that are really of serious concern today.

I think the facile assumption that we've gone as far as we can go and we have now reached that point ought to be looked at.

What about the issue of costs and benefits? There had been a time when benefits - which is reduced disease, suffering, psychic loss due to deteriorated environment - were estimated in terms of market signals that gave evaluation in terms of dollars.

In the workers' situation, people talk about hazard pay as measure of risk of acceptable exposure to toxic substances. I think the time is rapidly diminishing when the people really have much faith in the dollar evaluationof the

health costs and so on.

They realize they're trying to monetize benefits in comparing them to costs and asking whether the benefits exceed the costs is not a very acceptable market measure.

What has succeeded the comparison of benefits and costs in terms of dollars is the magic benefit to cost ratio. At first glance, it's appealing.

Take something like NHTSA, National Highway and Traffic Safety Administration, the number of talleys per dollar expended. Why shouldn't we try to maximize the benefit to cost ratio?

Here we have two different concepts coming in. We have cost effective criteria, or health and safety effectiveness criteria.

Cost effectiveness type criteria means really, technically, the following: Given that you want to reach a certain target of fatality reduction, let's see if we can minimize in doing something in health effectiveness or safety effectiveness.

In other words, hold it constant and minimize the costs with cost effectiveness. What you're trying to do is, given a given expenditure that the agency is given of that it can impose upon an industry, how much health can you get for the bucks? You maximize the benefits to be derived.

That sounds manifestly sensible except when you even

as uncomplicated as traffic fatality prevention, then you realize it's not just the number of fatalities. It's the number of serious injuries, disfigurement.

On the benefit side of the ratio, you have to start to ask: How many serious injuries is a fatality worth? Five? Five serious injuries equal a fatality. How do you relatively rank the different kinds of health and safety consequences?

And you find there is no real magic rule. There is no unified theory which allows you even to aggregate the benefits so that you can make a sensible comparison.

The glaring example of failure to look in a sophisticated manner is with the OSHA benzene provision. Well, it's not just cancer deaths from benzene, but it's other kinds of blood disorders. It's pain and suffering.

These are the things that just haven't lent themselves to the consensus in terms of evaluation. So it becomes very difficult.

The second thing that is really difficult is: On the compliance cost side, while it may be possible, let's say, to calculate for the industry what complying with the one part per million standard of toxic substances would be, you can generate a curve, a probability curve as to what the variation from compliance costs would be.

You get a rather narrow curve. That is, you can estimate compliance costs within a fairly narrow range. How

about the number of cancers prevented from benzene exposure?

You can take a simple-minded view of the world and use a linear extrapolation theory, and you get a single number, a single point estimate. But the trouble is, anybody who knows epidemiology and toxicology, the complexity of the real life situation, where other hazards exist, where there are predispositions in some cases to disease, where there's a history of past exposure --

Remember, we're in a transition period where there are disease mechanisms of many kinds operating. Do you realize a single model giving rise to a single point estimate, which is analogous to a compliance cost estimate, is really fraught with great difficulty?

The truth of the matter is, if you were to draw a curve which will demonstrate the risk profiles compared to the cost profiles to comply with the one part per million standard, it would be from theoretically grounds, from mechanistic grounds, from computation grounds very broad indeed.

And the truth of the matter is you can never really get the curve.

It may be that the most likely estimate, most likely single point estimate in the number of cancers from one part per million exposure to benzene is five lives per year, but with the taking of previous exposures the number could probably be five hundred parts per year.

It's not the most likely possibility, but what do you do faced with a situation that there is a five percent chance that it might be five hundred deaths per year. You see it's no longer a single point estimate and you can't get the data.

What you can say, perhaps, is that exposure to lead, which is a classic toxin, might give you a narrower range of uncertainty on the health effect than carcinogens. You might, you might not. Different toxins are different.

But it really does require - I've done this in great detail, it's hard to do - require a tremendous knowledge of multiple exposure that people are exposed to.

The mobility of populations out of a polluted or work area, age differences, sex is a determinant, in some cases, of disease - smoking habits, lifestyle, alcohol - and it is very difficult.

I must recall to you, there was a panel that sought to look at all the data that has been accumulated between air pollution and mortality and morbidity; and the conclusion of that intense look by a panel of experts is that they have made so many assumptions and not controlled for so many variables that there is not very much we can do about the relationship between air pollution and disease, and we've been doing these studies and spent millions of dollars on them for fifteen years.

Now, what do you do then? Do you just throw your hands up and decide to be arbitrary? No. The answer is: No, you don't do that.

We know from animal experiments that there are some very powerful toxins out there. There are around two hundred carcinogens that very few people would disagree need some sort of regulation. There are classical toxins that have special limits set for them because they were set on the basis of acute exposure and animal exposure.

We have in the order of a thousand materials in commerce today that will take all the resources for many, many decades to regulate if that's the mechanism of control.

Now, faced with that difficult decision-making part, what does an agency like EPA do? Does it conduct benefit-cost calculations to decide which is the priority list?

I think not. I think you can't do that. I think what you'll have to ask is: What is the real impact and what is the real benefit to be derived from regulation?

There are two. One is to legitimize, in the eyes of the regulated and the general population, the fact that real problems are being addressed, that we're going after whales and not minnows. I don't believe we're going after minnows.

I think we're really going after some of the serious problems.

The second thing you have to do, you have to give a

signal to the industrial establishment that it's time to redesign an industrial plant, to redesign an industrial process and there are tremendous market opportunities for penetration in international competition for an industry that is ingeneous.

We had Monty Thodow at a conference a few days ago stand up and volunteer that they think regulation has created market opportunities for the company, and they think it is about time that they got about the task.

I think this evolution in attitude is occurring certainly among some firms, not as many as we would like; but the leveragine effect of giving enough signals to enough of the sectors, not just the chemical-using industry, is really what the payoff of regulation is about.

Now, if you do a benefit-cost analysis and construct a benefit-cost matrix, what you can put in there and what requires some faith and judgment and art is the answer to the question: If you regulate benzene, will you have compliance with toluene and xylene?

Will the people who could produce vinyl bromide begin to control without regulation? The answer is yes. So even if the benefit-cost matrix doesn't look so attractive from a particular substance perspective, if it leverages in an anticipatory way - and, by the way, in a cost-effective way because each firm has come to do what it needs to do for most of

the substances that are not regulated - then you really have a payoff.

I can't calculate the payoff any more than you can calculate what the Internal Revenue Service managed to encourage in terms of voluntary compliance by its selective auditing. You certainly couldn't compute all the fines that people have paid for violating IRS rules and say, that's the payoff.

That's now much dishonest reporting we managed to catch; and the value of the agency is that there's a tremendous amount of voluntary and participatory activities, and that is the real point.

How does an agency regulate? Let me suggest that it should look at how many different sectors it is affecting, where the chances for real improvement are, where the industries are that have not been innovative and stand a chance either to be innovative themselves or to be replaced - yes, replaced - by new entrants, new products.

And that is why we need to move the economy ahead in terms of producing sensible kinds of products and product exposure.

And, now, given what is necessarily a very broad view and which is difficult to justify except by looking at the few cases in which regulation has occurred, I would find it difficult as an analyst to stand in front of the Council of Wage Stability and say how many dollars in terms of health costs

saved or how many bodies did you save in terms of benzene regulation under the OSHA Act?

To give you an example, the tremendous leveraging effect gave rise to a regulation that said, workers have a right to refuse hazardous work. Well, that means that people in the workplace who objected to dangerous hazards have a right to refuse to work with that substance.

That's the effect of OSHA regulation. That behavior alone can do more than any single regulation ever issued, argued about or having a cost-benefit equation.

So I've termed cost-benefit analysis in other places a paradigm in a closet; and the reason I say that is because what goes outside is not looked at, and what you looked at inside is to beset by darkness that really no rational approach can give rise to guidance for an agency.

I believe in accountability. I believe in laying out the ranges of uncertainty of the kind of health effects you think you can have, but if you devote too many resources to that you'll be going after an ant with a sledge hammer and you're not going to get where you want to go.

I've said this many times. I just question continually the continued demand for rigorous analysis, not accountability. I applaud the demand for accountability and if this is a way of getting accountability that may not have been there in earlier times, okay.

But I think we have to move away from analytical techniques and I've done these analyses. They just don't yield very useful results in too many cases.

DR. CLARK: Given a short summary of what we're doing and what Nick thinks can be done, then I thought we would have David talk for a few minutes about what the Regulatory Analysis Review Group would like to see done.

DR. HARRISON: Let me just spend a couple of minutes summarizing what the Regulatory Analysis Review Group - or, as it's often referred to, the RARG - is and give a couple of examples of what kind of analysis we would like to see done.

I will say that my general impression is the kinds of things we would like to see done are not very different from what Toby has described; and I think, in many ways, not very different from the kinds of accountability that Nick has described.

But let me basically describe what the group is.

What it is is an inter-agency group that consists of several representatives from within the Executive Office of the President and representatives of eleven major Executive Branch departments that are responsible for implementing economic and regulatory policy.

The group was established by the President in conjunction with the promulgation of Executive Order 12-044, at this point a well-known Executive Order, and the task of the

Regulatory Analysis Review Group is to review, during public notice and comment period for proposed regulation, a relatively small number of regulations.

One of those is review the regulatory analysies that Toby mentioned are required by this Executive Order 12-044. As was suggested, most of the staff is from either the Council of Economic Advisors, which is a small group, or the Council on Wage and Price Stability which has a somewhat larger staff for this purpose.

The RARG is chaired by the Council of Economic Advisors and the person with primary responsibility - member with primary responsibility is George Eads right now.

The RARG has an executive committee that is made up of four members: two of them are permanent, one is representative of the Council for Economic Advisors, and the other permanent representative is from the Office of Management and Budget.

The other two members are rotating and the way the rotation works is that at any one point in time one representative from an economic agency and another representative of a regulatory agency; and, right now, the current rotating members are from the Department of Labor and from EPA.

So, right now, EPA has a representative on the Executive Committee.

In addition to the regulatory agencies, there is

also representatives from the Office of Science and Technology Policy and the Council on Environmental Equality, and also the domestic policy staff.

Well, what the Executive Order requires is, as Toby I think has suggested, that agencies do regulatory analyses of major regulations.

Now, the Executive Order defined major regulations as at least those regulations that impose a hundred million dollars per year, and there are other procedures the agency has developed, including EPA, to implement the Executive Order and define under what circumstances they will do a regulatory analysis.

EPA has a set of procedures that are thought to be very good in terms of defining process for reviewing major regulations and for doing regulatory analyses.

Now, the formal mechanism for the RARG review is that when an agency issues its Notice of Proposed Rulemaking it also issues a draft regulatory analysis and the executive committee will vote to decide whether to review the draft regulatory analysis, and the mechanism is a requirement that two members of the executive committee vote to do a regulatory analysis.

Then a Notice of Intent to Perform a RARG Review is sent to the agency. There is a list of concerns that are sent to the agency and the agency then can suggest that the list of

concerns ought to be supplemented or clarified in some way so that there is a procedure of making sure that the issues RARG focuses on are the issues that the agency think are relevant.

Then, as the RARG draft is prepared, it is submitted to all RARG members, this entire group consisting of the regulatory agencies. Any dissenting views are incorporated in the final version and the RARG document is then placed in the public comment, in the rulemaking record before the close of the comment period.

Now, I might just mention that one of the -- You ask, how does the RARG go about selecting various candidates for review? One of the things that has been very useful is that we now have a calendar of federal regulations that probably most of you are familiar with that the regulatory council puts out.

It will prescribe the menu of future regulations, and there is some sense that that document provides what regulations are important and so forth. But in decided which to review, we basically look at which regulations we think are those of which our review could be most useful.

I should point out that the primary purpose of RARG is not to do a regulatory analysis because there are a very small number of reviews that we actually undertake each year, but to improve the agencies' rulemaking and regulatory process.

So we like to choose regulations where we think our involvement could have some useful impact.

One criteria might be large cost of compliance. So given the gigantic number of possible regulations to review, one criteria would be the size of the sectoral impact. But we also might review regulations that were relatively small or their economic impacts were unknown, but when the particular regulation would have a presidential value.

For example, recently we reviewed the EPA's regulations on effluent guidelines for the leather tanning industry, which is the first in a series of regulations on water effluent guidelines, particularly regulating toxic substances.

And the leather tanning industry was chosen for the focusing of the review because it was a first, and presumably the methodology used in that first one would be carried over to others.

We have also recently reviewed EPA's air cancer policy for which there was no formal regulatory analysis done because it was thought - I think it is correct - possible to quantify the costs and the benefits of the regulation and its alternatives, but that that policy might have an influence in subsequent regulations. It might have a large influence.

I should also point out that one of the restrictions on the Regulatory Analysis Review Group is that it does not review more than four regulations for any one agency in a year.

So that the total number of regulations, the maximum, was placed at 20.

So you can imagine, there is a relatively small number of regulations actually subject to review by this RARG procedure.

Well, Toby suggested that I mention some of the issues that come up and the recommendations that tend to be made in these reviews.

MR. BARAM: David, before you go on, you said there were for EPA, four reviewed by RARG out of 20, no more than four, but you have a sister which also does economic analysis of proposed regulations on virtually any regulation they choose to focus on.

Is that right?

DR. HARRISON: That's right.

MR. BARAM: And they are under the White House and part of the Executive Order function.

DR. HARRISON: The Council on Wage and Price Stability has a mandate. They have a mandate under presidential order of some sort to provide --

MR. BARAM: Additional economic analysis.

DR. HARRISON: What I am describing is the RARG process.

MR. BARAM: When they also continue to be involved in these analyses of proposed regulations, also?

DR. HARRISON: OMB is the other permanent member of the executive committee or RARG, so that it's involved in any decision. It has a vote in any decision, whether to do a RARG review or not.

Well, what might be some of the issues that seem to come up?

First of all, let me say that what these RARG reviews tend to focus on is methodological issues rather than issues of cause or interpretations of scientific data. We will sometimes ask for guidance or support from the Office of Science and Technology Policy or the Council on Environmental Quality on wome of the issues.

But typically the RARG might point out that there appeared to be large variations in the costs or the effectiveness on the part of an agency or various industries or other interested groups, such as environmental groups.

But we typically would not come to any conclusions on what the right costs were or what the right interpretation of various scientific data was, and that makes sense given our small staff - and it is a small staff that's involved in this - and the fact that our expertise in not in those areas.

The second thing is that, in terms of methodological issues, my sense is that the overwhelming methodological issue has to do with cost effectiveness. My impressions of that are based largely on the evaluation of EPA's air cancer policy and

the toxic water regulations, which are the RARG reviews I had primary responsibility for.

To take examples, those are cases where one is regulating a great many substances, a great many sources of those substances, and the question is: Is there a way to determine roughly some sense of rough consistency among the various regulations?

As it's reflected in the regulatory analysis, does it encourage that sort of rough consistency? To the extent that the data is available, is it used in a way that would encourage that kind of relatively consistency?

What you really want to do is avoid situations where you're spending a high cost and getting relatively little for it, or you want to encourage cases where there are low-cost options that may not be taken full advantage of for increasing the benefits of various sorts of environmental - or other.

Another review that is already review going is public transportation regulations on fuel economy for trucks. The same sort of issue comes up: Are we encouraging a cost effective regulation to increase fuel efficiency in the general automotive vehicle fleet?

So what one wants to do, I think, is to avoid relatively inflexible rules and automatic responses, given the existing information.

I think Nick has alluded to some difficulties of

collecting information on some of these problems and it is very clear that there are difficulties and this should not be interpreted -- at least, the RARG reviews I've been involved with make it clear that this is not a council of perfection.

One doesn't have in mind trying to squeeze out ever conceivable ounce of benefit and make everything completely internally consistent. That is now what is involved. Given the uncertainties in these areas, it's not possible.

What one wants to do is to organize the data in a way that allows one to make the best use of it.

A second issue that often comes up is the distinction that is made between resource costs and what are sometimes referred to as economic impacts where the economic impacts focus on issues like firm closures and the possibility of some unemployment generated.

Now, our defense is that while closures and unemployment might be one aspect of various regulations one might want to look at, that there ought to be some measure of the resource costs as opposed to focusing on economic impacts.

So, for example, we don't think it is appropriate to only regulate so far as to avoid any either plant closures or unemployment as a result of any particular regulation, although that factor ought to be included in the overall analysis.

Another issue that comes up is the treatment of

alternatives. Toby mentioned some possibility of using economic incentives as one major type of alternative, but there are other alternatives that one would want to explore.

For example, looking at the regulation of benzene from a particular source category, does one look at a variety of levels of control and evaluate their cost benefits and make the analysis as explicit as possible?

I guess, finally, my sense that in terms of improving agency regulation, that there would be substantially more agreement on appropriate regulations and appropriate regulatory analysis than might be apparent when the issues are quite general.

That is, is economic analysis at all useful? Does it have underlying value judgments that are difficult to believe in all cases?

If you actually get down to examples of regulatory approaches, you might get much more agreement than disagreement. Frankly, one of the things that we did in reviewing EPA's air cancer policy, we asked the agency whether they could give us an example of how the policy might be implemented in practice; and they suggested - they encouraged us to look at benzene as a possible case study, and their procedures for looking at various source categories for control and for regulating one particular source category which happens to be benzene from hydraulic plants.

And our sense for doing that review - after having gone through some suggestions for how those regulations might be structured - is that I suspect there is far less agreement that one ought to look at the costs and benefits, comparing the cost benefits of various source categories, for example.

Another thing that came up on this, there are, in fact, eight nyla hydrid plants that would be subject to control. It turns out if one looks at the cost benefits of those various eight plants, most of the benefits come from regulating one particular plant which happens to be located in a relatively densely populated area.

So that one issues comes up: Ought one to, in some sense, concentrate more of the control effort on that particular plant and perhaps go to other source categories rather than the other seven plants where the controls are rather small and the costs are rather large?

I think there is some sense that one could do that within the context of EPA's mandate for, by example, defining different source categories to include plants located in different population exposure areas. And that is only one example, I think, where one might have more agreement on the application of these principles than if we tried to argue something at some relatively abstract level.

I think those are some of the issues that have come up in some of the RARG reviews, and some of the principles

that we think would be usefully demonstrated in the various regulatory analyses.

DR. ASHFORD: Could I just make a comment because I think it's really instructive to show how one focuses onto different parts of the problem and be persuasive, in either case, if you hear either argument alone.

This benzene statement, the EPA posture - what David said - has an immediate appeal. You can get more health for the bucks by going after the few sources than the ones that are really expensive.

Let me say that is a beautiful example of a static field, of the way you approach the problem because any cost effective criteria merely rubber stamps the present economic arrangement between the firms in terms of their competitive structure and between the users, the producers, the consumers, and workers.

If you impose the heavy costs on those sources that are not efficient compliers, what will happen dynamically? You will raise the cost of those products, for those producers to be less competitive, eventually have them replaced by the low cost compliers; and that is what it's all about.

If you excuse, in the basis of present economic ability to comply, those high cost compliers, you will never have a reintroduction of different technology. You will not shift the prizes of industrial production to those firms that really

deserve it. The people who anticipated problems and have lowered their expenditure costs, and now are leaders in terms of technology ought to be the ones who are reaping benefits.

And by saying, you - the firm who has done, already, so much on your own - it isn't going to cost you very much to take your benzene down, but we are going to excuse the firm who hasn't done a damn thing for ten years on the basis that it costs a lot of money.

MR. MOONEY: Is that what Dr. Harrison just said?

DR. ASHFORD: No. I think the high cost sources of controlling benzene ought not to be cut off on the basis that it's cost ineffective. If you want to move those people out of business or to give a clear signal that next time around it's not going to pay you to wait - and that's a dynamic view of industrial - then you can't use this technique to make that kind of division.

DR. HARRISON: Let me respond because I think that raises what, in theory, would be a useful point and one would want to do some analysis on that issue.

In fact, in this particular benzene case, it's actually the opposite of the case I described in the sense that the high cost and low benefit cases were those plants with already-adopted controls, and the nature of the controls that would be required by the regulations would essentially have eliminated the advantages of those previous controls.

So, in fact, in this particular case - and I think there is something to the general issue that he raises in this particular case - the high cost, low benefit compliers were those firms, those plants that had already controlled to roughly 90 percent, and the controls that were being considered were 97 percent.

And the best guess was that this previous control would not be of much value in getting to the 97 percent level. So they would essentially have had to have gone to a completely different kind of control mechanism essentially eliminated the advantage to them.

So I think, in this particular case, it didn't work out in terms of empirical questions.

I think that is the sense in which my overall judgment in a lot of these, there might be agreement on the general way in which are not to do some of these analyses, and a lot of these cases are empirical questions.

And that is why we would like to see the analysis explicit on some of the issues raised.

I don't think - this is my personal view - that cost effectiveness is the only aspect that ought to be included in a proper regulatory analysis. It is, however, an important aspect; and, where it is not taken into account, I think the regulatory analysis could be improved.

CHAIRPERSON BENDIX: Mr. Mooney?

MR. MOONEY: It was just on the last point.

Perhaps I don't understand your jargon, but it seems to me what Dr. Harrison was saying was exactly you had in mind: in fact, a reward for those companies who had moved out ahead to do something without a regulatory club over the head. And the company that had failed to do so was going to get zonked with a very focused regulatory requirement for control.

DR. ASHFORD: I think, though, that would be the exception, really, to the general rule. David might even want to comment on it.

In point of fact, if you look at the lead problem, people who really have the high compliance costs facing them in lead are people who have done very little in the past. This may be true for benzene.

I won't argue the case. I'm just saying, unless you look closer - and I don't think David will disagree - that you have to look close at what the history has been, but it is not just a matter of rewarding the goods guys.

It's a matter of encouraging industry to substitute for each other and new entrants and all these other things.

There is a big question: Should we have saved Chrysler?

I won't argue here, but there is a lot of emotion. It is connected because the allegation is they couldn't comply because of the pollution requirements, and those questions are

troublesome.

The point I was trying to make is a simple one. If you use cost effectiveness criteria in place of cutoff as to where you will no longer require regulation, then you aid the people who have not done things, very often.

And, secondly, you do not move the economy to substitute its industrial plant when you reward those entrepreneurs and new entrants.

DR. HARRISON: The only point is, you simply don't want to only let intuition be the only thing that you use to make these sorts of issues explicit. I think all of us have raised an issue, a complicated issue, of technological innovation as to how one incorporates that in the regulatory structure.

That is not to say that that is not a relevant question. I think what one would like to do is to make those kinds of concerns explicit, and if you have good information, what that will do is essentially lower the costs and maybe even increase the benefits in some areas because of other substances that are controlled when you focus on a particular substance. All the better.

DR. ASHFORD: The problem really comes down to how much data you expect the regulator to move on when he really is striking on an article of faith. Say I'm the regulator, I'm the head of EPA. I want to regulate arsenic and if I

looked at the industry and I believed, by having this stringent regulation, new entrants will arise and we will be better off in ten years; and then you ask me: How do we know that?

I don't know how I know that. The data is not there. Would I be predicting? Is it prediction or is it prophecy? There is a line drawn between prediction and prophecy. It comes down to your political views and religion, and it is not, repeat, is not derivable from economic principles.

And I think we ought to call a spade and spade, and that's the point of disagreement that I say you and I have, here and elsewhere, is to how useful you can push the justification for that decision.

Will you accept, where you're sitting, my judgment that I think in ten years we're going to have a different kind of smelter in Tacoma, Washington? I don't believe you'd accept my judgment on that.

DR. HARRISON: I think we would have more agreement on specifics rather than we would on which religion is appropriate.

CHAIRPERSON BENDIX: Dr. Radford and then Dr. Eisenberg.

DR. RADFORD: May I have the microphone, please?

I would like to speak to the issue from the standpoint of an educator who has been involved in the environmental movement for a long time and certainly in the early

days of the - well, cranking up of EPA in terms of its regulatory functions.

There was no great concern that we pick out the worst problem and tackle it first, and the next worst problem and tackle it second. We went ahead on all fronts and, in many cases, probably in a misguided fashion as far as the air pollution regulations were concerned; at least in my opinion.

I mentioned the educational issue because one of the salutary side effects which Nick did not mention, about the impact of regulation, is that the word is finally filtering down into the educational community that they jolly well better have chemical and electrical engineers and a whole bunch of engineers who are designing a plant that know something about the potential toxic effects of what they're doing because it may wipe the whole process out, even though economically it's beneficial.

If it turns out that there's going to be something released that is extremely hazardous and then, for that reason, the company doesn't go with it, they can waste billions of dollars designing a plant.

That's a long-range thing. I would just like to raise, I think, two questions to anyone and everyone.

The first is that it became an article of faith in the environment movement that technology followed regulations and not the other way around.

In other words, the issue of whether it was technologically feasible to do this, that, or the other was a secondary issue from the start. Now, of course, that we're the environmental cost-benefit stuff, that has been somewhat turned around.

But I would like to know if, in fact, that aphorism still holds. I was told, for example, when I was living in Maryland, that when the regulations for air pollution control in Maryland were about to go in effect, there were 15 vendors of new equipment waiting on the border to pounce on all the industries to sell them their product, and this was brand new stuff that wasn't going to be factored into any economic balance that would have been done months before.

The second question gets a little bit more specific.

I have been told - and I would like to have it confirmed, if possible - that at the time that the one part per million vinyl chloride occupational standard went into effect, the industry immediately proceeded to hire Arthur D. Little or any number of hot shot economists to do cost benefit analysis; and these varied anywhere from one million dollars per whatever unit to up to billions.

It was in at least that order of magnitude variation, depending on who did the calculations.

There was an instance, I've been told, where, after the fact, OSHA, for once, stuck to its guns and said, "Not,

it's going to be one part per million," and within eight months all of the existing plants were in compliance, and somebody had the bright idea to actually calculate how much the cost was.

And, as I understand it, it came out something like ten percent of even the lowest estimate that had been done before the fact.

All I'm saying there is, if the facts are correct as I have stated them it shows how bad the cost, even the cost side, is calculated by those who are supposedly doing it in an expert fashion.

DR. ASHFORD: Maybe I can respond to the issue of technology.

I think, Ted, it's a little bit the other way around. The early water and air pollution was based on present technology. It turns out that there wasn't very much technology forcing.

That's why we got stack scrubbers. That's why we got lead traps. And that's why we got no process redesign.

OSHA came along with a series of creative legal decisions and was recognized to have technology-forcing capabilities, such as in the vinyl chloride case; and history does show, in fact, that the polemerization process for PPC was accelerated greatly, not the minute the regulation hit but months before hand.

Regulations is not a single event. It's a series of

dances and people who have a lot of time to get their act together: Consumer Products Safety Act, the Toxic Substances Control Act, the OSHA Act, all that new kinds of legislation that really has an ability to force technology.

The reason we've had bad luck in regulation in the past is because it was not stringent enough, not because it was too burdensome.

Look at the International Harvester case. Here was Ford ready to go ahead with the requirements and it was acknowledged in the court case to be the leader in the area, and the court gave lip service to the fact that if they allowed the one-year delay on lead and gasoline they would penalize the leader.

Well, that's exactly what they did.

What kind of signals next time around does Ford Motor Company have to benefit from its thing competitively? I had, in the dimension of the environment, environment in reality.

When you take the emotional reason, it is no more than an additional competitive element.

I would like to requote, they see tremendous opportunities in grabbing a greater part of the market if they can comply faster than their daily competitors.

I think we have to recognize that.

MR. BARAM: We quoted Monty Thodow, also, yesterday.

We've quoted him a lot yesterday and today.

CHAIRPERSON BENDIX: Dr. Eisenberg?

DR. HARRISON: Could I just say something and emphasize one point that I think you made that is a useful one?

That is that the kind of cost data that one has are obviously highly uncertain, but that there are other sources typically that regulate industry.

And you mentioned in the beginning that there are some industries that are ready to provide the kind of controls that might be required by regulations; and what happens, particularly, is that they are to the extent that they have incentives to look at cost differently.

Shall we say that their incentive is to underestimate what the cost would be by using some cases? And I think that's extremely useful because what it means is that the agency has some other source of information about compliance costs than simply the industry that is being regulated.

As Toby mentioned, that has some obvious incentives and so you have a possibility of getting some more cost data. To the extent that it has biases, it has the opposite sort of bias.

DR. ASHFORD: This is a misleading statement.

The pollution control industry selling stack scrubbers and devices isn't necessarily the kind of technology you want; and, yet, those independent cost estimates go to retrofit.

I will emphatically insist that the agencies do not have the kind of expertise to do the engineering process redesign technology estimates which need to be done, which is the real way to solve these problems, the quick fix.

And the merchants on the street, that way, are not going to do much better in the pollution area internally and with products than they did in air and water pollution.

I think it is time to go in a little bit deeper in terms of process redesign and those kinds of technological exposures.

DR. RADFORD: What about vinyl chloride?

DR. ASHFORD: I did a study. The prediction was 250 thousand workers out of work. It turned out to be less than a hundred. The total price rise in vinyl chloride products cannot be more than three percent at a time when the feed stock costs force an eight percent increase.

DR. HARRISON: I might point out, this is completely consistent with the kind of analysis that one would like to see done. That is, we would like to have some retrospective analysis to ask the question: How, in similar cases, have the costs of similar kinds of technology been developed?

And that's the kind of things that, in a regulatory analysis - if there is some previous information on what the costs are likely to be - that's the kind of thing I would like in regulatory analysis; and I would encourage that.

DR. REDFORD: Can I add one point? I don't want to usurp your time. I'm sorry.

As I understand it, one of the things that tipped the scale markedly in favor or, at least, reduces the unit cost of regulation was the recovery of monimer. They just recovered a higher percentage.

MR. MOONEY: Was there not also considerable debate about zero exposure levels? I'm just trying to clarify whether the economic perspectives are based on a presumption of no permissible or acceptable exposure as opposed to one part per million.

DR. ASHFORD: They were based on no possible exposure, which is not different from what you are saying.

Using the technology which was already being developed and which was, in fact, accelerated, there is not a difference between the cost estimates. In fact, the technological assumptions made in cost estimates for no permissible exposure and the cost estimates there are for one part per million --

This whole business of focusing on one versus two-tenths versus five-tenths is fatuous because you can't measure that.

You never design, if you had to comply with one part per million, to one part per million. You design to below. So let's not pretend that one part per million is really much

better than two parts per million because it's not.

DR. EISENBERG: David, in you analysis of that maleic anhydride situation, are you suggesting perhaps that regulators should look at these things or regulation should be written in such a way that they're flexible enough, that they're not geared industry-wide or they aren't geared to be handled equitable in a situation but rather on a case by case basis?

And then, on the other hand, my question would then go to the EPA representative, how he would see implementing such a regulation?

DR. HARRISON: This is my own personal view.

I think that it is useful to avoid blanket regulations where, in some cases, the benefits are very, very small and the costs might be substantial. But I do recognize that there might be or there are likely to be more administrative costs as well as, perhaps, other influences that cut on the other side.

So I guess my argument would be to look at the particular cases and ask whether there is some administratively feasible way of avoiding high cost, low benefit controls.

DR. CLARK: You've asked the question that I would have commented on.

RARG will make some suggestions like that and come back to EPA, and EPA will then interpret the suggestions in

terms of the statute they're trying to implement.

And, aside from the administrative costs that David referred, Congress has preferred, it seems, to have national standards in order to eliminate the environmental programs affecting competition among plants.

Most of our programs are national and don't allow --

DR. ASHFORD: Bob Crandall, the former Acting Director of - challenged the vinyl chloride case as being the single exception to the rule.

You see, you're never going to be able to satisfy criticisms, and I'm not saying David's criticisms - cricitisms that the agencies are not accountable when you say this is an exception and that is an exception, and key people are defensively doing these anlyses.

If the regulatory impact bill passes in the Congress which requires full consideration to honest alternatives, you're talking about the Beltway Bandits in Boston - an enormous amount of money to do these analyses when they know what the answers are beforehand.

You're talking about half a million to six hundred thousand dollars, 750 thousand dollars an analysis to satisfy RARG requirements.

As a person concerned with technology, I would like to say, for 750 thousand dollars, I think the government could encourage development of new technology, could stimulate new

entrepreneurs, could stimulate --

However, I might have misguessed on benzene at one per million versus five, there's going to be a lot more payoff if we can stimulate new technology than to conduct these analyses which, in the last analysis, aren't believed by anybody anyway.

I question the cost effectiveness of cost effectiveness research.

[Laughter.]

DR. HARRISON: I guess I would simply say, in my sense, that is an empirical question.

MR. BARAM: Selina, I would like to ask a question to TSCA.

You started out discussing the asbestos case from your remarking remarks on asbestos, which is a proven carcinogen. You implied that a decision to regulate asbestos, the very decision to work on the asbestos problem was going to be based on the results of some economic cost-benefit analysis or balancing health versus economic effects.

David has, then, talked about the RARG economic policy analysis as well as some of the others that may be going on in terms of cost effectiveness, but it seems at this juncture here you are talking about, Toby, whether or not to regulate asbestos based on economics whereas David implies that once a decision is made to regulate asbestos it bubbles up to

RARG and then RARG, and then RARG just tries to help you determine the most cost-effective way to do it.

I think that's a critical distinction because we're worried that OTS will never produce any regulations at all.

DR. CLARK: I think it's fairly clear that we have decided to take on asbestos.

The question of how we take on asbestos, to what extent we try to control its use, how we try to control its use, and where we try to control its use requires some balances.

Our economic analyses will be a part of that.

MR. BARAM: Do you h ave any guidance in terms of a set of health criteria in selecting OTS regulatory targets? For example, items which have attributes like the greatest severity, the greatest irreversibility, or the greatest magnitude of health effect?

Is there any attempt to develop an health impact analysis as a basis for selecting targets so that David and his group can work on a cost-effective way in attacking those targets?

DR. CLARK: We, at this point, do not have any formal criteria, but the way in which things enter the queue, so to speak, is basically health-based analysis - relative priority in terms of the number of people exposed.

MR. BARAM: Is that explicitly spelled out anywhere, a guidance document we could take a look at?

DR. CLARK: As I say, there are no formal criteria. Well, if you look at that report I just handed you this morning, it's fairly explicit in there, yes.

CHAIRPERSON BENDIX: Dr. Sutton?

DR. SUTTON: Good things have a way of being abused, but it seems to me that what we are really discussing is some process in which we collectively decide how to far to go on the regulation, not only what to go after but how far to go and in which way.

And to complete ignore any aspect of cost, for example, and benefit seems to be unwise.

You seem to say that you can't do it at all so let's not --

DR. ASHFORD: No, I didn't say that.

DR. SUTTON: -- whereas RARG seems to say, let's do some and see if it sharpens our analysis of the situation to allow us to make a better decision.

I tend to identify with that posture a little more, probably biased by religion and experience and so forth.

My question is: How much effort are we actually putting in on this process right now? I don't have a feel for that in EPA and I would like your two estimates of what percentage of that effort has any useful impact at all on the decision-making process.

DR. CLARK: How much effort are we putting into TSCA

or into all of EPA?

DR. SUTTON: Quantify it in some way: numbers of people, percentage of dollars spent, something like that.

DR. CLARK: Our budget to support our work in performing economic and some benefit analysis is roughly 2.7 million dollars for this past fiscal year.

DR. SLESIN: How much of that is --

DR. SUTTON: That's total contract.

DR. CLARK: That is for the regulations we issued this past year or are issuing. So I don't know what you would come up with in cost per regulation.

There are substantial resources being spent on this regulatory analysis.

MR. BARAM: Well, there are also other attributes to this whole process, such as delay on presenting any regulation at all.

As Alfred Kahn was quoted in the New York Times, the whole purpose of this process is to, ". . . grind down on health safety and environment regulation." That was the quote in the Times. That is the exact quote.

MR. MOONEY: Probably a misquote.

MR. BARAM: I don't know. It was pretty honest.

DR. CLARK: He says some outlandish things.

MR. BARAM: Even though David's group only does four analyses, there are other agencies that do other analyses. So

your total effectiveness goes far beyond the few regulations that are assessed.

It does have a chilling effect on a lot of health safety initiatives, and that's what we're concerned about, too.

DR. CLARK: Don't let us mislead you. Every analysis or every regulation that comes out of EPA has some analysis done on them so it's not just those that RARG selects. Every one has additional analysis.

DR. SUTTON: Can I continue, finish my question, and give you two a chance to give a personal opinion about the impact of that 2.7 million dollar effort that is going on?

DR. ASHFORD: I don't know that most of the money that has been spent to date has brought forth any analysis that is worth having an influence. I think it is too early.

The office is relatively new in this game so I can't answer the question with regard to the EPA. I think I can answer the question with regard to OSHA who has been doing this for a longer period of time and which is contracted out.

There has been a tremendous amount of money spent on economic analysis by OSHA. Most of it was pretty terrible analysis done by contractors who worked both sides of the street, quite frankly. It has ended up embarrassing the agency rather than helping it because it was so inadequate.

Where the very few pieces of analysis were done well and correctly, it cause the agency to adopt more stringent

regulations that it would otherwise have done.

In other words, the back-of-envelope calculations to regulating OSHA's standards has generally been more appreciative of the economic effects than our rigorous analysis has ended up showing.

So it's amusing that if you really do the analysis right it turns out that OSHA doesn't go far enough, and I want to quote Nordhouse from the Council of Economic Advisors, and he said, "If anything, this standard should have been more stringent."

Of course, he didn't say that in public. He never once complimented OSHA on having done good work in that area; and I'm going to press motivation, and not David's motivation, but I'm going to press motivation from the large thrust of support given for these analyses.

I think we ought to call a spade a spade. I think it is a diversionary technique.

I think that the back-of-envelope calculations - and I'm not saying no analysis, honestly - I think the kind of analysis that deserves to be done is not particularly sophisticated and does not cost, particular, a lot of money.

It puts a great deal of discretion where it belongs, on the heads of the agencies who take the heat. And I think we can't forget, this is an administrative law process. If the agency starts going after minnows, it will be corrected

mid-course; you can rest assured of that.

DR. ASHFORD: We are under-regulated, on the whole. Taking regulations' portfolio approach as a stock investment in health, we are not doing nearly enough. So I want to question: Why are we continuing to divert resources where I would like to have that 2.7 million dollars spent in assisting small firms to comply by giving them technologically information, by viving a little bit more technological expertise and knowing what is possible to drive the regulation, not what the economic impact is which ignores the leveraging effect, which is the real payoff of this regulation?

DR. SUTTON: Are we in a learning curve in the economic analysis business? Are they getting better and getting more useful?

DR. HARRISON: Well, I think in terms of the regulatory analyses that are done, I am assured that they are.

We actually have not done any reviews of the TSCA regulatory analyses, so I don't know. I really can't comment on how useful they are.

I guess my defense, though, is that, in a lot of these areas, some sort of economic analysis is useful and I guess Nick would agree.

My sense is, the kind of analysis that is required under the Executive Order, under the presidential order, is reasonable and is likely to improve the overall nature of

regulations; and while it is costly - the overall compliance costs and the overall benefits are quite large in magnitude - I think one way of looking at these regulatory analyses is as investments in better decision-making and that, sometimes, the RARG process is part of that.

DR. CLARK: Can I add one thing, too?

I think that, with respect to TSCA, it will be balancing act regardless of what the President said we had to do. We would have to do these analyses or something like them in order to determine unreasonable risk.

CHAIRPERSON BENDIX: Becky Moon?

MS. MOON: I went back to my notes that I took as a result of your discussion, Dr. Clark.

First of all, you said it was a balancing act, risk versus cost control. Then I have a big long paragraph of how you do your cost of controls.

Ever since I came on this committee, three years ago, I've just been dying to know how you analyze the other and I can't get anyone to tell me what you do.

Then someone else said, we do a cost analysis and then we do "some benefit analysis". Now, I don't know what "some benefit analysis" is, but I'm really curious what this "benefit analysis" is.

I see all the evidence here. What's on the other side?

DR. CLARK: What is on the other side?

The point I was trying to make, it's not done by economists.

MS. MOON: Who does it and how does it come in?

DR. CLARK: It is done in the Office of Testing, Warren Muir's office, and the risk assessment group. They take the evidence that a substance is toxic. This is animal tests, some epidemiological studies.

They try to estimate expression in the workplace by consumers, et cetera. And they try to, then, estimate the risk to risk assessment, both qualitative and quantitative. EPA, you know, tends to be more quantitative than other agencies.

The risk associated with not regulating that substance - and that is the benefit side, that's the benefit of the regulation.

MS. MOON: Who does the balancing once you put in the economics and Muir brings in the other side, which we've yet to define?

DR. CLARK: The Assistant Administrator.

MS. MOON: Is that between stage two and stage three or our little thing on significant regulations, or is that after three, after proposed?

DR. CLARK: I don't know about your stages on significant regulations, but when the Assistant Administration decides to propose in regulation or ask the Administrator to

propose a regulation, he has essentially done that balancing and said, this is the regulation we want because it's going to eliminate substantial risk and we don't think the costs are unreasonable.

MR. BARAM: Toby, who is that so we can talk to him? Who is that, Bill Dreighton?

DR. CLARK: Steve Dillon. He is the person that proposes the rule. All the other officers in EPA have an opportunity to comment on that and discuss it, and the Administrator finally makes a judgment.

It's a proposal from Steve and a decision by the Administrator.

DR. EISENBERG: Toby, you were saying that you don't have the economists involved in this, primarily, the scientists.

Do you ever factor in the cost of raising a retarded child? Do you factor in the cost of hospitalization for a certain illness?

Those are costs.

DR. CLARK: Those are definitely costs associated with the risk, yes.

Those costs are not usually computed explicitly.

DR. EISENBERG: Why not?

DR. CLARK: Because they don't add a lot of information.

If we went to this, we say, "Okay, ten people a year

would get cancer from this," and this involves, everybody knows, hospitalization. It involves the pain and suffering in the family. It can involve a lot of other things.

And we will compare that against costs. The Assistant Administrator is taking those types of costs you are referring to into account when he's doing this balancing.

We don't think that making explicit cost estimates of them would add to his information. We have those. They would be easy enough to do. But you couldn't add them onto the risk. That would be double counting.

That's part of the risk. That's part of that side. Those costs are taken into account, but we don't try to put monetary numbers on them because we don't think that adds to information.

CHAIRPERSON BENDIX: I would like to make a comment on that; and that is, I think in terms of public understanding of the justification for the regulation that it is a mistake not to publicize these kinds of costs because many of these costs - raising crippled children and so on, training doctors, building hospitals to care for them - are borne by society at large.

And one of the ways of getting general public support for a regulatory activity of the agency is to have the public understand that they are paying the costs for not regulating.

MR. MOONEY: It would be interesting to see an economic cost analysis on the tobacco industry.

CHAIRPERSON BENDIX: Dr. Slesin?

DR. SLESIN: I would like to pick on two points.

We've been discussing vinyl chloride and learning curves. Did your group ever go back and look at how good your estimates were in an economic analysis? Do you do a retrospective study as to the economic real costs?

DR. HARRISON: I guess I wasn't clear enough.

The RARG does not do any economic analysis. What it does is review the agency's economic analysis, but we don't go out and make independent estimates on what the costs are.

DR. SLESIN: Do you act solely as economists? Do you satisfy the rules of a good cost-benefit analysis?

DR. HARRISON: What we might suggest - and I also mentioned it, and let me just reiterate it - is that most of the emphasis is on methodology so that one --

The way I interpret your question is, ought one to recommend to the agency, when it comes up with a regulation D, that it looks at what happened in regulations A, B, and C and whether that experience sheds any light on how to interpret costs or what the likely benefits might be?

MR. BARAM: You said earlier that RARG files its own economic analysis.

DR. HARRISON: No.

MR. BARAM: You do do independent economic analyses in RARG?

DR. HARRISON: Let me clarify what the economic analysis is.

I have tried to point out that we don't go out, and it is not a substitute for the agency's regulatory analysis. What is submitted for the record is not, "Here is the regulatory analysis you ought to have done." It's not that at all.

What it is is a comment on strengths and weaknesses of the agency's regulatory analysis and some suggestions for modifying the framework, the methodology, suggesting what data issues might be clarified because there seems to be a considerable amount of disagreement.

We should be very clear. These are not substitutes for the agency's regulatory analyses. That is not the purpose.

MR. BARAM: I will try to clarify my understanding.

These are more than just responses to what the agency has done. For example, you go to OSTP and ask for technical information, reviewing what the agency has done technically, and he will suggest a number of alternatives for regulating or not regulating that the agency has not considered.

For example, in ozone standard. I saw your response, which was loaded with criticism of agency assumptions on whether ozone should be controlled or not because it wasn't cardinogenic and there was some melange of technical and economic

response which was more than just a response to what the agency had done.

It was a whole new thrust of philosophies and scientific and economic findings.

DR. HARRISON: There is something. I think that the ozone RARG review was done before I was there, but I am familiar with it and the kinds of recommendations that are made - and, remember, they are recommendations for what the agency ought to consider and they are filed in the public comment.

So that the expectation is that these comments would be one among the various comments that the agency is going to address as it produces its final regulations.

And, frankly, my sense is that while we do occasionally ask for the Office of Science, Technology and Policy to give us some insights on what technology is involved and what other kinds of evidence might be available, that is not the focus. That is relatively unusual.

MR. BARAM: You have reflected in an improvement in the sensitivity or RARG to lots of procedural and other abuses in the past, and I think things are changing.

DR. SLESIN: You will not comment on actual numbers, and you won't comment on -- It's purely a methodological view.

I find this very hard to believe.

DR. HARRISON: Let me say, I say, focus on methodology. For example, how could this group, a very small group,

the senior staff of the Council of Economic advisors is ten, and that staff has the responsibility to assist three members - the Chairman and two members - in providing advice to the President on economic matters, if which regulation is one aspect.

So you can imagine there are one or two of us who get involved in regulations.

As I mentioned, the COUPS staff is larger, but it wouldn't be possible for us to be familiar with all the science and technology or to go back. It's not productive.

So that what might happen in some cases is to point out that the cost range is quite large and it will be useful for the agency to try to narrow that range to further evaluate, as they go forward in promulgating final regulations.

I understand why the range is so large and why it should be clarified, but I don't think it could be by a review of all of the cost data, effectiveness control.

MR. BARAM: Could you send us a couple of copies of different analyses, such as the ozone, and also something more recent?

DR. HARRISON: I am most familiar with the two most recent ones.

CHAIRPERSON BENDIX: We need to take a break, now, for the benefit of our Reporter.

After the break, if Dr. Selsin wants to complete the

thought there - and then the order would be Dr. Radford and Tom Mooney, and Becky Moon.

[A short recess was taken.]

CHAIRPERSON BENDIX: If people could start moving back to the table, please, so that we can reconvene.

All right. Lou Slesin doesn't seem to be back yet so we will go to Dr. Radford.

DR. RADFORD: I would just like to follow up on a point that Becky Moon made.

I think it's the concern of a lot of us: How does the scientific evidence get factored into the decision-making process?

And the impression that a lot of people have, and maybe a lot of people in this room, is that the scientific community produces nice clean evidence which is easily interpreted and, therefore, because it is much more quantitatively precise than the evidence that is obtained in the economic realm, that we have a disproportionate degree of uncertainty.

I would simply like to point out that the scientific evidence is anything but clean. It is subject to exactly the same kind of religious, philosophic, and other pressures that motivate, perhaps, some of the difficulties in the economic field.

And I think the example of the scientific uncertainty or, at least, scientific disarray, if I may put it that

way, of the whole question of the effects of low levels of radiation is a classic example of a way in which the scientific community can be swayed, I believe, on either side by their emotions and so forth.

So one step we are taking to help maybe correct this situation a little bit is to hold a symposium in Pittsburgh, and this is a sales pitch and I have brochures for all members of the committee and I've handed out several already; and I think I will have enough for some members of the audience.

It's going to be on April 28th to the 30th, and just to give you the title of the symposium, it's "Epidemiologic Studies as a Scientific Basis for Environmental Policy-Making". And, of course, I think everybody in the room recognizes the hot potato that is.

On that note, I would simply like to point out that we need to get our scientific house in order, just as we need to get our economic house in order.

CHAIRPERSON BENDIX: Does anyone on the panel want to respond to Ed's comments?

DR. CLARK: There is certainly disagreement. The scientific information is certainly as uncertain as the economic.

DR. ASHFORD: I maintain it's much more uncertain. Science is reductionist as a discipline. It tries to control experiments, to isolate one causative factor, do a neat rela-

tionship on one dimension.

And when you do an animal experiment and isolate your test substance, life isn't that way. When you try to extrapolate to real life situations, previous histories of exposure, distress, it's not that it's always worse. It's that there is a good probability that it may be worse.

And how risk adverse you are, really, has to be factored into how you look at that data. Scientists tend to want to simplify life. That is the thrust of scientific inquiry.

And, by the way, the real work that is to be done - it's difficult on the benefit side of the equation, which is to construct a risk profile, a probability of harm for a real population. It couples the techniques of toxicology, epidemiology, and econometrics.

It almost takes a superhuman person who understands how to deal with cohorts, mobility, different age groups. Calculation is very difficult.

You begin with a dose response curve for an organism, but that is the simplest part of the job because that dose response curve has to be superimposed on people with varying characteristics and multiplied through; and it is a very difficult task.

I have done it. Other people have done it. It's immensely difficult to do correctly, and terribly easy to do incorrectly.

We don't yet have a science. It's not risk assessment in the sense of dose response. It's risk assessment in terms of target populations. And we have not yet sophisticated our techniques to be able to do that; and the number of scarce resources in terms of people that are able to do that work is very small.

CHAIRPERSON BENDIX: Lou, there were some points you wanted to clear up?

DR. SLESIN: Yes. I'm not sure who to address this to, but before you said that the agency had decided to go after a specialist, before the break.

I applaud that decision. I was wondering, given the performance of OTS on the schools, asbestos and schools, and the decision originally that they should go with a voluntary program over a mandatory program, who in the government thinks about a decision like that in the context of how much money is being spent in other parts of the government, like NCI and NIH, in general, on cancer research?

The numbers we're talking about are billions of dollars a year in research on cancer, of course. That is a pressure group that builds up with that kind of money being pumped into it.

Whereas, perhaps, there is not a similar pressure group to look after the schools and the children in them.

But how do you work with prevention there in terms of

getting the asbestos out so we don't have to, perhaps, worry as much about finding a cure? How does one look at those two budgets at the same time and reach one decision on schools and another decision on the cancer budget; if there is some clearing house in the government to worry about those kinds of decisions?

DR. CLARK: Well, there is, I guess one could say. There would be a clearing house which would probably be OMB. I don't know if Henry Beal told you yesterday or not, but there is a suggestion that we start a formal analysis at that time, another one of these on top of all the other analyses we are doing.

I get sort of defensive when you make suggestions like that, but, yes, thre is going to be an analysis to determine the impact of our regulations on other governmental units.

It will be very hard, I think, to relate anything we do on asbestos in schools with a budget of NCI. I think NCI is going to be doing research on carcinogens, and there are many more than just the asbestos in schools.

There might be a small reduction, there, because they are doing some work that is related, but that budget tradeoff is not going to justify the regulation. It's going to be relatively small.

So far, I guess, I have to admit it's not formally taken into account and I think, unfortunately, it may be in

the future.

CHAIRPERSON BENDIX: Ted, you had a comment on this point?

DR. RADFORD: On this particular point, yes.

I would just like to say that I quite agree with Toby: nothing is going to happen of that nature.

We made an attempt, when I was working the CEQ back in the days when Toby and Steve Jellinek were in it trying to bring some rationality into the whole cancer area in relation to environmental influences and to try to stimulate research which would define what the hazards were in the real world.

And it was a complete failure; and I learned the hard way that these agencies have enormously effective ways around any efforts to look into their practices, do anything about them, change priorities or anything else.

Of course, the NCI and NIH have been essentially diagnostic and therapeutic medicine, not preventive medicine at all. You can look at the budget allocations within NCI to see that.

But one little glimpse that I recommend to anyone interested in this question is to look at this co-called Labosy Report last year, which was an inter-agency group to evaluate the federal radiation research program in detection of low level effects of radiation.

There the numbers were spelled out and they made very

interesting reading, very large chunks of money going to the government laboratories for, quote, basic research, unquote.

There appeared very little, relatively little money going into the study of effects on human populations and almost none, at that time, going to universities as distinct from Department of Energy or, let's say, NRC functions or other federal agencies that were using the research, in house, or directly contracting with non-university sources.

So that we don't get a very good glimpse anywhere in the federal establishment as to where the money actually goes and that tells you where the real priorities are in very loud, stentorian terms better than any statements made by any administrator; and you look where the money goes, and it's not going into preventive strategies. That's for sure.

CHAIRPERSON BENDIX: Did you want to comment on that?

MR. MOONEY: A couple of comments. I want to go back, very quickly, to the reference that was made to remarks apparently offered by Monty Thodow.

I didn't hear them and I won't presume to interpret what Monty meant in a statement which I didn't hear, but I don't think there are many of us - whether we work for companies or agencies or institutions - that have budget and people and more things to do than we have time who don't, in some way, engage in a process of sorting out what we're going to do with our time and where we're going to spend our dollars.

Perhaps he said something to the effect he didn't use a benefit-risk approach, but everybody uses something that I think involves those elements in figuring out where to put their priorities. I happen to think the right process is a very constructive and positive process, and I really am puzzled that people take issue with it or find it an intrusion.

We seem to be a government system that's built on checks and balances; and, to me, it is just another cross-check that is saying, "Hey, have you thought about this," or "Have you thought about something else?"

I do think if we press it to the limited extreme of trying to put precise numbers on everything, things would fall apart because I don't really believe you can do that, but there is the middle ground that I believe Bill Sutton was getting at: that that shouldn't make it less than legitimate to at least talk about the economic impacts, even if those can't be quantified right down to the last penny.

So I think it's a constructive process and I'm happy to see it going on, and I'm sorry frankly when I hear there are voices outside of the industrial community, within the government, that contend that the bureaucracy is a system that is out of control.

When I hear statements like that being made by people in the Congress and people in the White House, I get a little nervous.

I suppose it's all right for agencies to be doing their thing as long as that happens to be something with which you're in agreement, but it does scare me a little bit if there isn't a check and balance; and I think it's reasonable for an agency to address.

With regard to a remark that was made by Dr. Ashford, I am thrilled with the hypothesis that more regulation is going to deal with the problems of stimulating innovation and technology development in industry.

I don't happen to subscribe to that and I can agree with the fact that certain regulatory actions have led to the development of some new technologies to deal with particular problems.

In that context, I think there is something to be said for it, but I'm not sure I would, therefore, extend it to saying that we're going to revise the whole business system by more regulation.

We are dealing with crystal balls, I suppose, and what happens over the next ten years if we did take a broad stroke regulatory approach where somehow the process was simplified and the agency didn't have to concern itself with cost? And suppose it could take tremendous actions along the lines that are on the books in that list of, what was it, 180 or so regulations in process under EPA's authorities that was mentioned yesterday?

I wonder if there is anything, Nick, to address your thesis, in the Food and Drug amendments of '62 which added an interesting new dimension which I don't think I take issue with, but one might postulate: If your thesis is correct, the Kefauver amendment should have, perhaps, stimulated drug technology and weeded out some of the lesser firms and the things you associate with increased regulation.

DR. ASHFORD: It's funny you should ask that question. Let me address a couple of things, and I apologize for being verbose.

One is that I don't think that we ought to be undertaking regulation for the purpose of stipulating technical innovation. There are better ways to get the business community going.

All I'm saying is, it may not look so bad as the omenous predictions of the demise of U. S. industry.

There is considerable evidence for the stimulating effects of, particularly, product- and process-oriented regulation. Some of the evidence is in and some is not.

It will have to be an article of faith for a while, and I can give you evidence that exists and you can judge it for yourself.

I am honestly cautiously optimistic about what I'm saying, but let me answer your specific question about FDA because I am in the process now, under National Science

Foundation sponsorship, having just completed a report of the effects of the Kefauver amendments on changing the nature of innovation in the pharmaceutical industry.

MR. MOONEY: I feel like a set up.

DR. ASHFORD: I said, funny you should ask that question.

The final report was delivered last Friday and the results are the following. These are rough, but they're statistically significant:

That the nature of the drug development process has radically changed since the Kefauver amendments and it has moved from a serendipitous lottery approach to a much more systematic look at the drug opportunities in product development - just exactly what you'd expect.

Let me just say that the Peltzman Study that merely counts the number of new additives has changed. Unless you therapeutically wait for importance of new products, you can't merely count the number of new products and ask what they do. But the evidence is beginning to mount significantly that the process of innovation has really changed.

Now, whether it was worth it, whether the costs are worth the benefits depends upon how you view increased safety and more efficacy versus cost to the consumer. There's no correct answer to that.

But my thesis has been - and it seems to be borne

out - that the process has actually changed.

I once thought, but I did not suggest, that we require technological innovation impact statements. I quickly withdrew that recommendation.

MR. MOONEY: I think it's worth pursuing.

DR. ASHFORD: Let me address your earlier comments which I think are important.

On the surface, if I look at the RARG requirements, I can hardly be opposed to them. I think a rational process is required for agency decision-making.

Where I might depart is that I think it exists to a large extent already. I think it has existed; and where I object to the demand of a rigorous analysis - demand, even if the analysis is not rigorous, a rigorous demand for analysis - is that, in practice, if you look at the history of the way the Council of Wage and Price Stability has interfered, undemocratically, with the administrative process, I think you have to come to a different conclusion about whether the intellectual exercise is worth it.

I'll be specific.

On the cotton dust standard, we have countable agency heads who were taken to task in public oversight hearings and the hearings on the standard. Everyone had their chance to argue about the economic impact: whether the costs were worth the benefits.

The hearings closed. The Secretary of Labor is obligated to make decisions on substantial evidence on the record as a whole.

The fact that pressure was put on Secretary Marshall and he was denied access to the President while he was lobbied by the economists in the White House leaves me cold.

I don't care whether cotton dust is 50 parts per million or 25 parts per million. I don't think the kinds of hairs we begin to split matter that much in the whole picture, as much as that the decision be arrived at in a democratic process.

I'm deeply concerned that ex parte communication after the regular hearing is closed, which is being imposed upon the environmental agency, really deprives us of the purpose of the administrative process. I don't think that should be allowed.

That is, in fact, what happened. That is, in fact, what has continually happened with regulation.

Yes, Sir Douglas appoints, Douglas Marshall, but he has delegated the power to administer by the Congress, and it is an interference, I will maintain, of the separation of powers to deal with post-hearing back room maneuvering.

I don't have any problem with informal communication. That's how we avoid the conflicts. But I'm deeply concerned, as a democrat, small "d", with the process.

I want to tell you one example and this is on the record of how the interference occurs in the hearing process. We have heard about the magic benefit to cost ratio, cost effectiveness.

Let me give you a simple example of how an evaluation by the Council on Wage and Price Stability or like bodies can distort the analysis, and that is in the case of noise.

There are two basic ways to go with noise: require engineering controls; or stick hearing protectors on workers.

Now, you are hoping to get benefits of hearing loss reduction under both measures of control. It is obvious to everyone that hearing protectors are a lot cheaper than retrofitting.

The matter of the fact is that hearing protectors are 75 percent effective. That's what NIOSH says.

Let's give the upper limit and say that, 75 percent of the time, they will do the job an engineering job will do at one-tenth the cost.

If you construct a benefit to cost ratio for those two different approaches - one, a given hearing benefit for a certain price and, the second, 75 percent of the benefit at one-tenth the cost - it's very clear that the most cost effective approach is to stick hearing protectors on the workers.

That, Calp said, had to be the way OSHA went because that was cost effective. Cost effective for whom?

What about the 25 percent of the workers who weren't protected?

It's an equity consideration. It's a statement that has to be looking at within the context, in this case, of the OSHA Act; and ask if the Act was meant to protect 75 percent of the workers or as many workers as possible?

Congress spoke to the latter. The fact that it is not cost effective is really irrelevant, interesting but irrelevant. Cost effective for whom?

You can make things cost effective so that a very small percentage or not the intended population is to be protected: not the asthmatics, not the pregnant women, not the hypersusceptibles, not the people who suffer enzyme deficiencies.

The question is: Where does the legislation go? At whom is it targetted? And is the Council on Wage and Price Stability demanding these analyses, really, trying to reorient the legislative mandates to their own liking without accountability through this mechanism of cost effectiveness demand?

It is a very clear thing as to what's happening.

My opposition to the process is based on democratic principles: that is, I don't like post-hearing maneuvering; I don't like techniques being thrown up which artificially make an agency look bad by saying, "You can do the thing," 75 percent of the heart protection, "at one-tenth of the cost. Aren't you financially irresponsible?"

That's what annoys me in the process, not the intellectual exercise.

MR. MOONEY: You, therefore, support the conventional oversight means or dealing with regulatory mismanagement?

DR. ASHFORD: I support the hearing process, the checking by the way of the courts. The courts have continually stepped in and argued whether this is concrete to the position.

If you look at the legal decisions, the courts have done a remarkable job of having tremendous insight as to where the Congress struck the balance. You want to amend the OSHA Act? Damn it, amend the OSHA Act.

But let's not try to divert resources to continually fight the legislative battle all over again.

MR. MOONEY: The benzene division will undoubtedly be very important to the issue or what the intent of Congress was. Unfortunately, that intent is a little obscure at times, which is why I guess we have the court debates we do.

The only follow-up comment I will make on your drug report: I'm glad I asked a timely question. I will suggest that the process - at least in my sense of what constitutes innovation from a business perspective - the process is less important that what comes out the end of the pipe.

If you fiddle with the process, you can fiddle with reorganization in EPA, which we'll probably talk about a little later, but it's what comes out at the end of the pipe that

generates the business that translates into the jobs and, hopefully, some cost and benefit to society that constitutes meaningful innovation.

So I think, at least on my query regarding this, the jury may still be out.

DR. ASHFORD: When you change the nature of drug development, how do you evaluate, as I indicate, whether it was worth it?

MR. MOONEY: It's a different issue and lots of books have been written about the subject, but I thought you might have something to teach us on your thought about what I think was a substantially increased mention of regulation over a whole business area.

DR. ASHFORD: By the way, it's interesting that they went to efficacy and not safety. It's the only industry in the world that didn't have to say its product could do something in order to sell it.

You wouldn't buy a car if it didn't work. You don't know that with a drug.

DR. CLARK: Can I make a comment on Nick's point?

I think I will have to say that I have a lot less confidence in the admission of the court than apparently Dr. Ashford has.

MR. MOONEY: I was going to ask him if he preferred the fifth circuit to the first.

DR. ASHFORD: I will take the whole lot. I will throw the whole fate of the environmental movement to the courts, in general, because if you look at it they have substantially improved the level of debate.

If you look at the Leventhal decisions as scientific reasoning documents, they're marvelously impressive. Even the economic analysis of the D. C. Circuit is impressive.

I think we're growing up. We're moving into a transition period.

I will throw my lot with the courts, even if the fifth circuit reversal is sustained by the Supreme Court, which I don't see as possible by the way.

MR. MOONEY: Let me make a note of that.

DR. ASHFORD: It doesn't cost me anything to predict.

DR. CLARK: Have you read The Brethren?

DR. HARRISON: Let me just clarify that I was talking about the RARG reports and we mentioned the Calp filings.

I don't know about the specifics of the noise, Calp's filing, but two points I think are in order. One, those filings in the RARG review are on the public record and are filed in the public commentary. So in terms of their influence on the decision or any delay, they really don't cause any delay.

What they do is add to the number of comments that are filed in our public record in the public comment as decided by the agency.

I think in terms of this noise case, what might have been said in a review, if the facts are as Nick suggests, is that you might be able to structure a decision on how much noise control to require, what kinds of noise standards to set, by saying both:

You can go part way by using personal protection devices; and, if you want to go farther, the costs are going to be greater relative to the benefits.

I don't think, typically - and, as I say, I'm not familiar with the details of this particular COUPS filing, but typically they say you ought to stop at 75 percent control. It simply points out the characteristics that, in the decision you have in front of you, you can get a certain amount of the benefits at relatively low cost.

Then if you go beyond that you're likely to have higher costs relative to any increase in benefits.

So that is another way of saying it.

DR. ASHFORD: I wish it were so, David.

Unfortunately, you're my friend, and your boss, George Eads, is the one who wrote in print the benefits of this regulation do not exceed the cost.

I don't know how you can compare them anyway because it's hearing loss with dollars; and, secondly, I am afraid your sensible approach to the issue does not characterize what the analysis has been in the past.

That doesn't mean that we should say it can't be done correctly. COUPS is still involved in this business.

DR. HARRISON: COUPS does fine on the public record, too.

DR. ASHFORD: At the President's Council on Wage and Price Stability, there is tremendous leverage when you have this kind of a body making commentary not only on economic but scientific issues to which is has no expertise.

They couldn't evaluate an epidemiological study if they knew what one looked like. So you're talking about, benefits do not exceed the cost. They have no way of interdependently evaluating. They are not equipped to do that job.

MR. BARAM: The chief offender has been the CEQ. They feel not constrained in any way by the regular or the open notice in common proceeding, but also RARG and COUPS have done a lot of work on the record, whether it's airborne lead, whether it's ozone or cotton dust, there are many cases.

Whether they changed their policy in the last few weeks, David, that's another matter.

DR. HARRISON: I want to clarify that RARG, itself, does not go beyond filing of comments. RARG is the group that includes the regulatory agencies as well as --

MR. BARAM: Nick made the point earlier about the separation of powers doctrine. Don't you feel RARG is meddling in a lot of the internal conceptualization of what the agency

is doing, not in terms only of cost effectiveness but also whether it's worth going after certain targets.

There is a principle here that is very important for us to remember: that Congress provides the statutory agency, the funds to the agencies, funds the agencies. They're the sole source of authority.

And yet we have, today, in essence a whole new doctrinaire approach.

The important decisions, the major and significant ones which cost more than a hundred million dollars or whatever the measure is, are the ones that are precisely being routed through this process.

DR. HARRISON: I have to clear up again.

MR. MOONEY: It is, indeed, a political process.

DR. HARRISON: I understand there are different opinions among legal scholars and lawyers as to what the appropriate role of presidential advisors is in the setting of regulations. I think that is the issue you're talking about.

RARG is a group that is composed of regulatory agencies and files in the public comment and ceases to exist in terms of a particular regulation after the public comment period is closed.

DR. RADFORD: Selina, if I could make a couple of brief comments because I'm going to have to leave for a while and come back this afternoon.

First, I will leave a number of these notices at the back of the room.

With regard to the noise issue, I would just like to back up to what Nick said. The first point is that personal protection is no way to go in protecting the worker from hazard. That applies to respirators, noise control and so on; and I have seen some of the technology that is available in noise control.

I'm convinced, despite the capital costs, they are cost effective, anyway, across the board. They will improve worker efficiency because when you work in a noisy environment, you can't have voice communication and so on.

So I will drop the noise issue from the medical point of view right there.

I would just like to say, backing away from this whole regulatory process and getting to the question of the way in which the regulations potentially may influence the industries, I do a small amount of consulting with a company which I will not name but which is a moderately big company and one of the things they have me do is to look over their operations and see if I see any problem areas.

And I come up with a few, as I think most anyone who is knowledgeable in the field could do if they were around and were given pre-access to all operations.

I have been very impressed with the fact if I flag

an agent as a potential problem, they are usually able - and, in most cases so far, the really hot ones - to eliminate that from their process; and, in at least one case I know of, they made a bundle on it.

The conversion to a different process system ended up that they were economically far better off by a substantial amount.

Now, the point of that is, we can come up with antidote pill stuff like that all over the place, but the point is one of attitude: that people do things because they've always done them that way, and we've got an enormous amount of inertia built into the system because of that.

And all of this talk about cost benefit is basically because we've got this inertia in there. That's one of the big elements there.

In this particular case where they make a lot of money by converting the process, they had always done it that way and they had never thought, by doing it a different way - which eliminated the hazardous material, which was both an occupational an environmental hazard - that they could save money.

In the first place, they didn't have to buy the product which was expensive. So, anyway, I am just saying - and I find this in labor - the inertia in labor is enormous.

We don't want to wear hardhats because "I'm a tough

guy" routine, or we don't want to adhere to safer practices because, "My daddy never did it that way."

There's a lot of inertia in government and there's certainly a lot of inertia in academia.

So we can go on very extensively about that, but oftentimes it just takes a little bit of cerebration on it and, my God, you can solve these problems if the message of the representatives of labor and industry can be gotten across in this whole area as, let's look at a new way of doing things.

And, on that note, I will heave. But I'll be back.

Thank you.

CHAIRPERSON BENDIX: Thank you.

Becky?

MS. MOON: I pass. I've forgotten what it was.

CHAIRPERSON BENDIX: Ted, I don't think you've had any comments this morning.

DR. CAIRNS: This is all pretty well far out of my field. I'm interested in religion, but I don't argue about a person's own religion or the basis for it.

CHAIRPERSON BENDIX: Is there anyone on the panel who would like to make a final summing up commentary?

DR. CLARK: I don't see the possibility of doing that.

CHAIRPERSON BENDIX: I will, then, make a comment about what I see as a commonality in one respect between the

discussions we had yesterday and the discussion this morning; and that is that yesterday we had spent a considerable amount of time considering the question of how much documentation is enough to justify the promulgation of a regulation and if, perhaps, one of the reasons that it takes so long to get a regulation out is that too much documentation is being put together to explain why the regulation is needed.

I think we are seeing today what looks like another facet of the same problem: that something which is reasonable, done in moderation, may become unreasonable if it is overdone; and are we bogging everything down in overanalysis from many different standpoints - too much paper?

And do we need to look at ways of establishing criteria for how much is enough?

Perhaps we ought to take a look at the motto that CEQ has in saying a ten-thousand page environmental impact statement is ridiculous and let's turn it down to 150 pages and write something short enough that people will read and find something out about it.

MR. BARAM: And the court will find it inadequate.

CHAIRPERSON BENDIX: I'm not sure that the court will find it inadequate if it's done properly.

Thank you very much, to all of the panel members, for a very interesting and productive session. We appreciate your contribution.

I believe that Marsha may have some administrative matters that she would like to bring up.

MS. MOON: I think this has been one of the most informative and interesting sessions we've had in a long time.

MR. MOONEY: At least we've gotten some divergent views from the three of you.

MS. RAMSEY: First of all, I have travel vouchers. Does anyone need one? You have to fill them out with receipts and all of those things.

CHAIRPERSON BENDIX: You also have forms for filling out expenses.

MS. RAMSEY: No.

Who needs the other forms?

MS. MOON: I need the travel voucher.

CHAIRPERSON BENDIX: In view of these issues that have been coming out about the adequacy of documentation, I'm interested in knowing whether the members of the committee would have any interest in passing a resolution urging OPTS' staff to examine opportunities for limiting documentation as a means of expediting the rulemaking process.

Is there any sense of the members at this point?

DR. EISENBERG: Maybe that's something we can talk about with Steve when he comes in this afternoon.

CHAIRPERSON BENDIX: All right. We can defer the matter.

MS. MOON: Would you have a specific area that this recommendation could go to? I remember looking at our files pile and we sort of went, "Oh." I have a very strong feeling that there was a lot of concern about this big pile, be it from the industrial standpoint or any other standpoint, that we felt they had done an overkill on this.

MS. RAMSEY: There are a lot of different chemicals that they were addressing, and it wasn't just for one.

MS. MOON: I'm just referring back. That was the conversation and the presentation we were all groaning about.

CHAIRPERSON BENDIX: My understanding is that 500-page package was condensed from a 1000-page earlier version, and my question would be: If that 500-page document was further condensed down to 200 pages, would we have something that might be even more effective and more clearly point up what the clear issues are?

MS. RAMSEY: Can we talk briefly about our agenda recommendations?

MR. BARAM: I don't think you have enough committee membership here to pass a recommendation. And, also, I don't know if these papers are slowing everything down. That's a different issue.

CHAIRPERSON BENDIX: That's true.

MS. MOON: I think you're going to have to wait for Dr. Radford to get back. You have to get Lou up here.

CHAIRPERSON BENDIX: Informally, does anybody have any suggestions for an agenda for the next meeting?

In particular, I would like to know if anybody has any ideas for other issues which might be suitable for the kind of format we had this morning, which I think was very helpful.

MR. MOONEY: That was very helpful, and I think, in tying back to it, we had a document in our package. It didn't end the discussion, but it's the EPA contract or, at least, the communication from --

MS. RAMSEY: That was the strategy that was the result of the retreat.

MR. MOONEY: No, not the strategy document, but Judy Nelson's document to Joseph L. Kirk of ICB, Incorporated which authorizes this economic study relative to TSCA. It fits on a track that is going to apparently lead to all tasks completed by August 30, 1980.

And I wonder if this is something we might want to at least track in our meetings with periodic updates from Judy.

MS. RAMSEY: Judy was not able to come today.

MR. MOONEY: It's a document called -- Well, it is a letter.

MS. RAMSEY: Where was that?

MR. MOONEY: I've got so many papers in here.

CHAIRPERSON BENDIX: I think it was in the package

you sent out to us yesterday.

MS. RAMSEY: That was in the PMN package.

MR. MOONEY: Oh, it's in Blake's package.

In any event, it's a communication of November 10 from Judy Nelson to Joseph L. Kirk of ICF, Incorporated in regard to TSCA Order Number 3, Contract 68-01, et cetera, but it's basically dealing with an economic analysis, a number of important aspects of TSCA implementation, and it is generally, it would seem to me, to be appropriate to the subject we were talking to today; but more specifically focused on TSCA.

MS. RAMSEY: Would you see a discussion like that being a part of a subgroup on testing and PMNs, or do you see that as being something broader that the committee should address?

CHAIRPERSON BENDIX: What is the nature of this contract? Is it covering just a PMN or more generally?

MS. RAMSEY: New chemicals isn't it.

MR. MOONEY: It's develop a work plan covering all substantively gathered data, gather data by literature searches, et cetera, to conduct analysis of the PMN requirements, assess the feasibility of developing a methodology for doing formal economic impact analysis, conduct the economic impact analysis, and analyze it.

I think the net of it is the PMN focused economic study.

CHAIRPERSON BENDIX: It sounds to me like something that might be worth having a progress report to a subgroup and have the subgroup evaluate whether it was something that ought to be brought to the committee as a whole.

[Discussion off the record.]

WHEREUPON, at 1:00 p.m., luncheon recess was taken.

AFTERNOON SESSION

2:00 p.m.

CHAIRPERSON BENDIX: I would like to ask the committee members if the committee members could return to their places.

I know Mr. Jellinek has a very busy schedule.

Welcome, and we're looking forward to hearing the latest about the hearings you've just come from.

MR. JELLINEK: First of all, let me apologize and extend Costle's apology for not being able to be here. He is, this week, I think having to testify five different times in hearing or appearing for hearings all week.

He has to make sure that we work something out for the next session, of this next meeting of the group so he can attend.

When is the next meeting?

MS. RAMSEY: The 19th and 20th. You are going to be in Paris.

MR. MOONEY: Of course, we could meet you in Paris.

CHAIRPERSON BENDIX: If you want to take us with you, we'll reluctantly consent.

MR. JELLINEK: We will get together with Doug as early as possible.

ASSESSMENT OF TSCA IMPLEMENTATION AND DIRECTIONS

MR. JELLINEK: The hearings today were before the

Senate Appropriations Committee as chaired by Senator Proxmire and we were extremely uneventful as far as the Toxic Substances Control Act goes.

I didn't get one question because they go through the budget document by program as the programs are displayed in the document, and Toxics is toward the end of the document. So they'll be to us tomorrow.

But Senator Proxmire is probing - in his questions, he's concerned about waste and the efficient, effective use of the taxpayers' dollars, but he also has been historically a very strong supporter of EPA and EPA's objectives.

Two weeks ago, we appeared before the House Appropriations Subcommittee and it is always hard to predict how these things go, but I came away feeling fairly good about it.

They were concerned about our ability to hire up to our projections, and we have not been able to do that the last couple of years and they have been somewhat concerned about us being overly optimistic.

This time, we gave them a very detailed assessment of what we thought we could do on our hiring and our spending, and we think we can fill all of the positions that were authorized, but we don't think we can spend all of the salary money that goes with those positions, although we think we have the numbers looking very good to justify that we think we'll get around to about 95 percent of the salary money; or,

the way it's expressed in the budget, full time equivalents.

We'll get about 95 percent for that.

Today, as of Friday, we had 423 on board and we are authorized something close to 500. So we still have 80 or so vacancies, 75 vacancies or so. But we have a lot of commitments out. So we think we can get a lot closer this year to making our projections for our budget and hiring than we did in previous years.

DR. RADFORD: Steve, is this a general problem?

MR. JELLINEK: It's a problem with the agency, yes.

It's a worse problem with new programs that have a lot to do and it's been aggravated by a couple of freezes and by our lousy space conditions which some candidates look at and decide they would rather work for National Cancer Institute or for private industry or for academia.

I don't have anything in the way of a report, but I'm prepared to answer a broad range of questions in detail.

CHAIRPERSON BENDIX: I would like to start by asking a question which may be premature. You may not know the answer yet.

But do you have any sense of what the affect on EPA and, in particular, on OPTS will be with the new presidential directives at budget cutting?

MR. JELLINEK: The bulk of the FY fiscal year 1981 reduction in budget outlays will be taken out of our major

construction grant program so that the operating programs of the agency will suffer only minor cutbacks, comparatively minor cuts. Everyone will suffer some cut.

The details have not yet been worked out, but frankly compared to what other agencies are experiencing, EPA has I think been very effective at persuading the Office of Management and Budget that the agency generally - the agency's operating budget is generally a very tight budget and there is not a lot of fat; that the agency, over the past two or three years, has done a tremendous amount of reprogramming within its base to cover major increases in new programs.

Most of the increase in the toxics programs has been taken out of the hides of other programs in the agency, and many of the shifts and increases in other priority programs have been taken from base programs.

They are not non-important programs, but just programs which just represent the fact that we could not go to Congress every year with a huge marginal increase. There is just no way we can get it, either from Congress or the President.

So we have made changes and shift in our own base.

DR. EISENBERG: Just as an aside, that construction grants program - are the funds just being impounded, or are they being cut substantially?

MR. JELLINEK: What is happening is, it is a fairly

complicated formula which I am sure will be explained in detail to the states, if not already within days, but it involves, primarily, deferring obligations in 1980 in order to cut outlays in '81.

There are a couple of complicated accounting practices involved which I can't explain with any precision, but the means of carrying out this cut in '81 outlays will primarily involve deferrals of funding for construction grants.

MR. BARAM: I read recently about the National Toxicology Program over in HEW.

Is there any attempt anywhere in government to weave all of this together somehow so that it is the most efficient support for this program?

MR. JELLINEK: I think the National Toxicology Program represents a very clear attempt at the weaving. I mean, it's a major part of the fabric.

EPA is a member of the executive committee of that program and I represent EPA on the executive committee as an alternate to Doug. Doug is the official representative and attends most of the sessions.

We participate in not only setting the policy for the committee, but the staff participates in selecting chemicals for priority testing and we try to balance those that ought to be tested using government funds versus those that should be tested using private funds.

We try to balance our ability to act on the testing and the timeliness of our actions versus the timeliness of their actions.

So I think the program was set up to meet regulatory agencies' needs.

One of the major needs we have beyond the testing of chemicals is the development of new test methods and the validation of emerging, sometimes even existing test methods. We have been working to make that a major function of the toxicology program because we just see the need for developing it for promulgating under Section 4 good, effective, hopefully cost-effective methods for testing chemicals when we ask industry to test under the test rules.

The research community and the government and academia should be mobilized to help us by developing and validating those.

MR. MOONEY: Steve, from the standpoint of disciplines in your hiring process, are there any obvious places where we're having difficulty or it is across the board in terms of your staffing?

MR. JELLINEK: I think we're having the most -- Pathologists are just about out of the question. So we have decided, over a year ago, to get most of our pathology done through consultants who contract.

We are having pretty good luck with toxicologists and

other biological scientists and chemists. I would say the biggest problem - there are three big problem areas: economists; industrial chemists, that is people with real industry knowledge; and chemical engineers, also, people that can understand the hardware side.

So we have been doing better at that lately than we had in the past, in the earlier part of our program. But I would say, at this point, it's not the toxicologists or the biochemists or the biologists who are the problem. It's getting experienced chemical engineers, industrial guys, and good economists.

Economists are a dime a dozen. Good economists are a different story.

CHAIRPERSON BENDIX: That is what I was going to ask.

Is it your problem that the average economist doesn't know anything about the chemical industry and the kinds of problems you have to deal with?

MR. JELLINEK: I can't go into detail on that aspect of the problem, but we are trying not to compromise quality or standards. We have been trying to attract very well-qualified economists and operations research staff, also, that ilk.

DR. SLESIN: Would you like to talk about the reorganization package? I have some questions.

Maybe you would tell us, first, what you were

thinking about when you decided to embark on this and get into specifics.

MR. JELLINEK: Well, there are two major reasons for the reorganization.

One was that it just had become very obvious to me that a trifurcated situation was essentially inefficient and adding time to the production of decisions. It was engendering a certain level of attention that might not otherwise be there, and it was overforcing too many decisions backward to me that really should have been made by officials at lower levels.

The DAAs each had a right of thinking of themself as doing a very important job in most other agents. DAA has a total hegemony over major law or a major section of a gigantic law and can organize and direct and manage and make basic policy on his or her own, getting general policy guidance and directions from the Assistant Administrator.

In the case of the toxics program, because the Act is an organic act and because you can't separate one section from another and expect it to carry out the objectives of the Act effectively, the three-headed DAA-ship has lead to more problems that it was worth.

And I just decided, after a lot of agony, thinking that even though reorganizations are disruptive, that this one would be an intermediate one and certainly the long run. I

hope the intermediate run and maybe even the short run are major positive moves in terms of getting things done more efficiently and more quickly under TSCA.

The second reason why, frankly, to elevate the level and the importance of the integration function, particularly and especially as it relates to the integration across various agency programs of chemical issues and problems.

And, for that reason, that function is proposed to be located in my office with a significant staff support.

So those are the two major reasons.

Once we made those changes, then we made a number of other changes that we thought made sense; but, for the most part, most people in the program will be working on the same things that they were working on before the reorganization and will be working for the same immediate supervisor that they were working with before the reorganization.

Just to summarize, to make it more efficient, to make administration of TSCA more efficient, and to give more stature emphasis to the integration function.

DR. SLESIN: As you know, some of our concerns revolve around the ITC list and meeting those deadlines, and now we see that Warren will have a great deal more responsibility following up all of the other rulemaking activities under the various sections of the Act.

Are you going to take some load off Warren to

facilitate test rule development?

MR. JELLINEK: Let me answer that question this way.

I don't think that the problem that we've been having with Section 4 is a management problem. I think it is either a legal problem or there's a problem of going down one basic policy approach towards Section 4 as opposed to what might be alternative policy approaches that might result in being able to test chemicals more quickly.

I frankly think that, without the reorganization, if we kept doing test rules the way we've done the first test rule, it would take too long. It was just unacceptable.

We are going to have to figure out ways to get AMRPNs or notices out more quickly with less work for ITC or we're going to have to figure how to approach testing chemicals in a completely different way.

DR. SLESIN: I heard you speak in New York about no decision being a decision, and I must say I like to hear that and applaud that.

But what you're saying is you're going to have to find new ways of thinking through these problems and a new policy direction for the program, which I also agree with.

But new direction and policy means new thinking, and I'm sure that means time. And if Warren is directing that, surely does that make a difference if he has to make decisions on 14 other ruling procedures?

If you are starting down a new road, is the ball game still in Warren's court?

MR. JELLINEK: You know, as a DAA, Warren is going to have to play and will be playing a major role in developing new policy. He will be spending proportionately less of his time on Section 4. There is no question about that. But the kind of time he spends on Section 4 will not be the kind of time he has been spending on Section 4 up until now.

He's been spending a major portion of his time and been in the trenches on various issues.

He is going to have to distill his time and focus it on the policy direction because he's not going to have any other choice. He's going to have to do other things.

He's going to have to upgrade the quality of his attention, the percentage of his attention that he gives to Section 4. It's going to have to be high quality attention, and Joe Mirinda and Al Hertz are going to have to do more of the implementation of the policy.

DR. RADFORD: Steve, I know that you did not mention, you had difficulty in recruiting epidemiologists. And I wonder if you would say a word about the role of humanist studies in TSCA and implementation, and whether you see that as significant.

MR. JELLINEK: Well, we have that trouble recruiting epidemiologists, particularly senior epidemiologists to meet

the mission of the branch on epidemiology.

I can't respond in detail as to the role of human studies. They are extremely important and, as you know, they are the best studies we can get when we can get them and if we can get them.

But I don't see them as having any less important role than other major aspects of science. It is extremely important and the more we can get out of epidemiology, the better cases we can make and the more certain will be out ability to act.

Epidemiology is playing a major role in our asbestos proceeding.

DR. RADFORD: That is one where the epidemiology was already in place. I am concerned about what I perceive may be overstating the case, but I see numerous golden opportunities for evaluating human effects, effects on human populations on a variety of agents that we don't have an epidemiological base on, and I see the Act as providing a wedge for the acquisition of this data, which has not even existed under OSHA.

MR. JELLINEK: Could you be more specific?

DR. RADFORD: I think --

MR. JELLINEK: The acquisition of data that already exists, or the imposition of studies?

DR. RADFORD: The acquisition of the data, primarily, or making records available in order to sustain the claim that

no harm exists or whatever.

MR. JELLINEK: I think there are both opportunities in general and it is an area that we want to do more in and will do more in as we begin to attract --

We essentially have one or two epidemiologists on board, but I could be slight out of touch and I might be a month or two off, and the one that we have on board in the TSCA program is also working in a third to half of his time helping the pesticide program, in particular helping us on 2,4,5-T. So we are thin.

It is a well-deserved criticism if there's a criticism, but I know it's a constructive one.

DR. RADFORD: It's not really intended to be.

DR. CAIRNS: Steve, I don't have any clear picture of what happens after you impose a testing requirement.

Let us say there are nine manufacturers and two hundred processes, and you decide that thing has to be tested for carcinogenecity. What do you do now and what do they do?

MR. JELLINEK: I can't answer that in detail.

DR. CAIRNS: But you can tell me what you will do. You notify all nine plus three hundred processors.

MR. JELLINEK: I frankly have not been involved, at this point, in the details of the reimbursement and exemption procedures.

DR. CAIRNS: We have some stuff and I read it, and

it's sort of a policy of mine.

MR. JELLINEK: That's part of it, but we've got to come out with a regulation on reimbursement and I think those --

DR. CAIRNS: Who decides who tests? Not all three hundred are going to have to run tests.

MR. JELLINEK: No.

I can't answer that question.

DR. CAIRNS: What you're saying is, I think, that the issue will be forced when you face it, so to speak. You will have to decide what to do when you actually put out a test case.

MR. JELLINEK: That issue will be dealt with through the reimbursement proceeding because that is the regulation by which we decide to test, deciding who pays for the test.

DR. CAIRNS: Suppose somebody decides not to test?

MR. JELLINEK: They've got to test.

DR. CAIRNS: Well, the way I understood it, somebody has to test but somebody has to decide who that is.

MR. MOONEY: Ted, I might mention, there has been a major filing with the agency by CMA addressing some of those compensation issues, and there are a lot of open questions, I guess, that will have to come down to specific rules in the final analysis.

MR. JELLINEK: In the final analysis, everybody's going to have to test unless they can figure out to have

somebody test. It's going to be in the best interest so that everybody doesn't test.

I have read some of those comments that CMA sent in to our AMRPN on reimbursement. There was an awful lot in there that was encouraging in terms of the industry's apparent recognition that they're going to have to get together and figure out how to efficiently use the testing facilities and resources available.

MR. MOONEY: It's really kind of enlightened self-interest. The burden is on the industry group to get its act together and figure out how to do it.

The alternative in the final analysis, then, is the agency telling industry how to do it.

I think it will sort out that industry has done many, many testing programs on a cooperative basis. I am optimistic.

MR. BARAM: Steve, this morning Toby Clark, Nick Ashford and Dave Harrison put on a very good discussion with us. In fact, the two-day meeting has just been superb thanks to Marsha and you and the resources.

MR. JELLINEK: Mostly thanks to Marsha.

MR. BARAM: Toby mentioned that, in the new regime for regulation or regulatory decision-making in the agency, Toby's responsibility in OTS is to deal with the cost side and that the benefit side comes from Warren Muir, who is evaluating risks, more or less; and that ultimately the tradeoff or

decision is made by you.

I don't know whether that actually happened or whether that is hypothetical for the future.

But, in any case, can you tell us how you're going to play God on these kinds of decisions?

MR. JELLINEK: Well, Costle is going to play God. I'm not going to play God, yet.

We are trying to get some things delegated to me, but until those delegations, Doug is God, and certainly on the big decisions, he will.

But I don't recognize the construct that you're telling me.

MR. BARAM: That's what Toby said this morning.

MR. JELLINEK: The responsibility for developing both the benefits of regulation, in terms of the risk reduced, and the cost of regulation, in terms of the economic impacts and other social impacts associated with that risk reduction, and the development of in essence the data that leads to a recommendation of unreasonable risk or not is all within, I assume, the Office of Toxic Substances under Warren.

It is an integral process that will be contributed to by the various functions, the functions under Warren. The final decision, the weighing of the various options and analyses, will be done by Costle and myself.

The mechanism for doing that will be fairly formal

decision processes that will eventually end up in very formal things called regulations.

But that process involves an analysis of an assessment of risk and of benefit, and a kind of simultaneous weighing of them using both objective and subjective means.

MR. BARAM: Yes, that came through also in discussion: the need to deal with both objective and subjective kinds of information.

I guess what is of interest would be what constitutes a proper distribution of cost and benefits. Distribution of the issue seems to be a nagging question and must also be troubling to everybody involved.

MR. JELLINEK: The distribution process is one of the toughest in this whole thing.

MR. BARAM: Where the impacts are going two-fold one way and the benefits are on the other side.

Are there any guidelines? Do your formal decision guidelines have any guidance?

MR. JELLINEK: I don't know. It doesn't yet. It may. There are some very thoughtful people that are working with us and trying to help us define unreasonable risk, if not develop approaches to unreasonable risk that could involve decision rules of one kind of another.

It may not be, and I will be surprised if they would be totally objective decision rules. They may be decision

rules that involve ways of approaching data or ways of looking at different values as opposed to equations.

So we are struggling with that issue and are asking some very bright and thoughtful people how this thing, it grew. But until we come up with some formal way of defining or approaching unreasonable risk, we are going to have to do the best we can to tote up risks and benefits through a series of mental interactions and decide what we think is the right action on a particular chemical.

MR. JELLINEK: We do that regularly in the pesticides program and I think the toxics program will have many similarities, and already does, in the new chemicals area.

We are making decisions on new chemicals almost every day, certainly with respect to whether there is enough information or not and what to do about it. And we will be making decisions under Section 6 in TSCA in the same manner.

CHAIRPERSON BENDIX: Dr. Eisenberg?

DR. EISENBERG: Steve, I have two question, but the second one would probably lead out of the answer to the first.

In the PMNs, one underlying limit seems to be that you don't seem to be getting enough information for you to be making any kinds of valid judgments, and your people then take the course that since the information isn't provided to a large extent, it is not up to us to look at homalogs, to look at analogous compounds, search the literature ourselves, and normally

your time runs out.

All you spend your time on is a certain number of ends and the others run out.

Have you considered perhaps hitting a company with your first 5(e) action and then perhaps, after that point in time, you might be getting the information you need in the first place?

MR. JELLINEK: Well, first of all, we have received as of yesterday 83 PMNs and something like - I'm not sure about this figure, it could be one or two higher - something like 17 or 18 have finished the review process, totally finished the review process.

We don't think that any one of those that has completed the review process poses an unreasonable risk to the health and environment, hazard risk, as it is proposed to be used.

We are not getting as much information on these notices as we thought we would get and as we think we should get, and we intend to do a number of things about that. We are going to be taking 5(e) action, but will take 5(e) action only in a situation where we believe we can sustain that action.

In many of the cases that have already passed through the system, even if a chemical had little or no data with it, either the nature of the chemical itself or the use of the

chemical was such that it would be very difficult to sustain a finding that that chemical was going to cause the problem.

DR. EISENBERG: The point is, Steve, where you put the burden of proof. If you leave the burden of proof with the agency, that the agency has to make that determination, or you put burden of proof on the industry whereby they have to make a determination to tell you, "We feel this is sufficient information because of - - - "

MR. JELLINEK: If I had my druthers, I would love to have the burden of proof on industry throughout TSCA, but we don't have that luxury.

I agree with you that I think the 5(e) action will generate some response on the part of other submitters, and I agree with you, it would have been nice to get more information on most of these chemicals that we have not been given much information on.

I don't agree with you that we ought to tilt it at chemical windmills on 5(e). I think we should win the first 5(e) case because we know it's going to be challenged and, frankly, as long as I can justify to myself that even though it takes some staff work, that the ones that are passing through the system don't pose unreasonable risk, then I think it's worthwile, as a strategic matter, waiting for a 5(e) that we think we have a good chance of winning.

If we don't win the first one, the downside risk of

that is very significant and would be tremendously significant to the implementation of the Act.

The fact is that in almost every instance in the burden in TSCA is, in one way or the other, on the agency and not on the industry. Outside of 8(e), in most cases the agency has had to make findings and had to support those findings.

There findings are more or less rigorous in different portions of the Act, but the Congress did a fairly good job of giving the agency some fairly significant burdens in carrying out its mandate.

The other thing we're doing is we are going to be coming out later on this year with guidelines: "Here is what we think you should be doing, in general, as a mimimum." I think that will help, too.

DR. EISENBERG: My second question - and as we proceed on these meetings, Steve, I'm going to be taking up at least the state's role in many of these areas. I'll, perhaps, just address the PMN side now and that is, is there any way that notice of these PMNs can go to the affected states so that they would be in a position to start preparing themselves for a number of reasons?

Number one, even some of the questions that are addressed in the PMNs refer to things such as disposal method. I've looked through some of these things and it says, "Disposal method. Bury it." "Disposal method. Incineration."

There is no way that you, here at headquarters, are in any position to judge whether, in fact, there are any acceptable sites in the area that this firm is located in to either incinerate or landfill, or whether where they intend to take it is an acceptable site in the first place. There's no way you can judge that.

From what I've seen, the only judgment is made, is there is something filled out in that space.

Also, from a state standpoint, the states will wind up permitting the process. Many will wind up with the missions. The state will be involved in any enforcement action that is taken through one of the other EPA Acts.

For example, certainly from the monitoring standpoint, the environment as well as the occupational exposures.

What I'm really after: Is there any mechanism by which the state can get involved, just whether it's from a review or from an early warning standpoint?

MR. JELLINEK: That's a very reasonable point.

My understanding of the processes is that we would do more than take a look at the box on disposal when we're considering the risks of the substances.

As a matter of fact, when we go back we go to feed-stocks all the way through disposal and degradation products and byproducts, and things like that.

But what I would be glad to do - and I don't know if

you have raised this with anyone else you've talked to this week, but what I would be glad to do is see what kinds of opportunities there are for us to notify the states.

DR. EISENBERG: Where I'm coming from, Steve, is presently, some of the states, what they are doing - in fact, the legislatures in some of the states are requiring this - whereby, before new industry comes in or before a new process within an existing industry starts up, if there are any by-products formed by the process which need disposing of, unless we know what method of disposal, unless we know the method is an acceptable one, the process doesn't start in the first place.

MR. JELLINEK: I think that's something we ought to look into and perhaps have someone work, or at least work with you on.

One of the problems we'll have to overcome is the confidentiality problem. We don't have authorization to share confidential information with states as the Act is written unless you become our contractors, but that's something we have to work out.

DR. SLESIN: Do you feel somewhat uncomfortable sitting up there telling us that none of these pose unreasonable risk given that the exposure data that is provided is very preliminary in the sense that it's just starting up of a chemical in the first couple of years of production; given that, according to the statistics, you've given us 50 percent

of the toxicological data and 75 percent of the mutogenicity?

We'll look at an Ames test and we'll say, "We'll definitely do that. We can definitely do that." And I know the triple-A asked you, saying they were very disappointed about the statistics.

But don't you feel a little queasy about it?

MR. JELLINEK: I would feel better if I had more testing data, but the fact is that some significant portion of those first 17 or 18 that we been through are high molecular weight polymers; and, as a general rule, they are not a problem and we would be hardpressed to stop that chemical and then to tell a judge how that thing is a problem.

It would be very difficult for us to tell a judge how that is a problem, to demonstrate it. That is the kind of situation that we have found so far.

Now, there may be others in that first group that are not a high molecular weight polymer. There are other things that, in one way or another, we rigorously evaluated and decided that either it was almost certainly not a problem or the factual situation was a little too soft for us to make this case.

DR. SLESIN: From us looking in, it's very hard.

I must say, your generic usagy that you've given us doesn't have polymers in it. A good 30, actually over 40 percent of these don't even - we're not even told what the usage

is. It's either confidential and intermediate or no generic use.

I know your preliminary rules say you won't require a generic use, but obviously this is not in compliance with that voluntary. So it's hard to look in from the outside and say, "Yes, these are not a problem," because we don't even know that.

MR. JELLINEK: I don't blame you for being skeptical. I'm not entirely comfortable, by any means, but I was answering the implicit point in Max's question, that we may have been letting through some things that are real problems.

I don't think we have. I could turn out to be wrong, but I don't think we have.

One of those chemicals that came through with no data, which does not appear to be a problem in its present use, we are going to SNUR to make sure that if it is every used in another application we have another shot at it.

DR. CAIRNS: Steve, of these 40-odd that had no toxicological data, can you recall how many should have had some and how many honestly didn't need them?

MR. JELLINEK: I don't believe we've made that kind of a breakdown. We don't have those kinds of well-defined criteria.

If we thought there really should have been data, that we could defend the case that there really should have

had data, we would have.

It would have been nice to have data, though, because I frankly don't think that the Act contemplates us doing industry's job for it. In other words, we're doing the risk assessment. There's no evidence, in many of these cases, that many of these companies are doing any risk assessment at all.

They are not trying to figure out what the impact of the chemicals are. We are having to do that. We're doing more work in some of these situations, particularly the ones we think are potential problems, than the industry is in many of these cases; and we've had relatively few example of chemicals that have come in where it's clear the industry has taken --

I've heard some people in industry call it a products approach where they've tried to figure out of it's a chemical problem or isn't it. Should we test it more, or shouldn't we? Should we know more about this and that?

Those have been the real minority of cases.

MR. MOONEY: Two questions, Steve, unrelated, one back on the organization chart.

What is the status of this, at this point? Is this organization operable at this point?

MR. JELLINEK: Did Henry Beal explain to you the agency process?

MR. MOONEY: We talked regulations.

MR. JELLINEK: Well, there's a similar process for organizational change.

MR. MOONEY: Don't misread my question. I'm not asking you for too much, no charts or anything.

MR. JELLINEK: No, I don't want to give you any charts.

Major organization changes have to go through the process, and let me describe it to you.

We have done a lot of homework on this reorganization and have set out a schedule that we think will lead to approval of the reorganization in record time and, unless there are some problems that arise that I don't know about, it ought to become effective within another five to eight weeks.

MR. MOONEY: Okay.

My other question relates to your comments regarding reactivating your guideline 10 under Section 5. Can you say anything about the process by which that will happen? Will there again be something akin to the issues, the statement that appeared in the Register back in March when you went through that and when you received comment, and then it went onto the back burner and nothing has been heard of it since?

Or will we, at this point, suddenly see a guidelines position emerge?

MR. JELLINEK: Full-blown out of Warren's forehead or something.

Well, first of all, the March thing has not been on the back burner. It's been on the middle burner. And we have been working on what might be good guidelines.

If you are saying, will they come out in some kind of a proposed form where people will have a chance to comment on them?, the answer is yes.

MR. MOONEY: That is really my question.

MR. JELLINEK: That's the answer, but they're not regulations. We are not going to say, "This is it," when they are final because we think it would be useful to put something out in proposals to have people think them.

MR. BARAM: Steve, what interactions do you see between TSCA and the Clear Air Act on the airborne carcinogen issue? Are there any important regulatory implications of sorting out authority that has to be worked out?

MR. JELLINEK: We have worked closely with the air program in developing their policy in terms of, particularly, the carcinogen assessment parts of it.

MR. BARAM: Will the regs come out under the authority of the Clean Air Act?

MR. JELLINEK: It's not going to be under SIP authority. It's going to be under the NESHP.

MR. BARAM: But there will be a state program under the NESHP.

MR. JELLINEK: The National Emission Standards

for Hazardous Pollutants, NESHP. But they will be controlled under the authority of that.

DR. SLESIN: Warren spoke to us yesterday and you've mentioned the possibility of referring some testing to either a national toxicological lab or somewhere else.

Now, as you yourself said, the burden of testing should be on the industry rather than on the government or the new program.

Are you going to try to farm that cost back to the affected industry? There's an efficiency argument, which I recognize, if you can do it without going through red border, you might get a test result a little quicker and I'm certainly sympathetic to efficiency.

But, also, we wouldn't want to get the whole NTP process doing industry's job at that cost.

MR. JELLINEK: I happen to agree with you on that, Lou, and that's one of the things that disturbs me the most about the effort and time it has taken to get out a test.

In fairness to the red border process and the rest of the agency, our own people and our own scientists in the toxics program were the ones who decided that, on a professional and legal basis, the law appears to require us to do a certain significant amount of work to make those findings.

I find that being greatly disturbing. I can't believe that that is what Congress really had in mind on testing,

and we've either got to come up with some other way to do it or Section 4 isn't going to work the way it's supposed to work.

Now, in terms of getting money back from industry, if we test either ourselves or through NTP - we don't have the authority to do that, but that might not be a bad idea.

The most efficient thing to do would be, is there some efficient way for us to decide what has to be tested and either get the authority to have it tested ourselves or in our own contract labs, and then getting industry to reimburse the government for that. That would be the most efficient way to get testing done.

You would have all the problems of reimbursement to deal with, but you wouldn't have the hassle of just going through the adversary process to get it done.

DR. SLESIN: But you said at the outset there - I though mistakenly - there was a major rethinking. You did not have to satisfy the same kind of data requirements that had been sought for the first couple of test rules.

MR. JELLINEK: There will be a major rethinking on that.

DR. SLESIN: Reduction?

MR. JELLINEK: That's our objective. We're approaching it in two ways. One is to take a look at the process we're going through now and see if there's any way to cut that down, drastically cut it down, because cutting it down marginally

isn't going to make much difference.

And the other is to try to come up with totally and different new ways of getting technical studies.

DR. SUTTON: Would you like to discuss some of the alternatives you're considering?

MR. JELLINEK: We're at the early stages.

One alternative is to take the ITC report and say, that's good enough a proposal, and get a proposed rule out within weeks. Then see what industry has to say. That would, in essence, be shifting the burden.

We've got to analyze whether we can get away with that.

CHAIRPERSON BENDIX: Would you like to comment on that?

MR. MOONEY: I find this an interesting, but not surprising discussion between Lou and Steve on what the Act is all about; and I'll just simply say, for the record, that Section 5 remains at the best, to my knowledge, a notification process.

MR. JELLINEK: We're talking Section 4, but I would really like to get Tom under oath some time and ask --

MR. MOONEY: What did I do?

MR. JELLINEK: If they really think that Congress contemplated -- If we're doing it, quote, right - and we're going to look into that, but if we're doing it, quote/unquote,

right, if Congress really contemplated that EPA should spend a year's worth of effort, several hundred thousand dollars per chemical, and dozens and dozens of person-weeks per chemical in order to decide to propose that a chemical should be tested, maybe, that just doesn't seem --

CHAIRPERSON BENDIX: It seems highly unlikely.

MR. MOONEY: I will respond to that.

My earlier remark - the discussion sounded like it and I taped it down and it did involve Section 5.

As far as Section 4 is concerned, I guess that there's as much going on in court with regard to what the Congress did or did not intend, and I'm not very expert in that area. I think that's one area this committee has contemplated where it might do something constructive in taking a look at that process.

We probably all agree on a general observation, that there is a right amount of homework to be done before a Section 4 rule.

In more any area - literature searching, test protocol, any of the above - we will probably have differing opinions on where you would draw the line in any one of those areas, but I think it is a constructive area to take a look at on Section 4 rulemaking just to make a presumption that the Congress knows what rulemaking is all about and wrote a pretty complicated Section 4.

You can't get rid of it just by arguing that, "Well, it sure is difficult." They put it down on paper, and that's what you're going to have to find ways to deal with.

Conceivably, we could come up with some constructive thoughts on whether the process has gone too far, taken too much time in some areas that could be modified.

DR. EISENBERG: I tend to think that there is a tendency among the staff - yours or mine - when it comes to regulations to try to do as much as possible and try to have as good a case as possible before you go to rulemaking.

I think it behooves us, at times, to kind of cut it off a little bit and rely to some extent on the hearing record, and rely to some extent on the interested parties, whether they be industry or the environmental groups, to come forth with some documentation at that point rather than try to have our case thoroughly built before you go to proposed rulemaking.

MR. JELLINEK: I think that's a good point, Max, and that's the kind of thing we're going to look at.

But, as far as I'm concerned, I want to get chemicals tested that should be tested and I don't want to just shift all the time and effort from the preproposal process to the prepromulgation process or to a reproposal process.

One of the things lawyers are fond of reminding me of is that if we were to go to a very thin proposal, then, you know, six months later you're looking at a reproposal and the

total time lapse between when you decide to start the process and when a chemical actually gets listed is not much different. So you're going to have to deal with all of those.

Politically, at this stage of the game, I wish we had taken this en route because, at least, we would have a proposal on the street and we could argue later.

MR. MOONEY: There's a difference between a thin proposal and an air proposal.

If you want to look at where the air went, you can look at a number of places where the agency has, I guess, been thorough, but which would perhaps understate what the agency has tried to do in working its way through.

In some cases, it's reached beyond a fix noted by ITC that was of concern. The calls for data have not been, for example, narrowed to data pertinent to those effects that have been cited. There have been calls for all data and some of those dimensions are extensions that I think are just exactly the kind of thing that people legitimately take a look at and seriously question, and then things get all tied up.

Whereas, perhaps a narrower cut on some few chemicals with a tighter inspection of the data, tighter calls for data that exist -- I don't know how the process might work, but these are just some things that strike me that might have gotten you from here to there faster.

MR. JELLINEK: Those are good points which we're

going to look into and the question is: Would they have done this faster?

DR. SUTTON: I have a question to go back.

MR. JELLINEK: Excuse me.

One of the problems is that the chemicals that ITC gave us, many of them have had a lot of testing done on them in one way or another, and the more testing they have on them the more analysis we have had to do or thought we've had to do in order to decide whether or not that testing has been adequate.

MR. MOONEY: It sounds like we're on the wrong side of the issue if we have too little data, and we're on the wrong side if we have too much.

DR. SUTTON: I want to go back to this question of cost-benefit analysis.

We had a very stimulating discussion this morning, Steve, and there were points of view all over the place, as you might gather.

But one strongly and eloquently presented point of view was that the cost-benefit analysis is a diversionary tactic to slow down the process of regulation, at the worst; and, at the best, that it is misplaced and misguided.

MR. JELLINEK: I can't imagine who took that position.

[Laughter.]

DR. EISENBERG: It's sort of a simple-minded

question, but it would be useful, at least to me, to hear your viewpoint on whether or not, one, that process has slowed down the regulatory process in the case of toxins so far.

And, second, whether or not any of the judgments that have been made in the process thus far have been usefully influenced by the data available to you as a result of that process.

MR. JELLINEK: There is a difference, in my mind at least, between cost- and risk-analysis.

Cost-benefit analysis to an economist means a lot of things about trying to measure equivalents, using equivalent terms, using dollars as a measure of both cost and benefit, and get into all kinds of hairy questions of discounting and whatever.

To me, risk-benefit analysis, which is what TSCA calls for, means taking both the risks and the benefits into account in making a final decision on a chemical without necessarily going through some formal cost-benefit analysis as it has been developed in the profession that makes capital investments, such as major public works projects. That is where that really came out of.

I think, in a statute like TSCA or like FIFFRA where you're dealing with products that have adverse effects but that also have social utility, you have got to take a risk-benefit approach.

Now, the question is, how are you employing those factors in your decision-making? So far, we think we have avoided rigid formuli and tried to make the best subjective decisions we can using the best objective data at our disposal.

DR. SLESIN: Steve, if you come back from Paris with a mandate from OCED for some kind of testing, what are you going going to do?

MR. JELLINEK: Well, if we come back from Paris for some testing, we'll have to do something about it.

MR. SLESIN: Are you going to strain the authority of TSCA or are you going to go back to Congress to get an amendment through? Have you thought about that?

MR. JELLINEK: I think we will initially try to work something through the wall because it's just unrealistic, at this point, to go back before Congress for this year. That may be something we want to consider next year, but I think if we came back with something like that we would have to try to figure out how to implement it through existing legislation.

DR. SLESIN: You think it is a possibility, in fact, if the lawyer allows you to do that in some way or another?

MR. JELLINEK: With the emphasis on "in some way or another."

One way would be to make the parting of the testing guidelines which --

Another way would be to somehow make it into a Section 4 for new chemicals, but cut out some new chemicals so that the rule would not apply to all new chemicals.

MR. MOONEY: If you do bring it back, Steve, be sure to bring the one ton exemption with you.

MR. JELLINEK: If you were to totally drag the minimum premanufactured data set that has been discussed at OECD, it would include one ton exemption on intermediates and other things.

If we brought it back in that way, then one way of implementing it would be to look toward a Section 4 rule that would apply to such chemicals that met those criteria.

CHAIRPERSON BENDIX: Max, did you have another question?

DR. EISENBERG: Yes.

Again, Steve, I have noticed - Marsha just passed out something, the Federal Register of the 16th of this month and that was, I think, the reporting guidelines.

Wasn't that it, Marsha?

CHAIRPERSON BENDIX: "Statement of Interpretation and Enforcement Policy. Notification of the Potential Risk."

DR. EISENBERG: I notice you have an emergency notification and an emergency report, some of them based upon the severity of 24 hours and some of them are 15 days, whatever.

I would hope that since you have raised the -- You

don't have to look at it.

MR. JELLINEK: I want to see if I find it.

DR. EISENBERG: I'm referring to this in conjunction with your proposed reorganization where you are emphasizing, at the same time, raising the program integration section.

I would hope that they make it part of their effort, too, especially when you talk about the notification of spills or anything else - notification be made to the states that are involved.

MR. JELLINEK: One of the major roles that the program integration function is going to have is to work to integrate the toxics programs in the regions and to work with the regions, through the regions with the states.

DR. EISENBERG: I point that out only because what I'm trying to do is just raise the awareness.

MR. JELLINEK: That's a good point, and we have been working to figure out ways to get 8(e) information out of various types to people who should know about it, including workers.

CHAIRPERSON BENDIX: Does anyone else have a question?

One is brewing here, but let me ask a quicky.

MR. MOONEY: I thought I raised the question yesterday, but yet maybe I didn't.

Any contemplated revision - this looks like a

guidance. Is that right?

MS. RAMSEY: I brought that out. The wrong piece of paper was put into your 8(d) paper. That is a replacement.

MR. MOONEY: My Lord, this is the old one.

DR. EISENBERG: I didn't mean to imply it disappeared. It just appeared on the desk.

CHAIRPERSON BENDIX: I have a quick question and then a more substantive one.

First, you mentioned that you are contemplating SNURing one of the compounds that has come in on TMN.

Do you have any estimate of how long it's going to take to get that SNUR out?

MR. JELLINEK: It's already taken two months. It may be another month or so.

Would somebody tell whoever is working on that?

CHAIRPERSON BENDIX: Should we or shouldn't we ask at the next meeting, when next we meet?

MR. JELLINEK: You ought to ask one of the journalists from the trade press. I'm sure they'll know more than I. They get better information, better contacts.

CHAIRPERSON BENDIX: I think the appropriate point to end this discussion would be a request on behalf of the committee that you let us know where you feel currently we can be of greatest help to you, what kinds of policy issues are being discussed - that don't have to be decided in the next few days,

but that you obviously don't have time to interact with us.

What do you want us to be thinking about in the next couple of months and how can we be of the greatest help?

MR. JELLINEK: Do I have to answer that one?

CHAIRPERSON BENDIX: Yes.

You can answer later, also, but what first comes to mind?

MR. JELLINEK: Over the next couple of months?

That's a tough one for me to answer. I really haven't thought about that.

CHAIRPERSON BENDIX: Would it be easier if I said, over the next couple of weeks, and we can write you letters?

MR. JELLINEK: Let me think about it over the next week or so and get back to you.

CHAIRPERSON BENDIX: Let me say that this is part of a general feeling on the part of the committee that we want to be responsive to your needs in terms of our mandate to give some input on policy decisions, and we need to get some guidance from you as to where you need the input at any given time.

MR. JELLINEK: Okay. Will do.

DR. SLESIN: Let me ask a last question.

When do you see the final PMN regs getting into the Register?

MR. JELLINEK: I have a good idea on that. It will be late this year.

DR. SLESIN: It will be 1980?

MR. JELLINEK: We hope. We are waiting for the completion of economic analysis. If we didn't have to wait for that, we could get it out a lot sooner.

DR. SUTTON: That's a partial answer to one of my questions.

CHAIRPERSON BENDIX: If there are no more questions from the members of the committee, thank you very much, Mr. Jellinek. We appreciate your joining us.

We will have a break now, and then it will be time for public comments.

MS. RAMSEY: Why don't you ask for public comment now?

CHAIRPERSON BENDIX: Is there anyone who wishes to address the committee?

[No response.]

CHAIRPERSON BENDIX: Barring that, is there anybody of the remaining committee members who wishes to bring up any item for committee action?

[No response.]

CHAIRPERSON BENDIX: In that case, I think that I will hold the meeting adjourned.

WHERUEPON, at 3:20 p.m., the meeting was adjourned.

REPORTER'S CERTIFICATE

DOCKET NUMBER:

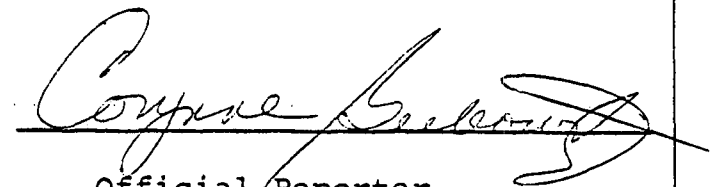
CASE TITLE: Administrator's Toxic Substances Advisory Committee

HEARING DATE: March 20, 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 Environmental Protection Agency, Office of Pesticide Programs and that this is a true and correct transcript of the same.

Date: 3/31/80



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