450R80101

U.S. ENVIRONMENTAL PROTECTION AGENCY

PUBLIC HEARING

ON

Proposed National Emission Standards for Identifying, Assessing and Regulating Airborne Substances Posing a Risk of Cancer, and Advance Notice of Proposed General Standards

Crystal Room
Shamrock Hilton Hotel
6900 Main
Houston, Texas

Thursday, March 13, 1980
9:00 a.m.

BEFORE: Joe Padgett, Chairman

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BEFORE: Joe Padgett, Chairman

EPA PANELISTS

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2-A

C O N T E N T S

ATTENDEES

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Richard Olafson	The Lubrizol Corp.
Clyde Roberts	Shell Oil
Richard H. Coe	Shell Oil
Frances V. Smith	League of Women Voters of Houston
J. B. Bates	Northern Petrochemical
J. E. Lihenberg	City of Houston BAQC
W. P. Anderson	Tenneco Inc.
Gene Speller	TACB
Martin E. Brittain	EPA, Region 6, Dallas
Carlos I. Diaz	Uvalde Rock Asphalt
Gary H. Baise	Beverage Fairbanks
A. Linkler	Dow Chemical
D. E. Fitzgerald	Atlantic Richfield
Roy McClure	Dupont
Rebecca S. Tolton	Gulf States Utilities
Dan R. Harlow	Diamond Shamrock Corp.
Ted M. Nairn, Jr.	Cosden Oil & Chemical Co.
Lisa R. Soldani	Texas Eastern Transcorp
V. P. Piana	Phillips Chemical Co.
D. Morrack	Individual
R. Helms	Kimberly- Clark
David Burroughs	Texas Eastern Corp.

NAME	REPRESENTING
Roger Tower	Celanese Chemical Co.
Dick Flannery	Texas Air Control Board
Harriet Mofore	Individual
Candy Peer	Individual
Elsie Randall	Individual
J. M. Annenheuser	Goodyear T & R Co.
B. F. Gallowav	Goodyear T & R Co.
D. D. Malzahn	American Natural Resources
Bruce Williams	American Hoechst
L. L. Krohn	Union Oil Co.
B. A. Buenehe	ICI American
P. L. Shipley	Phillips Petroleum Co.
J. W. Kaufman	Phillips Petroleum Co.
S. W. Fretwell	Oxirane Corp.
R. Krablin	Anaconda Copper Co.
W. D. Broddle	Conoco Inc.
D. R. Trew	Cities Service Co.
T. W. Sims	Texas Stell Co.
D. Vli	Houston Health Dept.
Phillip Morris	American Hoechst
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Robert E. Abbott	Conoco Inc.
W. P. Toland	Badische Corp.
W. L. Senn	Exxon Chemical Co., U.S.A.

NAME	REPRESENTING
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F. P. Miller	Continental Carbon
J. R. Venable	Rohmand Haas Texas
H. M. Walhen	Individual
H. H.Nelson	Monsanto
C. W. Umlkut	Exxon Chemical Co. U.S.A.
J. A. Mullins	Shell Oil Co.
B. R. Vehnekamp	Shell Oil Co.
B. F. Ainelins	Shell Oil Co.
Glenda Greene	Shell Oil Co.
M. L. Sagenhal	Shell Oil Co.
J. C. Ledvina	Conoco Chemical
T. J. May	Illinois Power
Keith Ozmore	(illegible)
Glenda Barrett	League of Women Voters of Houston
J. C. Molina	ARCO Chemical Co.
M. Lawsen	Deer Park Progress
Michael Tenoso	Harris County Pollution Control
James L.Loyles	Harris County Pollution Control
E. G. Stock	Westinghouse Electric Corp.
Norman D. Radford, Jr.	Vinson & Elkins

NAME	REPRESENTING
Don Cox	Temple-Eastex
Paul Vavra	GBCPA
Wm. D. Utidjihn,M.C.	Union Carbide Corp.
J. G. Collins	Goodyear
J. F. Erdmann	Union Carbide Corp.
W. F. Muller	Goodyear
Bob Skorpul	Rice University
R. E. Savory	Pennzoil Co.
A. Gomez	Texas Air Control Brd.
Joseph M. Baretincic	IMC Sterlington
John Harris	Shell Oil Co.
Gregory David	Dow Chemical
C. L. Green	Alcoa
Ron Lanz	AIHE
R. G. Dillard	Texas Chemical Council
I. G. Smith	Sierra Club
J. Tappen	Phillips Uranium Corp.
Dennis Lachtman	Envirotech Corp.
Al Auenoso	U. of H., Downtown
C. H. Rivers	Shell Chemical Co.
Elizabeth Lankford	Citizen, Environmental Coal
Edelia Lee	EPA, Dallas
Dr. Eugene Brams	Prairie View A&M Univ.
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NAME	REPRESENTING
Kurt T. Guenther	Rice University
Virginia Chaffee	Pennzoil Company
D. A. Kuhn	Conoco Inc.
R. D. Towe	Petro-Tex Chemical
Joan Jones	Galveston Bay Conversation P.A.
Michael D. Henke	Gulf Oil Chemicals
Charles R. Shaw	M. D. Anderson Hospital
Susan Duffrey	Rice University
Noll Shenor	Rice University
John J. Zimmerman	American Mining Congress
Stephen C. Davis	American Mining Congress
Dennis L. Lachtman	American Mining Congress
John R. Summerlin	Rice University
Jess A. McAngus	Pace Consultants
Dave Stang	Rollins Environment
Brenda Gehaw	Individual
Greg Retter	Rice University
B. Scott	Rice University
Jim Scott, Jr.	Individual
Jeff Lambert	Individual
Kurt Jackson	H-GAC Healty Systems Agency
J. T. Adams, Jr.	ARCO Petro. Products
Maureen Lennon	API

NAME	REPRESENTING
Thomas R. Scovel	Texaco Inc.

EVENING SESSION

John Fafoutakis	Individual
Judy Martin	Individual
L. E. Anthony	Individual
James L. Moore	Texaco Inc.
Jerold C. Lambert	Airtrol Corp.
Charles H. Medlock	Airtrol Corp.
J.M. Baretincic	IMC Sterlington
Brandt Mannehon	Houston Sierra Club
Janet Maier	Individual

(There were 4 illegible signatures which could not be deciphered.)

P R O C E E D I N G S

(9:10 a.m.)

CHAIRMAN PADGETT:

Good morning.

My name is Joe Padgett, and I'm the Chairman of this public hearing, informal public hearing, on EPA's proposed airborne carcinogen policy and the advanced proposal that we are making on draft generic for practice and operation standards.

This proposal was published in the Federal Register, October 10th, and a series of public hearings was scheduled for this week, the first two days of the week being in Washington, D.C.; March the 10th and 11th.

The third day, March the 12th, was in Boston; and today, here in Houston.

We will be meeting today during the day, and we also will have an evening session for several speakers who have elected to talk in the evening.

There is a list of speakers who have registered their intent to speak, and should be back in the back of the room on a table. I assume that you have that information.

The way we are conducting the hearings, they are intended to provide opportunity for interested persons to present their views and to submit information for consideration by EPA in the development of a final policy to identify, to assess and to regulate airborne carcinogens.

These hearings are informally structured. Those who are providing oral testimony will not be sworn in nor will formal rules of evidence apply.

Questions after each individual speaks -- questions will be posed by the EPA panel members, whom I will introduce shortly, for the purpose of understanding better what they have said and perhaps emphasizing or clarifying different points that may have come up in their testimony.

There will be no questions by the participants or others in the hearing room; but if individuals have questions that they would like to see asked, they can write those questions down and hand them to one of the EPA staff members who will be at the back of the room to bring up to the Chair for submittal; this, of

course depends on the time available.

We have asked each participant to try to limit his oral presentation to no more than ten minutes and then we will allow another period of time for questions by the panel.

Participants are asked to state their name and organization, if any, prior to beginning their oral presentation. We would also appreciate it if those participants who have prepared statements bring those up and make them available to the panel members and to the Hearing Stenographer.

This proceeding is being reported, and copies of the verbatim transcript will be available for inspection and copying at the EPA Regional Office Libraries and the EPA Central Docket Section in Washington.

Copies of the documents -- some of the copies of some of the documents are available at the hearing. The proposed policy and the AMPR for generic standards and several other pieces of material. If there is other information that you would like, I would suggest that you write down your request and give it to the staff person so that that information, if

available, could be sent to you.

The record, the hearing record, will remain open 30 days from this date -- that would be April 14th -- for submittal of additional information which is pertinent to information generated here or in prior hearings this week.

We plan, as best we can, to call witnesses in the order listed on the list that I think you have, the list of witnesses; however, if certain witnesses have special problems, planes, trains to catch, schedules -- whatever -- we will see if we can accommodate your desires.

With that, let me just run through the panel members, the EPA panel members, starting with my left. Over on the far side, we start with Bob Bauman, who is with the EPA Air Programs office.

Next is Bob Kellam, also with the EPA Programs office.

Next is Al Davis, who is the Director of the Air & Hazardous Materials Division, Region VI.

On my right is Todd Joseph -- my

immediate right -- Todd Joseph, Office of General Counsel and Doctor Elizabeth Anderson, Office of Health and Environmental Assessment.

And then, David Patrick, who is with the Emission Standards and Engineering Division in the Air Programs office.

So, I believe, unless there are some questions that someone may have relative to the organization of the meeting, we will just start with the first witness.

I would like --

There are a few seats up front for those who have just come in.

(There was a brief pause in the proceedings.)

CHAIRMAN PADGETT:

The first witness will then be Richard Krablin.

TESTIMONY OF RICHARD KRABLIN

MR. KRABLIN:

My name is Richard Krablin and I am from Denver, Colorado.

I am testifying on behalf of the Anaconda Copper Company as their Manager of Health, Safety and Environment. I appreciate the opportunity to address EPA today and will keep my statement brief.

Of the many issues attendant to the proposed regulations, Anaconda has chosen four that are of special significance tc our company, our principal business is the discovery and production of mineral resources.

Four areas of major concern to our company are illustrated by the following questions and statements:

Considering the often repeated concern by EPA of the scarcity of its resources, has the contribution of airborne carcinogens to the total cancer burden justified requiring these complicated and far-reaching policies and procedures?

Neither the cost nor benefits of this policy has been provided.

Does EPA, while living in a political climate and dealing with an emotional issue such as cancer, recognize the adverse impact on businesses that will result from listing a substance as having a high, moderate or low probability of carcinogenicity?

Serious adverse impacts are likely to affect such business operations even though only an incomplete scientific evaluation has been performed.

Is early listing under Section 112 of the Clean Air Act really necessary to increase the priority of consideration of a particular substance and thereby accelerate the development of regulations, or does the listing itself help justify the conclusion of carcinogenicity?

EPA has available other mechanisms such as Advance Notice of Proposed Rulemaking, ANPR, and the Toxic Substances Strategy Committee, to establish priorities and notify the public of impending rulemaking.

Is an industry such as ours, which is limited by the nature and location of the mineral resources, aided or hindered in

long-range planning by these proposed procedures?

Although, for example, EPA has listed factors that will be considered for new sources, no insight is provided for planning purposes as to how these factors will be implemented.

With regard to my first question on the need for an airborne carcinogen policy, Anaconda believes the EPA efforts are misplaced.

The advantages and disadvantages of these regulations are not sufficiently documented to support the additional bureaucracy, and the expenditure of taxpayers' time and money that will result upon their implementation.

The Agency should document in better fashion the contribution of ambient airborne carcinogens to the nation's total cancers when compared to other environmental sources, including diet, stress, cigarette smoking, and other factors in addition to air and water.

Can EPA expect the public to confirm the validity of the proposed regulations when, in fact, resultant costs and benefits are not provided and the health problem addressed may

be minimal when compared to other existing health issues?

It is our belief that the problem of airborne carcinogens has not been shown to be of such magnitude that this proposed complex policy is justified.

The second question is one of special concern to Anaconda, as a representative of an industrial category specifically mentioned in the policy as emitting carcinogens, which we might add, has been concluded only on the basis of a preliminary analysis.

Even without the listing of any particular substance as a carcinogen, our industry is already placed on the defensive. What has been gained?

The process of listing a substance, as proposed in the procedures, despite which category or list it is placed on, will automatically label the substance a carcinogen in the public mind. We do not agree that such an association -- and that's all it will be -- will be beneficial.

Guilty until proven innocent may be necessary in some cases of toxic exposure

where the evidence is strong and potential risk substantial, but not for suspected and unproven airborne carcinogens. At a minimum, full scientific analysis should be performed prior to a Section 112 listing decision, so that all parties can understand whether a risk is equal to, for example, an extra day of exposure to the sun, or in fact, is of serious concern.

Regulatory alternatives and consequences also need to be considered since the Clean Air Act requires promulgation of emission regulations 180 days after listing. This raises another very important omission by EPA.

No procedure for removing a substance from the listing has been proposed. Substances that are listed as a result of preliminary analysis may indeed prove not to warrant a Section 112 regulation and a mechanism to unlist them should be available.

The third issue which concerns Anaconda is that of the purpose of early listing, we believe, is not clear, nor does it serve any particular need. We do not believe that an early listing, a regulatory decision, is a valid way to focus EPA priorities.

In a mining situation a selected substance will in all likelihood be subject to controls from other Federal, State or local agencies since often the substance is emitted in combination with other substances, for example, with suspended particulates.

The result of the preliminary listing will not be to focus EPA's priority, but rather will result in an indictment of the mine. Other agencies may not wait for EPA to finish its information-gathering activities and regulatory analysis, and may act on incomplete information.

The selected substance will always be suspect in the public's mind. EPA has many internal mechanisms for establishing priorities. If this is the purpose, a regulatory decision such as Section 112 listing, should not be used except for proven, significant health risks.

The last issue that I would like to discuss is that the air carcinogen policy does not permit long-range planning for industries, such as mining. The obvious limitation on mining operations is that location is required at the site of resource.

The cancer policy has three sets of requirements for new sources: Presumptive emissions standards, risk-avoidance criteria and alternative standards, and describes factors that will be used to establish such levels.

However, no indication is given on the weighing of these factors and how EPA will arrive at the standard. This level of vagueness hinders industrial planning processes and prevents meaningful public input into the rulemaking process.

The purpose of the publication of these regulations and the hearings are to improve the process, to alert the public of regulatory proceedings and to allow for public input. Anaconda does not believe that the regulations accomplish these goals. Instead, they seem to be aimed primarily at avoiding challenges later in the process.

To us, airborne carcinogens are indeed unique air pollutants and may need special treatment. However, the effort is most effectively accomplished on a case-by-case examination, unfettered by an attempt to generalize with procedural regulations such as these proposed.

EPA should use its limited resources to make a thorough evaluation of the need for regulating hazardous airborne substances, which may or may not include carcinogens.

There is a epidemiological evidence which shows that industrial air contaminants account for less than one percent of the total lung cancer in the U.S. At this time, it is not apparent that these regulations would reduce that factor.

Anaconda and other industries will not be aided by these regulations, and let us not pretend that they shouldn't be. As part of the public, industries must be able to plan for the future within the existing regulatory framework. Procedures that allow for such planning are indeed aids to industry and the public at large.

We sincerely hope EPA will consider these comments and focus its attention on regulatory procedures that will improve public health in a cost-effective manner.

Thank you.

CHAIRMAN PADGETT:

Any questions?

MR. KELLAM:

Dr. Krablin, you mention in your testimony that you felt that EPA should not list a substance unless we had found or been able to prove that there was a significant health risk.

Could you tell me what kind of evidence you would consider sufficient in that regard?

In other words, do you feel that we need to be able to establish, epidemiologically, that people were dying as result of emissions of that substance from a source category?

Or would you consider that certain types of animal studies might be sufficient in that regard?

MR. KRABLIN:

Both of those points you mentioned refer to medical evidence of these carcinogenicity of a substance. I am not a medical doctor.

I might ask, instead, as an alternate question, just what it is that EPA may chose to decide as criteria for listing a

carcinogen, which I think is the real issue.

It is just not clear to us, or to me --

MR. KELLAM:

Do you feel that the criteria that are developed in the proposed policies are to stringent or not stringent enough?

MR. KRABLIN:

Our position is that the procedures are wrong. I cannot evaluate the criteria, as I note it, for assessing carcinogenicity.

What I am evaluating and what we are commenting here, is that the approach of EPA is to label carcinogens and then establish evidence after the fact. And that is what we are judging.

MR. KELLAM:

I understand. But you do say that you would, I assume, favor listing if there were proven significant health risks? And I'm just trying to get a better understanding of what you mean when you say that.

MR. KRABLIN:

I think that the use of

Section 112 for a substance, such as asbestos, was a case-by-case approach -- and an appropriate one -- to the concern over carcinogens.

MR. KELLAM:

Would you agree that the action that the Agency took in the case of vinyl chloride was also appropriate use of Section 112?

MR. KRABLIN:

I'm not familiar with your vinyl chloride details, so I can't comment.

MR. KELLAM:

Thank you.

CHAIRMAN PADGETT:

Ms. Anderson?

MS. ANDERSON:

Yes. In the Federal Register notice, the Agency specifically requested informational comments on the evidence for the airborne-carcinogen problem.

I notice you make a reference in your statement:

"There is epidemiological evidence which shows that industrial air contaminants account for less than one percent of the total lung

cancer in the ....."

United States.

I think we would be interested in getting your reference to that, or the study that you are referring to; and I think that we would like to have that submitted.

MR. KRABLIN:

We would be glad to submit that.

CHAIRMAN PADGETT:

Are there any other questions?

(There was no response.)

CHAIRMAN PADGETT:

Thank you.

Dr. David Marrack?

26

STATEMENT OF DAVID MARRACK

MR. MARRACK:

Mr. Padgett, I am here as a private, concerned citizen -- whatever may appear elsewhere.

I particularly wish to address the problem and the policies needed to control airborne carcinogens. The -- To come to the right place, as you are well aware, this area has some quarter of or thereabouts of petrochemical industry in this country, one of the highest concentrations of such in the world.

We welcome you here today; it's very nice to see you down here.

The epidemiology of cancer in Texas has been particularly studied in detail -- and detail that's not available anywhere else -- by University of Texas M.D. Anderson Hospital, Epidemiology Department.

The cancer-mortality data were collected by looking at the clinical records and the histology of autopsy and surgical specimens, probably the most accurate epidemiological data available anywhere, and certainly for this county.

The Macdonald's -- Eleanor

Mcdonald study of the incidence of lung cancer in this area is published -- and I have copies of that for you, sir -- and is done by census tracks around Houston and covers the period 1940 to 1969 and an update is being done at the present time.

An earlier study demonstrated three important facts, that lung cancer in White males increased some twofold in the fifteen-year period.

The tracks which increased lung cancer correspond to those under the prevailing winds from the ship-channel industries.

And there is other evidence -- both wealthy and poor-- on either side of that area didn't have this problem.

(Handing out materials)

And I thought you might like to pass that down to the Chairman.

(Due to the speaker's foreign accent, his diction was partially unintelligible.)

The (unintelligible) and the wind wheel which you have illustrates this clearly. This has your major water supplies; they don't correspond with this distribution. It

28

also has the food-distribution system, which doesn't correspond either.

The obvious, common medium is air. I point out, naturally, that about one quarter of the current population tend to get cancer and about one-fifth of it is going to die from it, which is extremely sensitive.

As much as eighty percent of this cancer is considered to be induced from industrial products -- and, of course, I include in that tobacco.

Including mass productivity, including injury compensation, and emotional trauma, the direct costs of this infliction is around eighteen billion per annum, recurrently.

I point out to you that about three times the cost of an Alaskan pipeline occurring every year.

The reason is not apparent. You are not addressing birth defects, and I would submit to you for consideration, that there are factors that cause abnormal cell growth leading to cancer are the same that cause birth defects.

About three percent of fetuses needing treatment before their fourth week have

birth defects.

The cost of these to the nation has been estimated to be about three times that of cancer; in other words, some sixty billion per annum. That's ten to the ninth power.

These costs are a non-productive, economic burden and represent, to a great degree, a public subsidy of the industries making use of chemicals.

To put it another way, the hugh recurring annual costs are part of the production costs which are externalized by industries' accountants. This makes a mockery of the product selection by the market place costs. It is urgent that the real cost of cancer and birth defects and some other diseases, too, which are induced by similar cancers, be placed where it belongs, on the products precipitating these conditions.

Testing for mutagenic properties of chemicals singly or in combination by the hierarchy of the Aimes test is not accurate. Dr. T. C. Shoe (phonetic) has shown that non-mutagenic -- i.e., non-DNA events -- could lead to cell-multiplication disruption, as in cancer.

The (unintelligible) cells must

also be used as (unintelligible). Further, that many inherited variances in humans and their susceptibility to cancer. And (unintelligible) of any testing program for chemical carcinogens.

And this, incidentally, was discussed in this building last week, at the Indiana (unintelligible) Symposium.

EPA, making of standards for only four agents, I think it is, in the last ten years is far too slow, again. You need to reach a rate of about twenty per annum to catch up.

The sources of carcinogens reaching the public are tobacco products, other chemicals and radiation and the manufacture, transport and use and waste disposal.

EPA must require that each of these steps be effectively managed to contain our human exposure. Regular monitoring and quality control are steps which are also required.

Let's have a quick look at some of the carcinogenic problems that are going on around.

The bar graph taken from the data of Dr. Saccomanno, and the American Cancer Society and prepared by Dr. Saccomanno, it shows

the effects of uranium mining and of smoking, taken singly and, in combination, together.

Both factors together cause seven hundred per hundred thousand lung cancers compared with 12.6 for a non-smoker, non-miner. Now, that's unacceptable.

Vastly more important, it attempts to reduce uranium miners' exposure since the seventies is causing that seventy per one hundred thousand rate to fall; i.e., controls actually work.

I pointed out to you the data appears to not reflect the induction of other cancers that may occur from uranium mining and smoking.

The impact of a (unintelligible) smoker is equally ghastly in terms of human health and just as costly to the public. Smoking with active uranium exposure, uranium miners' exposure, greatly aggrevates the problem. This was discussed by Dr. Cellokaus (phonetic) in the Journal of American Medical Association for August 3, 1979, page volume 2 -- volume 242, page 458.

The inter-action with other

carcinogenic chemicals and smoking have been less carefully studied to date.

The available data suggests that they are equally viscious combinations.

(Unintelligible) are carcinogeni You would expect this from the nature of thier chemistry, and this is discussed by Reynolds in "Toxic (unintelligible) Energy --"

Sorry. "Toxic Injury of the Liver," Part B, Chapter 14. The editor is Dekker; Farber & Fisher, published in 1980. I'm not sure it's yet on the bookstands.

And also in "Free Radicals in Biology," Volume IV, edited by Pryor; 1980 at Academic Press.

Prior to (unintelligible) hydrocarbons seem to be regulated at the top.

Well, let's just look at the ethene dichloride (phonetic) and vinyl chloride as these regulations in Texas (unintelligible). Ensuring the adequacy of the current regulations.

The standards are set in the upper limit of air concentration. Yet, what's needed is a limit for total air -- air mass in the region. You must cover all releases: fugitive

excursions, start-ups and shut-downs. It's absurd to have a limit of parts per million for fugitive vinyl chloride and then ignore the excursion releasing 20,000 pounds of vinyl chloride monomer on an unsuspecting and non-consenting public -- and I might point out it happened in June of 1976 within five months, again, in two different parts of the ship channel.

In fact, a review of the Texas Air Control Board records shows for the year '76 and '77 there was average of six excursions per month along the local area. The initial releases recorded stem downward from 20,000 pounds per incident.

There's no data on the public and fetal-health effects of these releases; none's been sought.

The present regulations do not cover all plants processing or handling vinyl chloride monomer. It's an intermediary or bi-product waste; it's outside the Federal regulations. And that's obviously not (unintelligible).

Smokers and airborne carcinogenic agents are permitted together, both

34

in the workplace and amongst the public, who are not advised of and not consenting to carcinogenic exposure. The informed consent, as understood by members of the medical profession, is not practice(by Industry. I consider this discriminatory. It obviously needs correction.

Transportation of carcinogens should be minimal and on-site use should be made an attractive, economic sort of advantage. EPA, at least in this area, has been tardy in analyzing the composition and acting on the known, hazardous toxic wastes in the area, like the one on Highway 146 and I-45, which is outside Texas City. We have a lovely miasma of vinyl-chloride vapor over it. It's been known for 18 months and yet nothing of significance has happened yet.

The responsibility of control of these carcinogenic and birth-defect-causing agents and the proof and justification of all actions by Management and the introduction and use in commerce for export are done to protect human health and the environment must rest squarely and clearly with those who produce, otherwise have or use these agents (sic).

It's two hundred years, sir,

since the birth of (unintelligible), the first recognized carcinogen. And a mass of accummulated evidence since then.

It's clear that smokers and carcinogenic smokers are incompatible with (unintelligible).

Statements of parties who deny the effects of airborne chemicals and cancer carcinogenesis is obviously suspect and their motives for denying the obvious should be reviewed.

Western Europe and USSR are vigorously proceeding to clear up their carcinogens in the environment. We tolerate a (totally unintelligible). We brag about our high chemical living but quality of our health-care systems (unintelligible) the high quality.

Get our house cleaned up.

Thank you.

CHAIRMAN PADGETT:

Questions?

MS. ANDERSON:

Pursuing the same question I asked the last witness, in these hearings we have heard a range of testimony along the nature of the airborne carcinogen problem.

From your testimony, it is clear that you have looked at a lot of the evidence. Just to review the range of testimony that we have heard, we have heard one witness say that the: is no evidence whatsoever that air pollution causes cancer.

Another witness says that it is de minimus. Another one says it is less than one percent. Another says between one thousand and two thousand cases of cancer caused by air pollution.

And we have heard a fifth one say it is highly significant.

But other than citing specific studies, to place no number on this. And I'm wondering if, in your work, you could add to this range of testimony that we have heard.

MR. MARRACK:

I thought I already had. You have in front of you a bargraph which shows one for uranium. And if you read that paer, it is appalling considering the number. I happen to have here samples -- not the whole paper; just the front pages. I have a number of pages.

There are two copies. You might have them included in the record.

Yes, of course, there are a tremendous accumulation of data going from the more obvious chemicals, the chlorhydrocarbons -- whether they are our old friend, chloroform, the ethylene dichloride and vinyl chloride, which represent some of the largest mass of chloride hydrocarbons in the public domaine down to nickel compounds, chromium, arsenic, you name it, almost every one of certain metals, Group IV and V, and mainly, chlorinated compounds seem to be the obvious problem. Others I have not looked at so carefully.

MS. ANDERSON:

But in terms of the total contribution, would you say it is significant --

MR. MARRACK:

Obviously, if it goes -- I don't have it with me.

Looking at that bargraph for the uranium miners, if you don't smoke, never mine uranium, the figures are 12.6 per hundred thousand of population.

If you smoke more than two packs of cigarettes a day, it is 265 per hundred thousan break. And those are figures of the American Cancer Society.

The Saccomanno data for non-smoking uranium miners -- this is before 1970 in 1965, in fact -- it is 20, or double. And for the non-smokers, if you do both cigarette-smoke an mine uranium, the figure is 700. And that is almo 60 times.

You can't treat single chemicals on their own. You've got to take a holistic view, and maybe that's one of the major problems of EPA's approach at this present time.

MS. ANDERSON:

This is an impressive study in terms of occupational exposure. Of course, the emphasis today is on the ambient exposures. And

I suppose --

MR. MARRACK:

Some of the papers on the vinyl chloride are in that bunch that you have there. And others clearly show the problem.

And unfortunately, we are really not going at -- as I can see it -- really getting out to get the data.

Obviously, the first place to start -- The lead time for cancer is anywhere from 20 to 30 years; that's an awful long time to wait to find out what's happening.

On the other hand, pregnancies don't last forever and represent the same kind of biological defect as when birth defects occur. They occur with very high incidence today; about three percent for reasons we don't entirely understand. And, obviously, part of that at least is environmental.

And the fact that the component is environmental is rather easily determined. The only problem is you have to regard miscarriages as a form of birth defect.

Something like 80 percent of miscarriages are associated with deformed fetuses.

And most of them don't know when they are aborting Records of these are hard to come by. So these are the kinds of data that would be well worth getting hold of.

And these are the sort of data that I submit should have been an urgent matter after that release of 20,000 pounds of vinyl chloride in the ship channel area. But no one knows a thing about it. Unfortunately, it is a totally improper experiment on a non-consenting public.

And I just think we didn't know anything about it.

MS. ANDERSON:

We have a question submitted to the panel from the floor. It is really a request for information.

"The witness said 80 percent of cancer is caused by industrial products. Can he supply data to show that?"

MR. MARRACK:

The World Health Organization has a publication on that. The New York Academy

of Sciences, I think it is Volume 272, has a massive data on that and a more recent one I don't remember the volume -- No. I don't know it. It was within the last year or so. It was a symposium last year.

The American Cancer Society comes up with the same sort of figures.

USSR has the same kind of figures. Now, admittedly, in the area of industrial products, cigarettes don't grow on trees. We process them.

We throw all sorts of fungicides and pesticides all over them and all the manufacturing processes.

It is obviously an important factor in the development of carcinogens as a whole.

The data on the birth defects in operating-room women is extremely interesting. I'm sorry I didn't bring the papers or reference with me, but I can find it, about the increases of weighted birth defects and miscarriages in operating-room females by about three percent -- three times, I mean, and more interesting is the partners male -- who work in operating rooms, their spouses or those who get pregnant by them have about half that incidence. In other words,

the male is carrying a defect to the female and appears to be directly acquired by exposure to something in the operating rooms of which the volatile anesthetics are an obvious factor which is not present in exposure to other hospital personnel which are controlled.

CHAIRMAN PADGETT:

Any other questions?

MR. KELLAM:

You mentioned the use of formalian (phonetic) cell transformation tests and bacterial mutagencity tests. It wasn't quite clear to me. How do you feel that EPA should view such tests in trying to evaluate the potential for human carcinogenicity of a substance?

MR. MARRACK:

I don't think it's EPA's job. I don't see why I should tax-fund that. I think it's the job of the industry who wants to use this chemistry and put it in the realm. It's their responsibility. It is clearly their job.

If you want to change these things, you got to show it's safe. You've got obviously a built-in backlog of things that EPA investigates.

MR. KELLAM:

Thank you.

CHAIRMAN PADGETT:

Any other questions?

(There was no response.)

CHAIRMAN PADGETT:

Thank you.

Mr. Gunkler, from Dow Chemical?

36

STATEMENT OF DR. A. A. GUNKLER

MR. GUNKLER:

My name is Al Gunkler, and I am an employee of Dow Chemical Company. My degree is in Chemical Engineering at the Ph.D. level. I have had 29 years of experience in plant operations and have managed research, production and process engineering design functions.

I am very much aware of the many requirements for the design of safe, environmentally responsible, operable production units. My philosophy is not unlike yours, in that I feel we should continue to reduce emissions and exposure to chemicals in a practical manner, just as we have done in a remarkable way over the past 30 years.

I have also had many years of hands-on experience in handling a multitude of chemicals, some of which are carcinogenic by your proposed definition. I have a healthy respec for the properties of chemicals -- respect, but not fear.

Incidentally, many of these chemicals are the ones that our former speaker talked about; and if they were like they say,

I -- and my 8,000 fellow employees -- would be gone by now.

The importance of the proposed EPA air carcinogen policy is shown in the following statement, which appears in the supplement of the EPA proposal.

I quote:

> "A requirement that the risk from atmospheric carcinogen emissions be reduced to zero would produce massive dislocations, given the pervasiveness of at least minimal levels of carcinogenic emissions in key American industries. Since few such industries could soon operate in compliance with zero emission standards, closure would be the only legal alternative."

Unquote.

The preamble points out that the administrator is not required to consider negative toxicology data nor risk benefit assessment and that he will use his judgment as to how much regulation is needed. For the EPA to place upon industry another barrier to

38

productivity with such an open-ended proposal, it would seem that all data would be considered a clear indication of the need for regulation would have to be apparent. But that is not the case with the EPA proposal: In our written comments, Dow expressed the following major concerns.

There is evidence that chemicals in the ambient air have contributed to the incidence of cancer.

The consequences of listing a product as a human carcinogen are significant, contrary to the document statement in the light of the limited direct consequences of listing.

In view of these two facts, a proposal that listing will be done without reference to contrary data or public participation is irresponsible.

The proposal fails to recognize pertinent scientific data essential to an accurate and reasonable estimate of carcinogenic risk.

The proposal is legally questionable if it does not meet the statutory requirements of Section 112.

Our written comments deal

39

extensively with the above statements. These comments emphasized that there was obviously no intent by Congress to regulate, under 112, a class of chemicals generically. It was reserved for chemicals of extra ordinary concern, to be considered on a case-by-case basis.

It was not intended to operate to preclude public debate and input into the scientific bases and assumptions that go into the EPA judgment of what is a human carcinogen.

We feel that the EPA has used a section of the law -- Clean Air Act, Section 112 -- to accomplish a purpose for which that section was not intended.

I would like to address those concerns which are supported by my personal experience in manufacturing, process engineering and business.

The first are the problems generated by easy listing of a chemical based upon a preliminary evaluation of partial data. Engineers pride themselves on being able to design plants to meet specifications. But the reality of the manufacturing world is that easy listing with the resultant uncertainty whether the

40

control requirements will consist of work practice standards, an unspecified best available technology, or something more stringent will hamstring significant process development and construction decisions.

Let me clarify that if there were evidence that the most probable estimates of risk indicated a significant potential health impact beyond that of competing relative risks or generally accepted levels of risk, I recognize that Section 112 would have to be applied as described in the statute.

The chemical industry understand its responsibility to deal with realistic uncertainties. But experts have shown there is no evidence of correlation of low-level air pollution with community cancer, let alone with identified carcinogens, and reduction of exposure to high-level concentrations in the workplace is being accomplished through other means. Thus, there is no need for this proposal.

The EPA proposal would provide listing of many substances. We anticipate that the loose criteria for listing would precipitate petitions for listing of many additional materials

For instance, it can be predicted that the Carter Administration's major initiative for a synthetic fuels program will be affected.

The comment in the document, quote, "In light of the limited direct consequences of listing," unquote, is false. Similar listings have already caused harm.

Realistically, we urge you to reconsider the fast listing part of the proposal. We must have realistic, most probable estimate of risk before listing.

We don't have to look far for an example of the ease with which this air policy can be needlessly overextended, beyond the problems of listing.

The EPA has drafted proposed rules for Benzene under Section 112. Since it has been singled out, you would expect it to be, at least, as much of a problem as any of the many chemicals the EPA may choose to regulate. Therefore, it is a good example.

The EPA has concluded that under worst-case assumptions, Benzene could conceivably account for as many as three chronic deaths per year among 7.3 million people exposed within 20

kilometers of chemical manufacturing plants. This involves multiplying one-chance in 2.5 million hazard by 7.3 million people to get three.

The point I want to make is that we are dealing with hypothetical numbers in an area close to statistical insignificance. Recognizing the ultra conservative assumptions that go into such an analysis, particularly the no-threshold linear response assumption, the most reasonable conclusion is that no one will die of cancer from Benzene in the ambient air from this source.

The mandating of technical solutions to non-problems -- and there is no evidence that chemicals in the ambient air contribute to community cancer -- will create real hazards that are, at least, equally significant.

Construction and operation of process equipment involves real hazards, as a process engineer, I would be very unlikely to suggest the same best-available-technology solution to all production units built at different times with different technology.

For instance, to return to the

Benzene-containment proposal, the EPA has suggested that all vents in 17 different production units be routed to furnaces, which they presume are on-site. No reference is made to the fact that flammable mixtures may have to be transported thousands of feet, in some cases, to obey this mandate.

A second technical approach with less inherent physical hazard was rejected because it is only 95 percent as efficient. The five percent difference in a given plant will presumably cause one theoretical cancer in 1350 years, during which time a half-million people will die of cancer from natural and life-style causes in that particular exposed area.

The probability of on-site accidents in over the same time frame caused by this additional equipment will be statistically, at least, as high.

Another example of over-reaction is EPA's suggestion that Benzene be banned as a future raw material in Maleic Anhydride production. This prohibition is based on the impossibility of containing all Benzene molecules. Therefore, some theoretical cancer hazard will exist.

44

The solution is to mandate the use of butane as a raw material. We know butane can be handled safely, but is must be admitted that handling a liquified flammable gas under pressure has its own hazards, versus the handling of Benzene which is a liquid at room temperature.

Additionally, the availability and costs of raw materials vary markedly over the years. Locking ourselves out of raw materials based solely upon upper-limit risk estimates is a luxury an energy-and-raw-material-deficient nation cannot afford.

We reject the idea that Government control is the preferred solution to perceived problems. There are economic and marketing reasons for industry to build safe, operable plants and to put safe products on the market.

There are, by EPA's own count, 47,000 commercial chemicals. An EPA estimate in ILRG document is that a maximum of 26 chemicals is presumed to have caused some chronic problems and these only in the workplace, not ambient air. Of these, only two or three account for over 90

percent of the perceived harm.

Personal freedom in the marketplace leads to the innovation Congress expressly wishes to preserve. It is a fragile benefit easily taken away by a Government pressured to do something.

Difficult as it may be, it is important that the EPA focus on real problems and not expend its efforts on generic solutions, for administrative convenience.

The principles of identification of carcinogens and risk estimation in this regulatory proposal are those of the IRLG document, published in Feruary '79. The IRLG is only now beginning to review the many substantive comments on their draft publication.

We urge EPA to recognize that many of the comments persuasively recommend the need for utilizing quality scientific determinations and risk estimations as the first step in the regulatory process. We understand that Douglas Costle has referred to the IRLG document as a negotiated document among five regulatory agencies.

Rightfully, public comment was solicited. Thoughtful and wise deliberation on

the public comment is now expected. EPA has the opportunity to utilize the public commentary on the IRLG document for its own decision-making under 112.

A lack of evidence suggesting that airborne carcinogens contribute to the incidence of community cancer allows a much more reasoned approach to the identification and solution of problems then is evidenced by this proposed policy.

The kind of analysis EPA made on Benzene is very useful and suffers only from a lack of realism as to its significance. A similar case-by-case approach will satisfy not only health concerns but the intent of Congress under Clean Air Act, Section 112.

CHAIRMAN PADGETT:

Thank you, Dr. Gunkler.

Any questions from the panel?

MR. PATRICK:

Yes, Dr. Gunkler, I would like to ask one question. In your discussion of some specific EPA suggestions on control of process units, I presume you were mentioning the Benzene-containment -- the 17 production units --

You mentioned that we had rejected an approach that was 95 percent efficient. Could you give me some more details on that. I wasn't aware that we had done that.

MR. GUNKLER:

Well, you proposed letting all of the gasses to a furnace. Another approach was to absorb as much as you could in the refrigerated condensor and run the gas to the vat, from that to a flare, and then you can't tell how efficient a flare is, but it would reject that after you absorbed most of the organics in the refrigerated condensor, the likelihood of the gas going to the flare would be inflare would be inflammable is much less than if you sent the whole thing to a furnace.

I think it is rather a peculiar rejection, incidentally. I don't know why.

MR. PATRICK:

As you said, the problem is that there are no data to support that, and that really was the point of the draft, to try to generate some information and see if we could get some more information. I think we would like to go that route.

MR. GUNKLER:

We're going to get 90 or 95 percent to the flare, if you want to send that stuff to the furnace. That isn't a solution.

MR. PATRICK:

Of course, most -- or a good many plants -- already do routing to their furnace and that was another major reason for -- for going that route.

MR. GUNKLER:

If the furnance is nearby, I have no dispute with that.

Now, there are some plants where it is three miles away; and so, obviously, that would be a problem.

MR. PATRICK:

That's all, sir.

MR. BAUMAN:

I would like to ask a question, sir.

In your testimony you state that a proposal -- that listing will be done without reference to contrary data or public participation is irresponsible.

And then furtheron you say that if Contress did not intend to operate to preculude public debate and input into the scientific bases and assumptions that go into the EPA judgement of what is a human carcinogen --

And I was not aware that we had implied that we would do that without any public participation.

But, irrespective of that comment, what procedures or precesses do you advocate or do you propose so that there be public participation and that there be evidence to the contrary --

MR. GUNKLER:

In the proposal, you have suggested that you will look at data from whatever

source and you will make an assessment, maybe. The administrator doesn't have to agree with the risk assessment.

You will take the position that you choose to use, and there's nothing in there that says that there will be a public hearing or that you will come to the industry who is being controlled and ask for their data. Nothi in that document that says that.

MR. BAUMAN:

So I gather, then, that your proposal -- or the position that you advocate -- i that there be some sort of a public meeting prior to the listing decision? Is that correct?

MR. GUNKLER:

My proposal is that there should not be a generic standard, but a case-by-ca basis.

But, in any case, there should be a meeting in which industry is allowed to present their facts.

Again, until the IRLG document is resolved, your answer is always going to be that there is no-threshold and we will draw a line straight to zero, which I find difficult to accept

We got tangled up in what is the definition of a polychlorinated biphenol. When we found out that "mono" was being called a "poly" by the EPA, within a month of two we were able to get that "mono" down below 50 parts per million.

But our customers said we don't want anything to do with anything that's got "poly" in it. And we quit buying and we have shut down one $6-million plant.

MR. BAUMAN:

Thank you, Dr. Gunkler.

You are saying that that was as a result -- that action was as a result of the listing and not the regulation? Is that correct?

MR. GUNKLER:

Yes. This is no longer a polychlorinated biphenol. It is well below the 50 parts per million. It's a legal product. There is no longer any reason for the customer not to buy it and use it. But he has chosen to say he doesn't want it.

MR. BAUMAN:

I see. Thank you.

MS. ANDERSON:

First, I had a comment and then a question.

This is with respect to the IRLG document and your statement that you think this policy rests heavily on that document, that it shoudl be held up until the document is reissued and the comments considered.

First of all, with regards to the non-threshold concept, the EPA guidelines for assessing carcinogenicity in the IRLG documen are consistent in saying that where there is evidence to the contrary, it would certainly be considered. If we don't have any evidence that can give us information about the shape of the base result, then one model that is recommende is the linear no-threshold model.

But with regards to the comments on the IRLG document, since it is regarde as a consistent scientific backgrounc document consistent with EPA's guidelines for assessing carcinogenicity, I wondered what in particular in that document you feel has such a heavy bearing on this policy that it might be changed and so substantially affect this policy that is should

be held up, the document is a rather general scientific background, scientific basis for carcinogen risk assessment.

MR. GUNKLER:

I think you expressed it. You said until they can prove that there isn't a straight line to zero. Therefore, we assume human carcinogens. The only reason we can't prove it is a straight line to zero is because we take a million rats to prove it. That is a very difficult thing to do.

The IRLG document leads up to the idea that one test, one positive test, will -- on an animal -- that we will now call it a human carcinogen.

It also says that no contrary data -- You can run this test once and it's positive for human carcinogen. And we can run it five times negative, and that will not be considered. That's in the document.

MS. ANDERSON:

That is not -- I think you are not understanding -- I didn't think that's what it said, because we have been very careful to be sure that we wrote into the document the full

consideration of all studies, including negative evidence. It does not state that this kind of evidence will not be considered.

MR. GUNKLER:

It will be considered -- you say the same thing about epidemiology, that it will be considered but that it will not be used -- that it will offset the idea of one animal test being a positive test for human carcinogens

I shouldn't be arguing with you. You're the experts. I'm not. I just feel -

MS. ANDERSON:

I'm not intending to set up an argument. I was just interested. I think it's very important to see what specifically in this document, you think, has a substantial bearing on this.

So it's the one-animal test.

MR. GUNKLER:

The one animal test; the rejection of epidemiological data, which you say can never be done --

You see, I'm quite concerned. We had a good study in our Michigan plant in 1954. We had 1,000 employees on the payroll. And we

followed them for 20 years and we found among those 8,000 employees who were exposed to much higher levels of chemicals than the public will ever be exposed to, that there were less cancers and less tests among the population that would have been predicted.

I just -- You know, I have a little trouble believing that parts per billion in the amibient air are the problem that we are addressing.

And I think when you carry it so far as to those 17 plants, what you are proposing -- we will save one cancer among two and a half million people exposed every four years.

That is the statistical significance of your controls. And I find that a mighty small number.

MS. ANDERSON:

That is not what I was asking. I was asking about the bases --

MR. GUNKLER:

I think the IRLG document says one animal test, regardless of the animal. And your judgement -- Incidentally, we are not saying

you only use good judgement. But it will be EPA's judgement that it was a valid test, that negative tests will not be accepted as proving there isn't a problem and the epidemiological tests will -- most will be considered but probably not be valuab because it will be so difficult.

MS. ANDERSON:

I think pertinent to the acceptance of data based on evidence from on animal tests, if there are submissions that you might give to EPA, we would be interested to see them and that is information that would indicate strong evidence from one-animal test should be rejected, for example, in the case of aflotoxin.

Aflotoxin would have been just entirely a human carcinogen if the evidence based on the positive results in the rat had been ignored and it was negative in the mouse and positive in the rat and it was only confirmed through positive epidemiological studies. But there is evidence only from one animal test to rely on.

I think evidence to the contrar is important.

MR. GUNKLER:

If there is one animal test where there is high evidence of carcinogenicity, it's different than if there is a very low statistical insignificance. It kind of repels the assessment.

If you have one test that is at very low levels, if you are running a tenth of a part per million or something like that, and you find a high carcinogenicity, I would find that would be good evidence. But I would think it would have to be pretty firm.

I guess we are saying it's very important that we not label our products human carcinogens unless we have sound proof.

MR. JOSEPH:

Dr. Gunkler, you have indicated that you think airborne carcinogens which are present at very low ambient levels in communities around facilities emitting those substances are not responsible for any amount of increased cancer.

Is that right?

MR. GUNKLER:

Yes.

MR. JOSEPH:

I take it, then, that you believe that these substances have thresholds for action carcinogens.

MR. GUNKLER:

I do.

I am not -- I am not a toxicologist. I just feel from my experience of exposure and everything that there must be.

MR. JOSEPH:

You also stated that it was next to impossible to establish the level of those thresholds because of the number of experimental animals that would need to be used to do that.

How, then, is EPA to establish what might be a safe level or where those threshol might be.

MR. GUNKLER:

I think the evidence is that there is no problem in the ambient air and that we syould be looking for those one or two or three or four that we might be able to establish are particularly potent carcinogens and work on those by a case-by-case basis.

I don't think that the evidenc

of problem in the ambient air is such that we need to go on a generic standard to suddenly control a whole lot of chemicals without considering all of the data.

MR. JOSEPH:

Let me just clarify that this proposal is not intended to do that.

This proposal is intended to be a decision framework and set of statisticals on which to proceed case by case, after consideration of all data available on a given substance and after the opportunity --

Well, if you read it closely, you will see that that in fact is what it does.

MR. GUNKLER:

Certainly, efforts to go out and monitor your area regularly -- which I have no objection to, incidentally -- although I wouldn't consider sending a man out there to leaks all the time. I would go to an area and monitor it which is not one of the possibilities.

You put that out immediately.

MR. JOSEPH:

You're talking about the leak-detection program?

MR. GUNKLER:

Leak-detection program and best available technology would imply that you do it on a case-by-case basis.

MR. JOSEPH:

No. That is not what the proposal says.

MR. GUNKLER:

You're saying the only thing would be done is leak detection.

MR. JOSEPH:

The only thing that is done in any way generically or automatically in any sense is the leak-dectection program. But even that does not come into play at all until the specific chemical has been listed and the specific chemical is not listed until EPA has considered all of the available evidence and part of the consideration of the available evidence is the review by EPA's Science Advisory Board after publication in the Federal Register of the notice that the meeting will take place and an opportunity for any interested member of the public to submit comments on any of the information being considered or to submit additional information.

MR. GUNKLER:

Is that in this document?

MR. JOSEPH:

For the most part, yes.

MR. GUNKLER:

I don't think it's in there.

MR. JOSEPH:

You might be correct, that the document does not refer to the fact that these determinations of carcinogenicty may be reviewed by EPA's Science Advisory Board.

MR. GUNKLER:

I think EPA --

MR. JOSEPH:

To that extent, we should clarify your question.

MR. GUNKLER:

I think EPA will be fair and all that.

But what you have done is laid out a program here, saying that you can shut down all of industry if you so choose and there is nothing in there that says that you have to listen to anything we say. But because you are reasonable people you will only do this to a certain extent

and that is exactly what that says and we have a problem there.

MR. JOSEPH:

We thought it was documented to control problems only where problems exist and to avoid shutting any large segment of an industry

MR. KELLAM:

Just a point of review, under Section 112 in the Clean Air Act, there is a statement that says that prior to listing any substance under 112, the Agency will consult to the maximum extent practicable with its advisory committee.

I think that's what Mr. Joseph was referring to.

MR. GUNKLER:

That's what I was saying, I think.

Nothing in there says that we get involved.

CHAIRMAN PADGETT:

Any other questions?

(There was no response.)

UNIDENTIFIED SPEAKER: I am Gary Base (phonetic), Counsel for Dow. And with

respect to the listing provisions in Mr. Bauman's question earlier, what we really want is spelled out in the AIC program, and that is a set of procedures to guarantee that you obtain all of the scientific data.

Right now, you have purely a discretionary approach. And I refer you to the AIC proposal, which sets out the requirements we think you should undertake for the listing.

CHAIRMAN PADGETT:

The next speaker is J. Bruce Bate.

STATEMENT OF J. BRUCE BATE

MR. BATE:

I am J. B. Bate with Northern Petrochemical Company. I will offer oral testimony to enlarge on written testimony previously submitted by Mr. B. J. Anderson of our Company.

There is little understanding of the mechanism that allows uncontrolled cell growth commonly referred to as cancer. A great deal of time and money has been expended over the years in exploring the subject.

Many causes and factors have been postulated including germs, virus, submicroscopic organisms, chemicals, complex trigger mechanisms, heredity, physical susceptability and others.

Learned researchers under government, private and business auspices have struggled with the problem. Mountains of data have been compiled, indexed, interpreted, misinterpreted, logically and illogically combined publicized, sensationalized, taken out of context and otherwise misused. Nevertheless, progress has and is being made in understanding cancer and

other toxicological effects.

Cancer, as our second leading cause of death in the United States today, is feared because of its frequency and because no obviously successful cure is known. It is hoped by all that the causes and mechanisms of cancer can be discovered and controlled.

The regulations in the form proposed can only delay the progress that must be made. The use of regulations not based on ordered scientific criteria but on rigid determinations will effectively freeze science.

The so-called cancer epidemic that has made sensational reading is in fact not with us. Most forms of cancer have not increased if the data from U. S. government and the National Cancer Institute is considered. Indeed in some forms cancer has decreased.

The incidence of lung cancer has risen alarmingly. The EPA and many researchers acknowledge that cigarette smoking may be the cause of this. The increase in lung cancer today can be shown to have a 20-year-lag relationship to the annual per-capita consumption of cigarettes.

EPA has chosen to dismiss this and instead have proposed regulations under the Clean Air Act, Section 112, to regulate classes of chemicals. The regulations proposed will not measurably increase public protection.

The EPA seeks to demonstrate a need for this standard based on three premises: Cancer is a terrible disease, and this is right. That a cancer epidemic exists, and this is not so; and, that the so-called epidemic is largely due to industrial stationary sources. The last two are not supported by facts.

The EPA policy will not measurably increase public protection but will place serious limitations on the U. S. economy and result in substantially increased costs for consumers.

EPA wrongly guesses that the cost of compliance will be small. An Arthur D. Little economic study of the policy projects costs of compliance to run into the millions of dollars. This impact in these days of runaway inflation should require an economic analysis before any regulations are implemented.

In addition to showing no

apparent need for the proposed regulations, no scientific validity can be seen. Terms are ill-defined; for example what is meant by potential human carcinogen and significant risk is unclear. Also, there is no mechanism for consideration of comprehensive risk assessment early in the regulatory process.

EPA has been a participant in the Interagency Regulatory Liaison Group and other efforts to develop a comprehensive and meaningful national cancer policy. Yet it now proposed rigid regulations inconsistent with such efforts.

That concludes my testimony.

CHAIRMAN PADGETT:

Thank you, Mr. Bates.

Questions?

MS. ANDERSON:

I wanted to ask two things. The first is on the second page of your testimony.

I think what you have said is a bit misleading. At least, I don't believe anywhere in the policy is there a mention of a cancer epidemic or that such an epidemic is largely due to industrial stationary sources.

Could you point out where the Policy says that or implies that?

MR. BATES:

The implication is the need for control and the fact of the cancer epidemic is broadly talked of through the press and others.

What is the objective of having a cancer policy?

MS. ANDERSON:

I think the legal mandate is clear. We don't have to have an epidemic to protect the public. I don't think EPA in any of its programs has ever taken the position that there is a cancer epidemic or that we need to have a cancer epidemic before regulatory action is considered.

And the second thing I wanted

to ask is: You say that this Policy is inconsistent with the efforts of the IRLG work.

I wondered in what respect you find statements in this Policy inconsistent with that effort?

MR. BATES:

The evidence of this is offered by the American Industrial Health Council, in both their written and oral testimony, which you have already heard.

MS. ANDERSON:

We are unaware of any inconsistencies. We will look at those documents. Thank you.

CHAIRMAN PADGETT:

We have some other questions.

I just -- On your first page you had a statement:

> "The use of regulations not based on ordered scientific criteria but on rigid determinations will effectively freeze science."

Will you elaborate on that.

MR. BATES:

Yes.

If you are going to classes of compounds and without first investigating them thoroughly and proving them to be carcinogens and be effective carcinogens in the concentrations that are encountered in the atmosphere, restrict those, put them on lists under the Section 112, this will to a considerable extent stop the progre that is being presently developed in determining what is the cause of cancer.

CHAIRMAN PADGETT:

In what way will it do that?

MR. BATES:

It will stop the research being carried on. It will make it non-meaningful.

CHAIRMAN PADGETT:

On page 2 you had a statement:

"EPA has chosen to dismiss this and instead have proposed regulations under the Clean Air Act, Section 112, to regulate classes of chemicals."

Are you referring there to the generic regulations?

MR. BATES:

That is correct.

CHAIRMAN PADGETT:

Are you talking about what we tend to call "housekeeping" regulations, not the basic best-available-technology regulations but other regulations that might later be set for specific sources, of specific sources of specific chemicals?

MR. BATES:

Yes.

CHAIRMAN PADGETT:

All right.

Any other questions?

(There was no response.)

CHAIRMAN PADGETT:

Thank you very much.

I understand that Keith Ozmore is substituting for Reginald Hirsch. Is that correct?

MR. OZMORE:

Yes, sir.

51

STATEMENT BY KEITH OZMORE

MR. OZMORE:

Thank you, Dr. Padgett, for the opportunity to be here this morning.

As you will note on your schedule, this presentation was supposed to have been made by Mr. Reginald Hirsch, who is Chairman of the Air Conservation Committee of the American Lung Association.

Mr. Hirsch, and conveniently, he found himself to have to be in court this morning. So I have been elected to fill in for him.

At the outset I want to say this This statement has been drafted through a consensus of about 12 people who serve on my Air Conservation Committee. And when question time comes, I want to emphasize that I am a lay person and I have never been bashful about saying that I don't know the answer to a question.

If I can answer your questions, I shall; if not, I would like to have the opportunity to take those questions back to my Committee and can come up with a consensus to the response and include it in the expanded version of this paper for inclusion in the record.

I wear several hats. I am also Environmental Assistant to Congressman Bob Eckhart, who represents the Eighth District in Harris County, which includes, possibly, the world's greatest chemical complex.

Most of the ship-channel industries are in the District he represents. While I do not represent the other two organizations, I am a member of the Citizen's Environmental Coalition in Harris County, and I am a member of the Air Quality Task Force of the Health Systems Agency which is in the process of developing a regional health plan. In all of those capacities, I am concerned about the question you are discussing today.

The Air Conservation Committee and the Lung Association, as you know, have long been involved in supporting programs to try to reduce respiratory diseases both in the anti-smoking field and through the control of chemicals that cause disease.

Thank you for the opportunity to appear here today to testify on the Environmental Protection Agency's proposed rules concerning the control of airborne carcinogens.

53

I am Keith Ozmore and I represent the Air Conservation Committee of the American Lung Association. The Committee and the Association, as you know, have long been involved in programs to reduce respiratory diseases, in both clean air programs and programs to educate citizens to the dangers of cigarette smoking.

We are confident that an unknown, but significant, number of future cancer cases can be prevented by an improved control of airborne carcinogens now. Current cancer rates probably do not reflect the growth in the use of chemicals since the early 1960's. This growth and use is likely to result in an increase in cancer rates in the future.

There is a lack of data caused by the long latency period required for such cancers to show up; for instance, consider the increase in number of asbestiosis and lung cancer caused by exposure to asbestos as long ago as the 1940's, when thousands of wartime workers were exposed to asbestos in the war plants. We feel like this question must be addressed by the EPA.

We would disagree with an earlier speaker on the concept that a person is

innocent until guilty applies here. We are not talking about people; we are talking about agents. We're talking about dangerous substances, and if they're not controlled before they are released into the environment, innocent people may very well be sentenced to death, because they were not controlled. So I am talking about innocent people who may die because of these emissions.

While the incidence of lung cancer among smokers who have been exposed to asbestos is extremely high, at the present time lung cancer incidence among non-smokers is increasing. Can this increase be linked to the increased production of carcinogenic chemicals in recent years?

There is evidence that lung cancer rates in highly industrialized counties such as Harris County are higher than the rate in non-industrialized counties. Would this perhaps indicate that the high production of organic chemicals in the world's greatest petrochemical complex may well have an impact upon the number of cancer victims? While all the facts are not in, we feel like this question must be addressed by the EPA. Let me discuss for a few moments what we

55

feel the EPA might do to implement an airborne carcinogen regulation program.

First, it should establish a candidate list of carcinogens which may be emitted from stationary sources as air pollution. As a minimum, the two dozen or so substances which are now known to cause cancer in humans should be regulated. Furthermore, the Agency should list other substances as hazardous air pollutants for further study and regulation where appropriate. On this point the Association is disappointed that the Agency has moved so slowly in implementing Section 112 of Public Law 95-95.

To date, only four substances have been so regulated, out of the several hundred potential hazardous pllutants. Because of the time necessary to carry out research and bioassays, the Association wants to call upon the EPA to expedite its implementation of the program at the earliest possible time.

Secondly, the EPA should resolve in the proceeding certain essential scientific issues which arise in the same manner and must be resolved on the same evidence for each individual carcinogen. These scientific issues

would be foreclosed from futher consideration in proceedings to regulate individual substances.

When significant new information is presented which calls for a different resolution of the scientific issues regarding generic classification, such issues will be reconsidered and then only in the contest of a general proceeding to amend the general rules.

This resolving and foreclosing of the generic scientific issues is essential if a national and efficient consistent airborne carcinogens policy is to be implemented and a significant number of substances brought under control.

The third point which we wish to emphasize is that the EPA should establish in this hearing that when a carcinogen is listed as a hazardous air pollutant, any reasonably available measure should be required to reduce emissions to the lowest point practicable, even if this were to require reductions below whatever emissions limits are justified by consideration of toxicity.

The reason for this recommendation is that no threshold value can be established for

carcinogenic agents, and the only practical recourse is to limit exposure to the public to carcinogenic agents whenever possible.

It is our belief that the burden of proof must be placed upon the manufacturers of chemicals to show that emissions into the air are not damaging to human health or the environment.

Our position is based on the old saw, the proof of the pudding is in the eating, or in this case, the proof of the air is in the breathing. If we have two or more industries emitting different substances, with those substances intermingling, the results of breathing such ambient air may be far more dangerous than breathing just the one pollutant. A program should be devised which would tend to decrease such a problem.

On this point, we would also add that dispersal of sources of carcinogenic air pollutants is not an acceptable alternative to controlling their emissions. Solution to pollution by dilution is not a viable alternative.

The Association generally approves the concept of risk assessment which includes both carcinogenicity and exposure to the

public. However, we feel that the EPA should abandon its arbitrary reliance on quantitative risk assessment methods. They are simply too unreliable and imprecise to play an important role in determining the level of controls applied to a hazardous substance.

While such estimates may have a role in the grossest form of priority setting, that would be valid only if the Agency more explicitly recognizes the uncertainties of the estimates and commits itself to not using them in any way in subsequent standards setting.

The Association agrees that the generic standards, discussed in the Register are appropriate for the current effort to quickly reduce fugitive emissions, storage and transfer of carcinogens.

However, we feel that the EPA should expand the scope of the proposed first-step generic controls that will be applied quickly to include those controls on process emission points which are not expensive, or likely to be inconsistent or duplicative of more effective technological controls to be considered thereafter.

Furthermore, the Agency should

consider restructuring these interim rules in ways which may enhance voluntary compliance and permit more effective enforcement.

Very careful consideration should be given to the siting of plants which emit hazardous pollutants. At this date, data is insufficient on the synergistic efforts of two or more pollutants as compared with the effect of a single pollutant. For instance, we know that cigarette smoking and exposure to asbestos exacerbates the lung cancer problem.

Finally, the Agency must take into consideration all the costs of implementing such controls. We agree that the cost to the industries must be considered, since that cost is passed on to the consumer. However, at the same time, the Agency must consider not only the costs of health care but the human suffering and trauma which is caused to millions of Americans who will contract some form of cancer during their lifetime.

How can you place a benefit-cost concept on human lives and suffering?

Thank you.

CHAIRMAN PADGETT:

Thank you, Mr. Ozmore

MR. OZMORE:

I would like to add one more thing. Congressman Eckhart supports this in its entirety.

MR. KELLAM:

Mr. Ozmore, I have two related questions and you may want to submit them later in writing during the rebuttal period.

On the second page of your testimony, you recommend that EPA establish a candidate list of carcinogens.

I would like to ask you if you have any suggestions as to the criteria that the Agency should use to select or nominate substances to that list; and, secondly, given that such a list would be put together, how should the Agency use this under Section 112?

MR. OZMORE:

How should the Agency use the candidate list?

MR. KELLAM:

Yes. It is not clear to me.

By "candidate" list, do you mean a list of substances from which some should be selected for regulation under 112? Or whether the

61

entire list should be regulated as resources became available? Or exactly what do you mean?

MR. OZMORE:

I would not answer that on my own since I am representing the Committee here; and I think I would need to refer that to the Air Conservation Committee for response.

MR. KELLAM:

Thank you.

MR. PATRICK:

Mr. Ozmore, I won't put you on the spot and ask you for details right now.

On the front page of your testimony you made the statement that your Committee recommended application of controls on process points which were not extensive or inconsistent or duplicative or more effective controls that might be considered later.

Any particular examples that you might have along that line, we would appreciate hearing about them.

MR. OZMORE:

Very well.

MS. ANDERSON:

I had just one comment that I

think that I would like to make for you to take back to your Committee and maybe have them think a little further on this point, and that is I would -- really largely discarding the notion of quantitative assessment since we know that the potency of carcinogens can vary as much as a millionfold or more; for example, if cigarette smoke and saccharin were potent carcinogens, we would probably have an epidemic on our hands.

It would certainly make some sense, as far as EPA's thinking is concerned, to take this into account in some fashion, that it's a potent factor, that the state of the art, while very under-developed, is sufficiently developed to take this into account and you emphasize the idea of looking at cost to try to get the most improved men in public health for the least cost.

I think the proposal has proposed limited use of quantitative risk assessment and I think it would be desirable to have your group rethink this and look at the proposal and think if you think what is being proposed is reasonable.

MR. OZMORE:

Surely.

MR. BAUMAN:

I would like to follow up just with one more comment on Dr. Anderson's remarks.

On page four of your testimony, you suggest that the Agency must consider not only the costs of health care but the human suffering and trauma which is caused.

And I would like to ask you if you could consider how that might be done. I realize that you are saying that quantitative -- your testimony is that quantitative risk-assessmen may not be a way to do that.

Yet I know of no other way to consider that other than just arbitrarily. And I would like to have some idea of how that might be accomplished.

MR. OZMORE:

Well, I could go back to my earlier statement, that we think the burden of proof has to be placed on the manufacturers of the chemicals.

This concept already is embraced in the Toxic Substances Control Act, which Congressman Eckhart was very active in having

enacted. We see no reason why this same concept should not apply to dangerous substances which are already in the marketplace and in the environment.

"The proof of the pudding is in the eating." If you test those chemicals and find out that they are dangerous, they should not be admitted into the environment.

We will look at that and see if we can expand on it further.

MR. BAUMAN:

I guess what I'm saying is that if you ask Industry to tell you how much human suffering and trauma is involved, it probably will be very little.

MR. OZMORE:

That's the point I'm getting at this morning. I don't agree with that.

CHAIRMAN PADGETT:

Thank you.

Excuse me. Are you finished?

MR. BAUMAN:

Yes, sir.

CHAIRMAN PADGETT:

I have a question from the Floor,

65

and I'll just read it as proposed:

"How does the witness conclude that the number of cancer tests presented by the Policy will be significant if the number is unknown?"

I don't know --

MR. OZMORE:

I think any increase is significant, whether it is known or unknown.

CHAIRMAN PADGETT:

Let me ask you a question relative to siting.

You mentioned very careful consideration should be given to the siting. Do you have any particular thought on siting?

MR. OZMORE:

I think you have to look at the possible synergistic effects of whatever is being emitted by the industries and look at those synergistic effects to determine whether there is going to be increased danger from the breathing of the intermingling of two or more substances. I is just not that simple.

Plants which cause synergistic

effects should be dispersed.

CHAIRMAN PADGETT:

Thank you.

Any other questions?

(There was no response.)

MR. OZMORE:

Thank you very much.

CHAIRMAN PADGETT:

Thank you very much.

We have a request from Steve Davis and Dennis Lachtman to testify now, based on personal scheduling problems.

So, if there is no objection, I will call on Steve Davis.

STATEMENT OF STEPHEN C. DAVIS

MR. DAVIS:

Good morning, Mr. Chairman, and members of the hearing panel.

My name is Stephen C. Davis. I am Corporate Manager of Industrial Hygiene for Utah International, Incorporated. I also serve as Chairman of the Carcinogens Subcommittee of the American Mining Congress.

With me today to testify is Mr. Dennis S. Lachtman. Today we will expand upon several of the points made in the written comments prepared by this subcommittee and submitted last month by AMC on the proposed EPA Airborne Carcinogens Policy and Procedures.

First it should be noted that the American Mining Congress is an industry trade association with membership of over 500 companies actively engaged in the exploration, development and production of essential minerals and fuel resources vital to our country's continued prosperity and national resources.

We are here to discuss a regulatory proposal that may greatly affect the ability of this industry to continue to provide a

stable and secure flow of basic minerals resources essential to our national productivity and security

The points I will address today concern: One, the lack of a sufficient demonstration of need for the proposed program; two, the allocation of limited societal resources; three, the premature nature of the EPA proposal; and four, inconsistency of the proposal with other Federal carcinogens control programs. My colleague, Mr. Lachtman, will focus his presentation on what AMC feels is one of the weaker points of the Agency's proposal, the listing process for carcinogenic substances.

In the preamble to the proposed regulation, EPA suggests three basic premises for its proposal. These are: one, that cancer is a serious life-threatening disease; two, that the United States is suffering from an epidemic of cancer, and that air pollution plays a significant role in this cancer epidemic.

While we agree that cancer is certainly a serious life-threatening disease, EPA's remaining premises are not supported by its analysis in the preamble nor by the existing

69

facts. Consequently, EPA has not demonstrated the requisite need for its proposed national procedures.

EPA's implication that the United States is suffering from a cancer epidemic is based on the broad definition of an epidemic as the excessive occurance of disease. In medicine, epidemiology, however, the term epidemic is normally applied to contagious disease and is restricted to diseases that spread rapidly and are temporary in nature.

Although the absolute number of cancers has increased since 1930, the cancer death rates, when adjusted for age, have remained relatively constant and in some cases have decreased. The overall cancer incidence rate, the number of new cases adjusted for age distribution of the population, has decreased slightly since 1950. The one major exception to this trend is lung cancer.

As reported by the Surgeon General in his 1979 "Report on Health Promotion and Disease Prevention", overall cancer death rates have increased only slightly for men since 1937 and have actually decreased slightly for

women over this same period. However, if lung cancer attributable to cigarette smoking, which has been shown to be responsible for as much as 80 percent of the cancer observed, is eliminated, the cancer death rate for both men and women is actually decreased.

To turn to environmental factors and air pollution, we see that EPA also attributes a large proportion of cancers to environmental factors. EPA indicates that the "World Health Organization, and other individual experts have suggested that 60 to 90 percent of all human cancers may be due to these factors." We believe byusing a very expansive definition of "environmental factors" which includes such things as smoking, diet, and occupation, EPA has by implication vastly overstated that proportion of cancer risk which is attributable to air pollution and in particular to industrial chemical sources.

Dr. John Higginson, founding Director of the World Health Organizations' International Agency for Research on Cancer, developed the concept that the total environment, cultural as well as chemical, was responsible

71

for environmental cancers. When questioned recent in Science about misinterpretation of his conclusions relating to environmental cancers, he stated:

> "They have been misinterpreted, funnily enough, not among the majority of the scientists with whom I have contact, but by the chemical-carcinogen people and especially by the occupational people."

He further stated:

> "I mean, people would love to be able to prove that cancer is due to pollution or the general environment. It would be easy to say 'let us regulate everything to zero exposure and we have no more cancer.' The concept is so beautiful that it will overwhelm a mass of facts to the contrary."

He concluded:

> "In other words, I believe that overemphasis on

chemical carcinogens has distorted our approach to the environmental theory for many cancers."

A little further on that subject, Dr. Philip Handler, President of the National Academy of Sciences, recently stated:

"Several hundred specific chemical compounds have been thus examined in the last few years and a considerable fraction found to be both mutagenic and carcinogenic. Nevertheless, we should lay to rest the idea that it is these man-made compounds, abroad in the land, that are responsible for the fact that 24 percent of Americans die of cancer. They are not. The possible effects of all known man-made chemicals, when totalled, could contribute only a miniscule fraction of the total of all carcinogenesis in our population. As I noted

72

earlier, current age-corrected incidence rates are much what they were before most of these chemicals were introduced into our surroundings. They certainly cannot account for the even higher age-corrected cancer rates in some, more primitive, countries which do not yet enjoy the benefits of a diverse chemical economy."

To turn now to the allocation of limited resources, EPA acknowledges the limits of our national resources in principle by suggesting in the preamble that generic standards will be "low cost and readily implemented control procedures." Yet the American Industrial Health Council, AIHC, points out, based on a study conducted by Arthur D. Little, that the total costs to industry to control a single organic chemical, Benzene, would be 1.1 billion dollars for generic and best available technology, BAT, controls. AIHC also notes that costs to control perchloroethylene would exceed 100 million dollars Fifty-five million would be required for generic

controls and 50 million dollars for BAT controls.

Thus, according to AIEC, the cost to control only two synthetic organic chemicals, Benzene and perchloroethylene, exceeds 1.2 billion dollars. Those figures do not include the other 38 chemicals or the countless others that may be identified in the other five source groups established by EPA.

EPA's proposal is not low-cost and it seems to misdirect our national resources away from other more vital and more clearly substantiated causes of cancer.

EPA proposed regulatory procedures are premature, in our thinking, and there are several reasons in our judgment that EPA's proposed rulemaking is premature at this time. Obviously, the first reason, as we just discussed, is the absence of a demonstrated need for these regulations.

EPA, as the hearing panel is well aware, is participating in the effort of the Regulatory Council to adopt a government-wide policy for all federal carcinogen programs.

The statement published for public comment in October 1979 by the Regulatory

74

Council was quite detailed and raised a number of significant, complex issues. Numerous comments were received and if the final statement is to have any real impact on federal agency programs, the development of those programs should await completion of the Regulatory Council statement.

Further, the EPA is part the Interagency Regulatory Liaison Group effort to develop a common scientific basis for identificatio of potential carcinogens and estimation of risks.

The ability of the IRLG to achieve this goal will be severely hampered by EPA promulgating precise regulatory procedures at this time. Similarly, EPA's flexibility to implement IRLG conclusions will be restricted.

The EPA's proposal is also premature because the Agency has not completed the regulatory analysis required by Executive Order 12044 and by its own regulations. We certainly agree with EPA that this is a major regulatory proposal.

The potential effects of this proposal are extremely far-reaching. AIHC has already demonstrated to this hearing panel that the costs of applying BAT controls to only a few

of the candidate substances far exceeds the 100 million dollar threshold for a full regulatory analysis.

To sidestep the requirements of Executive Order 12044, as EPA has suggested in the preamble, is to make a complete mockery of this Presidential directive. Until a regulatory analysis is done, this proposal is premature.

Finally, I would like to talk about guidelines instead of regulations..

Finally on this point, we believe if EPA adopts any procedures at this time, they should be adopted as guidelines rather than rigid regulations.

As Mr. Lachtman will discuss, the proposal contains many new concepts and important regulatory phrases with which there is essentially no operating experience under the Section 112 program. Many critical terms are either undefined or only briefly and vaguely explained.

However, EPA indicates clearly in the preamble that it considers that any final rule will only be subject to judicial review in the D. C. circuit. Further, EPA states that

"litigation of the issues posed by this rule will not be available in connection with subsequent rulemakings in which it is applied." While we seriously question this legal interpretation, to the extent that EPA is correct, a very clear understanding of the terminology and the process described is critical to public understanding and acceptance of the program. Under these circumstances it would be far better to publish procedures for this program as guidelines rather than rigid regulations.

The present proposal gives us the ver uncomfortable feeling that EPA wishes to suppress discussion and preclude adjustment of its procedures as the need arises. We definitely appreciate certainty in any regulatory process but not at the expense of burdening all of us -- the public, the Agency, environmental groups, and Industry alike -- with a process that experience may demonstrate is unworkable. Experience will be our best teacher; maximum flexibility is essential while we gain this experience.

Certainty, consistency and predictability in regulatory programs are, of course, extremely important goals to those

regulated. One way for EPA to achieve these goals is to assure consistency with other federal carcinogen control efforts. Whether EPA accepts or rejects our suggestion to publish its procedures as guidelines, there are several ways in which it should change its proposal to increase interagency consistency.

First, as discussed earlier in my remarks, EPA should withhold further action on its policy and procedures proposal until the Regulatory Council and the IRLG work is completed.

Second, as the Agency is well aware, the Occupational Safety and Health Administration, OSHA, just recently published its final policy on "Identification, Classification and Regulation of Potential Occupational Carcinogens." OSHA and EPA act under different authorizing statutes but, as in the past, both agencies will potentially be involved in regulation of the same substances and source categories.

Obviously, there will be a significant need to have harmonious regulatory procedures in these areas where the agencies' interest will overlap. Divergent controls should not result from essentially identical records.

Turning to the provisions of the OSHA policy, we note that OSHA's Category I Potential Carcinogens, equivalent to EPA's High Probability of Human Carcinogenicity category, is based on evidence of carcinogenicity in humans or in a single mammalian species in a long-term bioassy where the results are in concordance with some other scientifically evaluated evidence of a potential carcinogenic hazard.

EPA's equivalent category only requires that "best or substantial evidence exist from epidemiological and/or at least one mammalian study."

The EPA does not require concordant evidence of carcinogenicity to label a substance as a high-probability carcinogen. We believe the OSHA approach is more scientifically sound and at least should be used by EPA as well.

EPA makes no provision for the evaluation of non-positive results. OSHA, however, stipulates that "where non-positive and positive results exist in studies in the same species, the non-positive results will be evaluated." This allows the Agency to weigh evidence that refutes the categorization of a substance as a carcinogen.

EPA's unwillingness to acknowledge this type of evidence runs counter to good science and to the best interest of the public.

That's the end of my statement.

CHAIRMAN PADGETT:

Okay. Thank you.

We'll discuss this first before we move into the next one, I suppose.

MR. DAVIS:

Yeah. I think so. We were planning to just have the two testimonies together But if you prefer, we'll go ahead and I'll be open for questions now.

CHAIRMAN PADGETT:

Okay.

MS. ANDERSON:

Yes.

You started your statement by saying that, in the preamble, EPA states three basic premises --

MR. DAVIS:

I actually said "suggests."

MS. ANDERSON:

Your statement says "states" --

MR. DAVIS:

I know.

MS. ANDERSON:

Okay.

Because I find two out of the three are rotten.

MR. DAVIS:

Yes.

MS. ANDERSON:

But what I would like to do in a more constructive way, there is a paragraph that I think does raise the issue and I would like to know which parts of this statement you are disagreeing with.

The paragraph taken from the preamble says that:

"...although airborne carcinogens may induce cancer in a number of body sites, lung cancer is thought to be a principal form of cancer related to air pollution.

"While cigarette smoking is probably the most important cause of lung cancer

in the United States, many scientists believe that various air pollutants increase the risk of cancer from smoking and other carcinogenic insults.

"Available estimates also indicate that occupational exposures are responsible for a significant portion of lung cancer incidence in the United States."

Are you disagreeing with -- that -- I think that kind of summarizes what we were saying.

Are you disagreeing with all that paragraph --

MR. DAVIS:

Let --

MS. ANDERSON:

-- part of it and if so which part?

MR. DAVIS:

Let me state that you'll notice that we do say an implication that there is an

epidemic. There are several areas in the preamble in that same general area of the proposal that tend to suggest that there -- the Agency considers this an epidemic, not in the classical sense but also that the epidemic -- a significant proportion of that epidemic can be tied directly to air pollution.

Quote:

"Cancer is currently the second leading cause of death in the United States...."

A little further on down, quote:

"The most recent statistical --" "--recent statistics show a continued increase in total cancer incidence, due principally to increased lung cancer."

Further on down, under causes of cancer, importance of environmental factors,

"Studies of human cancer rates and world-wide

geographic variations and observation of incident rates in migrant populations revealed the factors in the human environment are probably responsible for a large portion of cancers."

Moving over to the third column, we discuss, finally -- part of the sentence, it says:

"The dimension of the problem posed by airborne carcinogens remains significant."

And with those kinds of statements, and particularly the link that is made between the incidence of cancer and the problems of cancer and environmental factors and then focusing on the aspect of air pollution one comes to the conclusion that -- that the Agency is suggesting this kind of relationship.

MS. ANDERSON:

Well, we certainly didn't intend suggesting -- I think the language as it was read to you -- that air pollution is causing a major epidemic of cancer. I think what I read

you quite accurately reflects what we're tring to say.

But more specifically in askin which of those statements in this paragraph you would disagree with just to dissect it a bit do you think that there are problems in occupational exposures?

MR. DAVIS:

Where precisely are you? I have the proposal in front of me.

MS. ANDERSON:

I'm just asking you -- I'm dissecting this paragraph a bit.

Do you think that -- are you saying -- do you think that there are or are not problems perhaps in the occupational environment?

MR. DAVIS:

I think that if you --

MS. ANDERSON:

-- from air pollution.

MR. DAVIS:

In the occupational environment

MS. ANDERSON:

Right.

MR. DAVIS:

Okay.

There are instances -- and certainly OSHA has regulated a number of carcinogens which have -- they had evidence of causing excess cancers in the working population.

MS. ANDERSON:

Do you think the problem stops at the fence line of that industry or can it expand into the immediate surrounding populations living near that industry?

MR. DAVIS:

I think that would be something that certainly a reasonable person might expect.

But in most cases it is yet unproven.

MS. ANDERSON:

Do you think that the mandate that Congress has given EPA to regulate carcinogens means that no regulatory action should be taken until we can actually see if that's in the surrounding population by positive epidemiology studies.

MR. DAVIS:

That is a hazardous position to take.

[Laughter]

MS. ANDERSON:

Then -- how do we -- how do we look at this particular problem outside the fence What do we use -- in other words, what are you suggesting --

MR. DAVIS:

Again, I would hate to -- retreat into a disclaimer, if you will, of not being a toxicologist or an epidemiologist. But some of the areas that Mr. Lachtman will address and hopefully we will have further developed by toxicologists and biostatisticians relates to the way in which the carcinogen becomes defined and the way in which it goes through the IRLG screen.

And I think it's a matter of the mechanism by which you establish carcinogenicity a high probability, moderate and low, which is very important --

MS. ANDERSON:

I have just another topic, one other question, and that is, you suggest that

EPA should hold up its policy pending the IRLG final considerations of permits.

First of all, just to commen a bit, the document that was released by the IRLG did have the agreement of the four major regulatory agencies active in this area plus participation from the National Cancer Institute.

Comments have been submitted but OSHA did not withhold its policy pending final consideration of these comments.

The IRLG report does appear to be consistent with other reports that have been issued by other scientific bodies. You seem to be dodging the OSHA approach. I wonder why you think that EPA should hold up its -- its policy --

MR. DAVIS:

Okay. Two -- two responses to that.

As I understand it, first of all, the IRLG document is not finalized and it has not received full scientific review by the scientific community.

All the comments are not in and have not been digested.

Secondly, with regard to the

OSHA policy that's currently presented, we were simply pointed out some advanteages not necessarily concurring with the -- with the total policy.

MS. ANDERSON:

Now, the --

MR. DAVIS:

And certainly the inconsistencies that exist between the two -- the OSHA rule and the current proposal.

MS. ANDERSON:

Yes.

We have heard some other comments, primarily from environmental groups, suggesting that it is more automatic to have a specific category.

EPA has -- took its approach three and a half years ago before OSHA's policy was -- was even proposed and that was to take it -- take the approach of considering all of the data in the aggregate on a case-by-case basis by certainly considering all negative data, all positive data, so as not to have automatic triggers that would throw a chemical into a particular category since in looking at the evidence we have seen that the quality and kinds of studies that

have been conducted have varied enormously.

I think in taking this approach they certainly didn't plan -- EPA -- to ignore anything but rather quite the contrary.

I wondered if you had happily been over or reviewed the EPA's guidelines for taking this weight-of-evidence approach?

MR. DAVIS:

One of the things that we find in the current proposal is the lack of explicit statements with regard to the use of non-positive data and I think there was an early statement and I'm not going to attribute it to which speaker but there is a concern that the terms are vague and that we just do not see any opportunity for full scientific input into the process.

Now, perhaps the Agency has implied these. But they are not -- they are certainly not explicit as we see it in the proposal.

MS. ANDERSON:

Do you find that the OSHA -- the OSHA approach to categorizing carcinogens more acceptable than this weight-of-evidence approach?

MR. DAVIS:

Not necessarily more acceptable. What we had spoken to was the aspect of concordant evidence, the need for having substantial additional evidence to back that up.

And, again, I would suggest, not to defer, but I would suggest that Mr. Lachtman will be dealing with some of those issues.

MS. ANDERSON:

And just one final question along this line.

Since you did mention the OSHA approach, do you think that in their policy they have permitted more public participation in a scientific presentation of data than EPA is considering in its policy is that one of your --

MR. DAVIS:

It would appear that there is more public participation available in the OSHA approach and also that the record, if you will, will be reopened and reexamined by any interested person.

MS. ANDERSON:

My colleague just pointed out one thing that I think you did admit from your

testimony and that is in pointing to inconsistencies between the EPA approach of what is substantial evidence on how probability carcinogenicity you mentioned that it's inconsistent with OSHA with regards to OSHA considering epidemiology plus a single mammalian species, OSHA's third category is a single mammalian species in an adquately-conducted long-term bioassay study in appropriate circumstances where the Secretary determines the requirement for concordance is not necessary (sic).

So I think this does put -- put the --

MR. DAVIS:

Where the Secretary determines that concordance is not --

MS. ANDERSON:

In other words, OSHA is saying that in appropriate circumstances, one species might be okay with them, too.

MR. DAVIS:

In certain circumstances. But that is not apparently an assumption at the outset,that would be by exception rather than the rule. That's the way I would interpret that.

MR. JOHN ZIMMERMAN, SR.:

If I might clarify just one point about our view of -- the Mining Congress view of this thing.

I'm John Zimmerman, Sr., Counsel for the Mining Congress.

In relationship to OSHA versus EPA, what we hear you saying I think I like the sound of.

But our problem is the words in the proposal don't seem to carry out all the contexts we hear coming from the hearing panel.

And, of course, what we're premising our testimony and our written comment on is the precise words that we see in the proposal.

In terms of the weight-of-the-evidence test, we certainly applaud your use of a weight-of-the-evidence test. But what we felt when we read your proposal, your October 10th proposal, was some pulling back from that weight-of-the-evidence test, a very selective use of phraseology from the interim guidelines.

And particularly in terms of

a seemingly reduction in this peer review that precedes the listing action, I think that the point we're trying to make on the OSHA policy here is the weight of concordant evidence and the consideration of concordant evidence seems to be partly OSHA proposals.

We don't like necessarily in OSHA the automatic-listing aspect of the proposal. But certainly the consideration of concordant evidence seems to be more possible in the OSHA proposal than in the EPA October 10th proposal.

And certainly when they do have that third category for one animal test without concordant evidence, they raise that to a very high level to Agency determination before they're willing to accept a one-mammalian test. It has to be a Secretarial decision.

We don't get that sort of feeling out of the October 10th EPA proposal.

MS. ANDERSON:

Just a comment on that.

If that's the way it comes across, I think that is just a problem with the verbiage in the proposal because I know the

proposal -- I can't tell you exactly now where it refers to both the IRLG document and the EPA interi guidelines.

And it says that policy will follow both and both policies certainly emphasize the importance of taking all data in the aggregate when considering evidence of carcinogenicity and the guidelines are quoted in part.

Perhaps if it doesn't come across clearly, that's a problem that we can take into account in rewriting, just to be a little clearer.

CHAIRMAN PADGETT:

Any other questions?

MR. PATRICK:

Just one real brief point of clarification.

In your discussions of resources, you reference this recently completed R. D. Little assessment for the American Industrial Health Council.

I don't think we need to get into that because they made their presentation in Washington. We will be getting back with them at a later date to discuss those -- their

assumptions and their numbers and their conclusions.

I did want to just clarify one point and make sure that you understood. You discussed -- you began a particular paragraph by saying the generic -- talking about generic standards as being in EPA's words "...low-cost and readily-implemented control procedures."

And then you immediately started talking dollars in terms of both generic and best-available-control technologies --

MR. DAVIS:

It seems like a reasonable thing to group those, because that is a sequential thing -- not an automatic, but a sequential ocurrence.

And we did split figures and show the figures for generic versus BAT -- and I think the Little study does that kind of thing.

MR. PATRICK:

They split the costs and we will be discussing their assumptions with them later.

MR. DAVIS:

Right.

MR. PATRICK:

I just wanted to make sure that you didn't think that our statement that generic standards were low-cost implied in any way that we were saying that the best available technology was low cost.

MR. DAVIS:

No.

MR. PATRICK:

Okay.

CHAIRMAN PADGETT:

I have a couple of questions from the audience. One I should have asked Dr. Gunkler, I guess, first.

"If there is no proof that industry emissions cause lung cancer, how do you explain the Anderson data which shows dramatic increase in lung cancer down along the Houston Ship Channel industry?"

MR. DAVIS:

Certainly, I'm at a loss to

to explain the Anderson data since I'm not familiar with it.

CHAIRMAN PADGETT:

Another question which refers to the guidelines. Perhaps this will be addressed by the next speaker, but:

"If you are trying to eliminate inconsistencies, why do you want guidelines an uncertain enforcement rather than rigid regulation?"

MR. DAVIS:

Perhaps we -- I don't know whether I can answer that, except that I guess in a sense by backing off the question a little bit and look at the procedures as they are currently written.

What we see is throughout the process, both in the process, if we look at the beginning stages of the candidate substance and the listing as a high-probability carcinogen with automatic implementation of generic controls and then the possibility of going on to BAT and then even higher control mechanisms, we see an automatic thightening process...

We see -- and again, maybe I should stop on this, because I believe Mr. Lachtman does refer to it.

We also see that the procedure as they are written at this point call for a review in five years, again with the view towards tightening the controls.

And if that gets locked in, that kind of thinking, then we have some problems with it. There are other areas, again, I think Mr. Lachtman will address, that we have concerns about in terms of vague terms which have not been defined. We don't they've been defined adequately in order to be able to define them.

MR. JOSEPH:

Have you identified them more specifically in your written comments?

MR. DAVIS:

Yes.

CHAIRMAN PADGETT:

Okay. Thank you very much.

MR. KELLAM:

Mr. Davis, on page 4 of your testimony, as part of your discussion of the implied cancer epidemic and the role of air pollutio

in cancer incidence, you consider the lung cancer as attributable to cigarette smoking, and I quote:

"...which has been shown to be responsible for as much as 80 percent of the cancer observed."

And eliminating that, conclude that the cancer death rate for both men and women is actually decreasing.

One of the earlier witnesses today presented testimony citing the potentiation of cancer risks by combination of cigarette-smoking and other agents, such as ionizing radiation and asbestos.

Do you generally agree with those studies that have shown potentiation?

MR. DAVIS:

I think there is evidence that would indicate that there is potentiation between cigarette-smoking and tobacco-smoking.

I would also further state that in the general thought of that thinking that we try to present with that argument is that -- and I think -- I can't find the statement and

precisely quote it -- but we feel that perhaps these efforts controls (sic) are misdirected when in fact it is acknowledged that cigarette-smoking is such a major contributor to lung cancer and that we do have limited national resources and that cancer is a severe problem and that perhaps these resources should be directed or allocated elsewhere in cancer prevention and controls.

CHAIRMAN PADGETT:

All right. I think we need to move on.

MR. DAVIS:

Thank you very much.

CHAIRMAN PADGETT:

Thank you.

STATEMENT OF DENNIS S. LACHTMAN

MR. LACHTMAN:

Good morning, Mr. Chairman and members of the hearing panel. My name is Dennis S. Lachtman. I'm Director of Health Sciences for Envirotech and I serve on the American Mining Congress Carcinogens Subcommittee.

We share with EPA the goal of assuring protection of public health from hazards associated with carcinogenic substances. I think we all recognize our national resources are finite so we should channel our efforts to maximize the health benefits derived from commitment of resources to pollution abatement.

There are several aspects of the EPA proposal which need improvement to optimize health benefits. I will concentrate my remarks on the changes we feel are necessary in the listing procedure segment of the proposal. Our written comments address other stages of the procedure as well.

Throughout the proposal there are numerous terms critical to an understanding of the listing procedure that are not adequately defined.

2-b

The very broad spectrum of interpretation is possible for many of these terms. Such terms, as "significant risk to public health," "ample margin of safety," and "unreasonable risk" need more definition. While such terms are discussed conceptually, the specific application of these conceptual phrases is left to interpretation.

A policy so critical to the interests of the public health should not be left to subjective interpretation.

The term "unreasonable residual risk" can only be interpreted on a subjective basis in the present proposal. Describing an unreasonable residual risk as a function of protection with an ample margin of safety compounds the ambiguity. To understand what constitutes a reasonable versus an unreasonable risk requires more guidance than is provided in the proposal.

The term "sufficient quality" is used by EPA to justify reliance on only one positive animal study without a second "positive" study in a different species. EPA states that when the original study is of "sufficient quality" an assessment of carcinogenesis can rely on that

one study. The undefined use of this term makes this EPA policy statement extremely ambiguous. No criteria are advanced to define what constitutes a study of sufficient quality.

Where critical terminology is so vaguely defined, there is a real danger that the best interests of the public health may not be adequately protected from potentially ill-advised subjective interpretations in the future.

Section 112 listing requirements basically hinge on two criteria. These criteria are: one, whether a substance appears to demonstrate that it is a high-probability human carcinogen and, two, whether there is evidence of significant public exposure via the ambient air from emissions.

We find these criteria for listing are unclear and incomplete. The probability-determination -- high, moderate or low probability -- fails to require adequate analytic interpretation of animal and human data.

The proposal also refuses to consider negative finds, i.e., data rejecting carcinogenic activity. It is strongly implied that any one positive result must prevail over a

4-b

spectrum of negative findings. As a matter of scientific inquiry, this viewpoint is unacceptable.

It is not appropriate to use a single positive response from an animal bioassay to always override the negative results from numerous other studies having an equal or superior degree of reliability.

Limitations and conclusions must apply to any study, be it negative or positive. Just as any negative conclusion must be defensible and reliable, so should any positive conclusion be properly interpreted and have adequate documentation.

A reasonable and prudent scientist has no difficulty in recognizing that in general, a "yes" statement has the same value as a "no" statement. Certainly a mechanism must exist to evaluate the quality and adequacy of study design.

The value of animal experiments and human studies can vary tremendously according to the quality of the experimental protocol and the adequacy and reliability of the data --

CHAIRMAN PADGETT:

Excuse me a second.

-b

If there's a way that you can summarize some of your statement, if you would do that, it would give us more time --

MR. LACHTMAN:

Surely.

The other variable for the listing procedure is evidence of significant public exposure. The problem here is one of terms.

Exactly what determines whether a significant or nearly significant or barely significant exposure occurs? The criteria for what constitutes the number of people exposed and at what levels needs elucidation.

It is unreasonable for EPA to expect people of divergent views to readily agree upon this vague term. This lack of definition has a propensity to deter efforts to protect the public health.

It appears that EPA in the listing requirements is relying in part on the draft IRLG criteria. The IRLG draft document does not take a well-balanced approach to evaluating animal data in determining carcinogenicity. The IRLG screening method would

6-b

be more effective if replication of animal data played a more important role in determining carcinogenicity.

While the IRLG report states, "The methods used for regulatory purposes in making a qualitative determination that a substance poses a carcinogenic hazard to humans are based on a substantial scientific concensus that has emerged from experience, research, debate and review," there is no indication of the false-negative and false-positive rates implied by the proposed screen.

They do introduce a note of caution on false-positives. However, the National Cancer Institute researchers go much further in their statement, and I think it is important to read this:

> "There is danger in relying solely upon statistical significance without incorporating biological knowledge and corroborative evidence such as the presence of a dose-response relationship or experimentally consistent results in different species or sexes."

The problem with the IRLG screen is that the quality of data and statistical methodologies consistent with biological principles are not adequately considered. As reported in a critique by the Engine Manufacturers Association, EMA, to the IRLG work group -- by using a study design similar to that recommended by the IRLG -- the probability of labeling a harmless substance as a carcinogen can be staggeringly large.

Further, for example, in using ten animal studies, like the one used in the IRLG screen, it was determined that of every thousand harmless substances tested only two will escape the carcinogenetic label. What this means is that 998 substances of 1,000 tested that do not cause cancer would be falsely labeled. These substances would be banned or saddled with a false label and subsequent unnecessary regulation.

While it is beyond the scope of this present testimony to go through EMA's mathematical derivations, we would be happy to supply them in the future and we are attempting to amend them in a more standardized form. But it is -- we will get back to that later.

8-b

But statistical errors and probabilities of this magnitude clearly overestimate the risk of cancer and appear to be disproportionately exaggerated.

False-positive and false-negative rates for any hypothetical screen can and should be examined in detail for a variety of hypothetical spontaneous tumor rates and carcinogenic effects. The optimal strategy should have both the false-positive and false-negative rates at reasonable low levels.

The bioassay procedures and screens relied upon in the EPA airborne carcinogen listing proposal do neither of these. Generally speaking, the cancer assessment listing methodology oversimplifies what is a very complex situation.

Ergo, the state of the art in cancer-identification is far more complex and far more unknown than I think is stated.

Another problem with the general criteria for listing of carcinogens is the failure to adequately consider potency. The two criteria -- carcinogen probability and significant human exposure -- contemplate prioritizing by the

9-b

Agency so that the most important substance from a public health standpoint are regulated first.

Potency should be an equally important consideration in setting priorities for listing. Accordingly, it is inappropriate to place substances which may vary as much as a millionfold in potency in the same category.

No consideration has been given to either the relative or absolute potency of carcinogens. This is surprising. It is widely recognized that chemical carcinogens exhibit a wide range of potency in laboratory animals. For example, using rodents, it has been estimated there is a millionfold difference in potency between aflatoxim B1, one of the most potent carcinogens known, and sacchrine, one of the weakest.

A rational balance should be attained between the risk and benefits in the regulation of carcinogens. It is vital to develop some scheme to estimate potency.

In terms of the mechanism for correcting listing procedures, by erroneously identifying substances as carcinogens, there is a potential danger to public health. Many important

10-b

and useful substances could be replaced by more harmful materials. Valuable drugs or chemicals could be discontinued on the basis of flimsy or unsound data. In cases where substances are of vital importance and substitutes are not likely to be as efficacious, it is necessary that a mechanism exist for correcting improper listing actions.

The results of one poorly designed animal study should not determine that a non-carcinogenic substance will be listed and regulated as a carcinogen.

There is no means identified in the EPA airborne carcinogen listing procedure for removal of an improperly listed substance. This is a major problem. A means must be devised to rectify this inadequacy. One suggestion is for the scientific review panel that you've heard so much about -- independent. I think another course would be to open up the criteria for listing.

In addition to the scientific flaws in the proposed listing process, there are significant procedural problems we perceive. Essentially, there is a complete absence of public participation in the listing of a substance as a

-b

hazardous air pollutant under Section 112 of the Clear Air Act.

I'm happy to see that this apparently is not the intent. As we've stated before, it is the language. But it is not the intent that we wanted.

The only public involvement prior to listing is the totally passive one of being "notified" of EPA's preliminary screening process and determinations of carcinogenicity. Such a lack of direct public participation prior to listing is contrary to Executive Order 12044 which requires that opportunities be provided for early public participation and comment. Further, EPA's proposed process violates the requirement of Section 117(c) of the Clean Air Act that EPA actively consult with appropriate advisory committees, independent experts and federal departments and agencies prior to such a listing.

Limited participation to the post-listing establishment of generic standards or final emission standards is too little, too late.

Public participation prior to listing is especially critical because the proposed

12-b

EPA scheme does not appear to allow a substance to be unlisted.

Nowhere in the discussion of subsequent proceedings, such as setting generic standards or final emission standards, is there recognition that regulation of the listed pollutant may not be appropriate.

This is particularly clear in EPA's statement that quantitative risk assessment will only be used for setting priorities or setting the degree of control necessary for a particular source category.

Every phase of EPA's process after listing involves decisions that can only lead to tighter controls. Even the five-year review of standards is limited to tightening controls. We sincerely hope that the lack of any procedure to remove a pollutant from the Section 112 list is an oversight. The absence of such a procedure in the present proposal is contrary to the authority provided in Section 112.

The procedures should allow relaxation of standards based on new or different-- or information which is received to change.

And I think that's the basic

13-b

tenet in science. This is basically not true if it does change.

And, also, as I said before, we don't share EPA's view that there are "...limited direct consequences of listing..." procedure.

And in terms of the use of quantitative-risk assessment under 112, we feel that, rather than being used in the prioritization sense, that that is really only being used or that that's akin to being used to tightening a noose rather than an open scientific process.

So we feel that there's a maximum -- there's a very limited -- finite amount of resources. And in order to prioritize things, it'd be helpful to have quantitative process available in the listing procedures, you know, rather than listing thousands of things initially.

I think the first things listed should perhaps be the most important.

And I think that's all.

CHAIRMAN PADGETT:

Thank you.

Mr. Kellam?

Perhaps I can just ask the

second part of my question which is, in view of the fact that there may be significant potentiation of cancer incidence for people who both smoke and are exposed to environmental agents, do you feel that it is appropriate to exclude the lung cancer incidence that you would normally attribute to smoking in reaching a conclusion that perhaps the overall rates of cancer are decreasing and, therefore, such things as air pollution may not play a signifcant role?

MR. LACHTMAN:

I think if one is looking at a significant role and stepping back away from EPA for a moment, if one were in a position of omnipotence, if you look at the problem, you certainly would eliminate cigarette-smoking, because that is the proven cause and there may be synergism.

I think that air pollution still remains a problem. If you see that syngerism, I think that is clear that there is still a problem there.

But I think that we have a situation of priorities here, and I hate to see something so simple as reduction in tobacco is

overlooked at the expense of something that is far more difficult to control. I think they both should be controlled.

MR. KELLAM:

Would you make any distinction between what some people would consider the voluntary risk of smoking versus the involuntary risk of exposure to environmental or ambient environmental substances?

MR. LACHTMAN:

Yes. Well --

MR. KELLAM:

Exclude the passive -- I am well aware it's not really a voluntary risk.

MR. LACHTMAN:

Yes. I would make a distinction.

MR. BAUMAN:

Mr. Lachtman, I would like to ask a qustion or go to a little bit -- might comment on your testimony, I guess, having to do with the comment that you made regarding public participation while I realize that you have summarize your comments, there are more intensive remarks in your prepared testimony, however you did

say that on page 8:

> "Essentially, there is a complete absence of any public participation in the listing of a substance as a hazardous air pollutant under Section 112 of the Clean Air Act. The only public involvement prior to listing is the totally passive one of being, quote, "notified," unquote, of EPA's preliminary screening process and determinations of carcinogenicity."

My comment would be that I think you quit reading a little too soon. The statement in the Federal Register notice goes on to say:

> "This notification will serve to advise the public [unintelligible & inarticulate]

the local agencies and industry of potential hazards associated with the substances examined will indicate which substances are receiving further attention --"

and I'd like to emphasize the next clause --

"-- and will request the involvement of interested parties --"

MR. LACHTMAN:

Is that notification prior to listing?

MR. BAUMAN:

Of course.

MR. LACHTMAN:

I'm pleased to hear that, and perhaps I did over look it.

I'm not sure of the context of that completely. But I think, you know, if that's mandated, I think there is a problem if you propose something be listed, you know, there are some psychological and other problems associated with that if that's done in a cavalier fashion.

I don't suggest that would occur, but it certainly is a possiblity. And I guess then that was the point I was trying to make.

MR. BAUMAN:

Thank you.

MR. JOSEPH:

I would just like to ask you two or three questions.

Two clarifications. I'd like to confirm for you that this proposal is not intended to override your Section 117 of the Clean Air Act under which we consult with EPA's Science Advisory Board before listing a substance.

I think we've mentioned earlier this morning. And it's not intended to override the provision of Section 112 itself under which a substance is removed from the list of hazardous air pollutants after a public hearing after post-regulations and certain showings are made.

My question is: You suggested that rather than listing some very large number of chemicals and then trying to sort out what we should do, we ought to proceed

to list just the most important substances first and work on them.

I take it that you agree that there are some substances, at least, then, which we may find pose some risk of increased cancer incidence?

MR. LACHTMAN:

Yeah. I'd be surprised if there weren't.

MR. JOSEPH:

If --

MR. LACHTMAN:

I mean, presumably, if you found nothing, then I don't know what we're all doing here.

I think that's an important problem.

MR. JOSEPH:

Thank you.

MR. LACHTMAN:

But in terms of your comment, I do respect the EPA Science Advisory Board. But I don't think that they alone have a responsibility of representing the entire scientific community.

I think there are pockets of

intelligence in the scientific community that are outside the Scientific Advisory Board that perhaps ought to be sollicited more often. They are on all sides of the spectrum, and people that don't have an opportunity.

And we're making our comments to get the processes broadly as open as possible and I feel that the people I have talked to on occasion from the Scientific Advisory Board would concur with that to have as much opportunity as possible, because the area of carcinogen estimation, treating cancer, is in such a state of the Dark Ages that I think to limit, you know, this course in conversation and exchange of ideas is a mistake.

MR. JOSEPH:

I think as Mr. Bauman indicate to you, the intent is not to limit it, but to sollicit it.

MR. LACHTMAN:

I'm glad to hear that.

MR. BAUMAN:

Are you aware of the fact that the Scientific Advisory Board meetings are open meetings, open public meetings?

MR. LACTHMAN:

Yes, I am.

MS. ANDERSON:

I am concerned about the rather extreme view taken regarding the language in the proposal about the significance of one-animal test and perhaps it is out fault but that seems to be one of the thrusts in your testimony.

The Agency does have a track record here for a little over three and a half years now the Agency has been conducting scientific risk assessments. There are quite a few documents that have been made public.

I don't think in reviewing this history you will find any evidence of a single decision where a snap decision has turned on one study without regards to all the evidence in considering the significance of the study, particularly where the response is borderline.

This one example comes to mind and it was a pesticide where a decision was made by the program office not to regard it as a carcinogen based on the scientific risk assessment where there were two slight blips in two studies in an array of about a dozen and these two slight

blips were based on one pathologist's review of the slides and in that case the data taken in the aggregate was regarded as not evidence (sic) of carcinogenicity.

So I turn your attention to the track record of the Agency.

Nonetheless, I wonder how you would feel -- are you saying that you think we should rule out the importance of viewing one positive result from a bioassay when you look at cases such as aflotoxin where the rat was positive, the mouse negative, the response to the well-known carcinogen bischloromethylether and now we're looking at results similar to this where in fact the site of action is the same as with bischloromethylether and that is the current studies underway on formalydehyde, are you saying that in no case -- understand your extremes on the one hand, but now getting to the other hand, are you indicating that you think there's -- there might not be cases where the significance of one positive animal-bioassay study would not be compelling evidence for the Administrator's consideration under this policy? (sic)

MR. LACHTMAN:

Oh, I think it certainly could be and I wasn't saying -- wouldn't rule out that case.

I'm saying that as I read it and I think maybe my testimony wasn't clear, but as I read the EPA policy, it appears that it has to be.

And what I'm saying is that I think in certain situations a positive study that's well-executed and, you know, would be considered by, you know, the state-of-the-art scientists, you know, whatever, you know, to be reasonably well conducted, you know, is an appropriate, you know, area of concern.

I think it should try -- they should try to replicate -- I know with the ANNO-2 (phonetic) data, you know, in Germany, there's a lot of problems trying to replicate some of those data. We've been over there and, you know, we've found some very interesting reasons for why you can't replicate it. And we don't suspect you ever will.

But getting back to the point, you know, I think that you have to consider those

things, because, you know, in the rhetoric, the way it reads, if you limit yourself to the language I think that it is very important to change that language and also to give some sort of guidance on whether it a high- or a low-quality study. I think there have been some attempts to do that.

But if you define it a little bit further, I think we will all benefit.

MS. ANDERSON:

The IRLG document certainly attempted to do that.

MR. LACHTMAN:

I reviewed that document rather extensively, and I think the data were actually -- we are more guilty of not doing that than your proposal.

The point I'm trying to make is that you often hear this statement, that there is "no free lunch." Protecting the public from carcinogens, from a public-health point of view, the best thing to do is to eliminate the exposure; absolutely. To just shut everything down. Just keep that narrow focus in regards to your objective

But perhaps there may be side-effects of that, like, you know, perhaps

substitutes --

[Extremely loud laughter from the audience drowned out several of Mr. Lachtman's words.]

MR. LACHTMAN:

-- perhaps people couldn't eat. You know, unfortunately, we don't have the luxury of being able to do that.

And so when you have a policy that I have referred to as being overly pessimistic and you make the Class-I-type error or you're overestimating the occurrence of something, you have no assurance in terms of a substitue that the agent you're replacing is going to be more efficacious -- or in fact it could be a real danger to public health because it may be more harmful.

And I think, you know, we have seen this -- don't quote me on this -- but --

[Again, a burst of extremely loud laughter from the audience obliterated several words.]

MR. LACHTMAN:

-- something such as DDT, you know, that was not a -- that was an environmental

problem in terms of human exposure in the organophosphates.

Certainly, there was some problems to humans that occurred with OP's that were never seen with DDT.

And I would suggest that there's a misapplication, there's an overreaction here. And I don't want to get some people in the petroleum industry upset with that. But I think that's a concrete example of where, you know, there's an abuse on one side, you jump the gun to the other extreme, you have more problems.

CHAIRMAN PADGETT:

Okay. Thank you very much.

The next one -- speaker scheduled is Ivan Smith. And then there's one other person who asked to speak before lunch.

Now, the question I have is -- Is Mr. Smith in the audience?

MR. SMITH:

Yes.

CHAIRMAN PADGETT:

Raise your hand.

Do you have any problem with speaking after lunch or do you have --

MR. SMITH:

Whatever you prefer. It will be less than ten minutes.

CHAIRMAN PADGETT:

Okay.

I suggest, then, that we take Mr. Smith and then Mr. Dillard, who is substituting for Mr. Hutton, who also has a short statement. So I suggest that we take those two statements before lunch; and then we will break.

MR. L. L. KROHN:

I was scheduled to -- In order to make travel arrangements, I request to speak before lunch also.

I was advised that you were going to go through lunch.

CHAIRMAN PADGETT:

This is much more interesting than eating.

Do you have any problem with speaking right after lunch? It will be one hour right after we break.

I think Mr. Dillard will be first and then we will take Mr. Krohn.

Is R. G. Dillard in the

audience?

(There was no response.)

Mr. Krohn? Sir?

[Some collateral, unrelated conversation ensued off the record.]

-b

STATEMENT OF R. G. DILLARD

MR. DILLARD:

Mr. Examiner, ladies and gentlemen, my name is R. G. Dillard and I am appearing on behalf of the Texas Chemical Council.

The Council is an association of 83 chemical companies and indirectly affects 420,000 Texans employed in the chemical industry.

Over half of the nation's petrochemicals are produced by member companies operating in Texas. The Council has a long history of cooperation with the State and Federal agencies in the furtherance of responsible environmental legislation and regulations. We appreciate this opportunity to comment on EPA's Airborne Carcinogen Regulations and Proposed Generic Standards.

First, the basic premise of the EPA's Airborne Cancer Policy needs to be examined. An often-quoted estimate used by the EPA is that 60 to 90 percent of all human cancers may be due to "envirionmental factors." It should be emphasized that the term "environmental" is being applied in a very broad sense. This broad definition includes:

15-b

"Chemical exposures from smoking, diet, occupation, drinking water, and air pollution; various forms of radiation, including sunlight; and some forms of physical irritation."

The use of these "environmental factors" in pointing to a cause of cancer, does not suggest any direct relationship between cancer and air pollution, and in fact, is not far from the erroenous view that everything causes cancer.

According to the American Industrial Hygiene Council, the evidence the EPA cites to link cancer to industrial air pollution consists of "recent findings suggesting that a large number of airborne chemicals and radionuclides to which people are exposed may be implicated in cancer and other diseases related to genetic damage."

From this quotation, the EPA infers that the ambient air is filled with chemicals causing serious harm to human health. A more accurate conclusion would be that some substances which may be carcinogens at high-dose levels are found only in trace concentrations

16-b

in the atmosphere.

The primary argument presented by the EPA in justification of the Airborne Carcinogen Policy rests on the Agency statement that cancer rates are increasing due primarily to increases in lung cancer, and that lung cancer is thought to be the principle form of cancer related to air pollution.

It is on this basis that the EPA feels that the standard is necessary to protect the public health. The fact is, as shown by an article in the Scientific American by Cairns and cited by the EPA, the lung cancer rate is increasing only in women. Further, the 1979 Surgeon General's Report on Smoking and Health, also cited by the EPA, states:

> "Increases in lung cancer mortality among females cannot be explained by exposure to Occupational Carcinogens. Increases in cigarette consumption are responsible for these trends."

Thus, by citing this report, the EPA itself has indicated that cigarette smoking, not air pollutants, is responsible for

17-b

the increase in lung cancer mortality rates in women.

The TCC is supportive of meaningful regulations which have a clear demonstrative need. The study cited by the EPA shows only that:

1. Cancer is a serious health problem in our society.

2. Various substances inducing carcinogenic effects at high dose levels can be found in trace concentrations in the ambient air.

The evidence does not establish that exposure to the levels of substances which are found in the ambient air either cause or contribute to cancer. In addition, the EPA fails to show that industrial emissions are the source of these trace substances. On the basis of these observations, the TCC feels that the EPA has not justified a crash program -- and I emphasize that -- has not justified a crash program to solve a problem for which there is a questionable need and an undemonstrated urgency. In fact, hasty adoption of the EPA's Proposed Airborne Carcinogen Policy could dilute ongoing

18-b

efforts for controlling the carcinogens through established regulations.

Once again, the TCC is supportive of meaningful regulations which have a clear demonstrated need. The generic standards proposed on October 10 failed to show a demonstrated need, and they are redundant with existing regulations.

Fugitive emissions, such as those the EPA proposes to control under the generic standards, include ground-level emissions already regulated by the Occupational Safety and Health Administration, OSHA, requirements. OSHA has adopted workplace performance standards for many of the chemicals that the EPA may ultimately regulate.

The EPA would be duplicating OSHA's existing regulatory efforts in adopting the proposed generic standards, and would impose detailed work practice standards in addition to those required by OSHA's existing performance standards.

If OSHA's performance standards are inadequate, or not being enforced, the answer is not for the EPA to establish its own regulatory scheme, but for OSHA to either more vigorously

19-b

enforce its standards, or to change them. The addition of the EPA Fugitive Emission Controls, as proposed on October 10, would appear to give little or no added benefit, in terms of reducing harm to the public.

Pursuant to Section 110 and 172 of the Clean Air Act, the EPA expressly requires all State Implementation Plans to adopt Control Technique Guidelines within one year of promulgation. The Proposed Control Technique Guidelines will allow more control of fugitive sources than the Generic Standards.

The Texas Air Control Board regulations, which are a part of the State Implementation Plan specifically control source emissions of volatile organic carbon compounds. Regulations V and VI of the Texas Air Control Board set minimum standards for existing sources and require any new construction or modifications to control emissions well beyond the proposed controls of the Generic Standards.

The Toxic Substances Control Act evaluates and prioritizes the effects of chemicals produced. These regulations zero in on the most harmful chamical substances and direct

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efforts towards their control.

The National Emission Standards for Hazardous Air Pollutants already regulate and control carcinogens, such as vinyl chloride monomer.

Consequently, the means of controlling airborne carcinogens through OSHA, State Implementation Plans, the Toxic Substances Control Act, and the National Standards for Hazardous Air Pollutants are already in existence.

These efforts should not be diluted by additional general standards, such as those proposed by the EPA on October 10. If allowed to stand, these Proposed Regulations would result in a needless duplication of efforts, one of the very practices that Administrator Costle and President Carter have most often spoken out against.

The Texas Chemical Council feels that the EPA's efforts would be much more effective by taking steps towards enforcement of the existing standards, rather than seeking a general and diluted approach to a problem to which no demonstrated need has been shown.

Finally, we feel that the legal

21-b

basis for adoption of a generic standard under Section 112 has a questionable origin. It seems to be clear that the EPA views the Generic Standards as interim measures to be adopted as part of the phased program of emissions controls. The Texas Chemical Council feels that this phased approach is at odds with the approach of Section 112.

The language of Section 112 clearly shows that Congress authorized the promulgation of only a single emission standard or, in exceptional cases, a design standard. There is no indication in Section 112 or its legislative history that Congress intended the Administrator to adopt a multi-step approach as proposed in the October 10 Federal Register.

Furthermore, Section 112 speaks in terms of setting an emission standard for such "pollutant," for a "hazardous air pollutant" and for such "hazardous air pollutants." It is not apparent that a Section 112 emission standard can or should cover a class of pollutants.

To avoid this legal problem, the Agency plans to propose the Generic Standards for a particular substance, when it is listed under

Section 112, possibly with some customizing of the standards. Such customizing, however, apparently will be limited significantly in that only unique and unusual situations will be a basis for modifying the Generic Standards.

Consequently, we believe that the Agency's scheme will apply the Generic Standards to a number of substances and, thus, it effectively becomes a generic standard which is not authorized by Section 112.

In addition, the TCC believes that the EPA misuses Section 112(e)(1) as a basis for the Generic Standards. This section provides that where the Administrator determines that it is not feasible to prescribe or enforce a numerical emission standard, a design standard may be promulgated.

Section 112 (e)(2) provides that, for the purposes of Section 112(e)(1), "the phrase 'not feasible to prescribe or enforce an emission standard' means any situation in which the Administrator determines that (A) a hazardous air pollutant or pollutants cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant, or that any

23-b

requirement for, or use of, such a conveyance would be inconsistent with any Federal, State or local law; or, (b) the application of a measurement methodology to a particular class of sources is not practicable due to technological or economic limitations."

The use of design standards is strictly limited to those situations which are enumerated in Section 112(e)(2). The Texas Chemical Council submits that there is no showing or suggestion in the Federal Register documents that carcinogenic substances, as a class, fall within the exceptions enumerated in Section 112(e), or that the Administrator willmake the necessary findings before applying the Generic Standards to a particular substance. Absent the required judgment of "infeasibility", the proposed standards would not be authorized under Section 112

The proposed rule's framework for listing also does not conform to the substantive and procedural requirements of Section 112. Based on its inaccurate estimation of the consequences of Section 112 listings, the Agency proposes to list substances without thoroughly evaluating all relevant scientific evidence to

4-b

determine if a significant public-health risk exists.

Rather than conducting the quantitative risk assessments and exposure analyses needed to make this determination, the Agency intends to sidestep them. Instead of addressing head-on the complex economic and energy issues posed by the threshold decision to regulate, EPA defers their consideration.

Under the Proposed Rule, the Agency runs the risk of promulgating costly regulations only to find out later, after conduting appropriate studies, that regulatory action was not appropriate in the first place. This approach is inconsistent with the language of Section 112, the legislative history of the Clean Air Act, recent case law, and fundamental policy considerations.

Finally, the Agency fails to show that the Generic Standards satisfy the ample margin of safety requirement of Section 112(e)(1). The Generic Standard scheme suggests that in most instances the Agency intends to impose additional standards to provide an ample margin of safety. If the imposition of additional controls is

25-B

required to provide an ample margin of safety, then the initial controls, the proposed Generic Standards, would not provide such a margin.

In summary, the Texas Chemical Council feels that the Proposed Generic Standards have shown little basis of need and no basis for urgency, that the Proposed Standards would be redundant with the existing regulations controlling hazardous air pollutants, and have a questionable basis of law under Section 112 of the Clear Air Act.

Additional regulations would divert time and economic resources away from the existing programs resulting in dilution of enforcement of meaningful regulations, which would in turn, be to the detriment of the public interest in developing an effective cancer regulation program.

We appreciate y'all giving us the opportunity to come forward.

CHAIRMAN PADGETT:

Any questions?

MR. PATRICK:

One clafification, in your discussion of Section 112(e), where it discusses, of course, the requirements for being able to apply work practice standards, your statement that we could not use work-practice standards under this part of the Act, and I'm am just uncertain whether your reason is that you don't believe or that you believe that these emissions could be controlled and/or measured, which seems to be the major reason in Section 112(e), that allow you to go to work practices or --

I'm not sure which one of those two are you really banking your conclusion on?

MR. DILLARD:

I would like for you to restate that because the first part of your question is a little vague to me.

MR. PATRICK:

Your discussion on page 5 of Section 112(e) --

MR. DILLARD:

Yes?

MR. PATRICK:

-- that section says basically that where it is not feasible to prescribe or enforce numerical standards, that design standards may be promulgated.

And then you give a couple of criteria for determining whether we can go that way or not.

I guess my question is: Are you saying that the emissions are not significant and that is why we can't use the work practices? Or are you saying that those criteria aren't met, that you can, in fact, control those emissions and measure those emissions -- which, really, are the two criteria?

MR. DILLARD:

I think your question about being able to measure -- I think the key question here is that, having done so, is it still something that should be controlled if it is not a data basis, if it is something that needs to be controlled?

MR. PATRICK:

So it is really significant?

MR. DILLARD:

Yes.

MR. PATRICK:

That was just really for my clarification.

Thank you.

CHAIRMAN PADGETT:

Thank you.

Mr. Krohn?

MR. KROHN:

My name's Les Krohn. I'm Manager of Environmental Control for the Marketing, Refining and Transportation segment of the Union Oil Company.

26-b

STATEMENT OF L. L. KROHN

MR. KROHN:

Union directs its remarks to the draft generic technical standards relative to hydrocarbon exposure and leaks from refinery, pipeline and terminal facilities. We would refer you to the comments of the American Petroleum Institute on EPA's proposed policy and procedures for identifying, assessing and regulating airborne substances posing a risk of cancer. We support those comments.

With respect to the draft, generic technical standards, the proposed standards parallelthe Control Techniques Guidelines, the CTG's, concerning leaks.

Union has particpated extensively with the API in developing these CTG's and worked with the Radian Corporation in developing a data base relative to refinery valve and flange leakage.

The EPA is currently proposing generic standards which are more stringent than those described in the CTG's and our experience indicates this additional control is not warranted.

Union would point out that many of our facilities are located in remote areas

27-b r

where exposure is at a minimum, far below any risk assessment currently under consideration.

Also many of our crudes and products contain minimal quantities of material thought to have carcinogenic potential. Sweeping regulations as proposed would include light oil terminals and pipeline facilities as well as refineries.

EPA is proposing a policy for the identification, assessment and regulation of airborne carcinogens. In that assessment, EPA must consider, possibly on a case-by-case basis, the impact of its regulations where actual exposure is well below any carcinogenic potential.

Union provides the following comments where we feel EPA is going beyond the established CTG in considering a more stringent standard.

With regard to the minimum concentration of Benzene in a hydrocarbon stream, we feel that 10 percent should be the concentration level to implement control procedures. This conforms to the 10 percent standards for vinyl chloride.

A gaseous leak should be defined

28-b

as 10,000 parts per million volume. This is consistent with the CTG encompassing a vast majority of emissions. Union has gone through extensive testing and has successfully demonstrated that the 10,000 parts per million level is the minimum concentration that demonstrates reproducibility.

The inspection schedule as described in the CTG should apply for the generic standards as well. Experience with equipment at our facilities has demonstrated that the duration of repairs and the frequency of leakage does not warrant a monthly vapor-detector inspection along witha complete and detailed record of emissions and leaks. The cost benefit of a program of this type is very unfavorable.

Although a 15-day repair interval is at times adequate, there are other cases where specialized labor and materials are necessary to complete repairs. We would suggest that a 45-day period be considered or that some allowance be made for extenuating circumstances.

With respect to safety-valve discharges, most refineries, including Union Oil facilities, vent their discharges to flares. Such

-b

discharges cannot be accurately or visibly monitored; however, the majority of carcinogenic substances that mey be present would be destroyed in the flame of the flare. Adequate technology for reporting discharges from flares currently does not exist. This requirement should be deleted from the standards.

The requirement to notify the EPA Regional Office at least one week in advance of certain inspections, observation and monitoring is unrealistic and overly restrictive. Currently, operational shutdowns and start-ups at our refineries are conducted with the knowledge of the local APCD and this should suffice for environmental control of the operation.

The monitoring of seals on compressors and pumps is routinely and adequately done by our Operating personnel. In order to inspect the shaft-seal interface by instrument in many cases required that the guards be removed, making the operation unsafe. Some leakage for lubrication purposes is required, and we feel that a visual inspection is much more reasonable and practical.

The requirements to paint tanks

30-b

white is completely unnecessary. Many tanks are painted aluminum, a color that is comparable to white. Much of Union's tankage has been painted a soft pastel for aesthetic reasons and has been readily accepted by the neighboring communities. The tank-painting stipulation should be deleted from the proposed rule.

The test method outlined calls for reporting results as "ppm volume as hexane." Test equipment can be calibrated with hexane and results should be given as "ppmv calibrated to hexane" as the test results cannot be accurately reported as equivalent hexane.

Union intends the above comments to be constructive and helpful in the development of the generic standards.

Union has had over 85 years of refining and pipeline experience that have developed techniques for minimizing the loss of fugitive emissions.

We are proud of our maintenance procedures and proud of our housekeeping and take pride in our facility operations. If you should have any questions requiring further comment, we'd be happy to reply.

CHAIRMAN PADGETT:

I'm sure we have a few. Just a minor comment on the tank painting. What is the -- What do you estimate that the white versus some other color or aluminum amounts to in terms of reductions of emissions?

Is it your opinion that --

MR. KROHN:

There's a slight difference. There are some engineering standards for that. There would be a slight variation.

CHAIRMAN PADGETT:

You're suggesting that it's just not worth it?

MR. KROHN:

Yes. It's not worth it, really. Of course, it depends in the area of products and crude just what level, whether it is once percent or ten percent and what level we come to and some tanks have a very minimal or some products -- crudes -- have very minimal amounts of suspected carcinogens and they may not need to be painted if the level is not high enough.

MR. PATRICK:

I just had a couple of

clarifications and a couple of requests, I think. I just wanted to make one thing, I think, clear really on something that you said; and also, Mr. Dillard, previously, you make reference to proposed generic standards.

I just want to make sure that you understand that this is not a proposal of generic standards.

The generic, technical standards are strictly an advance notice, not intended in any way to be a proposal.

MR. KROHN:

Okay. I understand that, and I want to "get my licks in now."

MR. PATRICK:

Another clarification: You speak about the CTG's and I do want to make sure that you understand that the distinction we see between the emissions that are being controlled with the CTG's, these are guideline documents aimed at controlling the law of organics strictly for the purpose of reducing organic emissions to the -- or contribution to the photochemical-spawn problem. We don't think it's necessarily to consider that and hazardous-chemical emissions to

be equivalent and that's really some of the reasons why we have looked at these a little differently.

You made two or three statements concerning extensive testing and successful demonstration of cost-benefit analysis as being applied for some of the things that Union has done.

We would certainly appreciate seeing that information -- it may be in the record already; I haven't looked through the complete record.

MR. KROHN:

I'd be happy to submit some of the work that we did at our San Francisco refinery.

And I think we demonstrated the mutagenicitability is below 10,000 and we just couldn't plan -- we could never reproduce the same results after --

MR. PATRICK:

You understand some of the problems. We would appreciate seeing that data.

MR. KROHN:

I'd be happy to send it to you.

CHAIRMAN PADGETT:

Does anybody else have any questions?

(There was no response.)

CHAIRMAN PADGETT:

Thank you.

MR. KROHN:

Thank you.

CHAIRMAN PADGETT:

Now I think it is time we can eat.

I would like for us to report back at 1:30. We will reconvene; and if Mr. Smith is in the audience, we will start with him. And if not, we will move on to the next speaker.

(Whereupon, at the hour of 12:29 p.m., the hearing in the above-entitled matter was adjourned, to reconvene at 1:40 p.m., this same day, Thursday, March 13, 1980.)

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

(1:40 p.m.)

STATEMENT OF IVAN G. SMITH

MR. SMITH:

I'm George G. Smith. I'm Vice-President of the Lone Star Chapter of the Sierra Club.

We welcome this regulation of airborne carcinogens as long overdue control of industrial toxic effluents into the air we all breathe. The regulation of airborne carcinogens is especially important in Texas where we have both large concentrations of petrochemical industries as well as a large population at risk.

We have at least eight vinyl chloride and polyvinyl plants in the Houston area for instance. There is real reason to view the emissions of the Gulf Coast petrochemical complex with alarm in the light of the elevated lung cancer mortality reported by Mason and McKay in their 1974 study for the National Institute of Health.

The approach of the EPA in this issue seems sound, but perhaps over-cautions in concern for business economic health and less

22-b

aggressive than it could be toward protecting the public health.

We agree with the concept of the zero threshold for carcinogens, recognizing that while zero risk and zero emissions are difficult to attain, they are important goals for the protection of public health. So we urge you to keep this goal for all carcinogens.

The models chosen for estimating disease resulting from exposure should indeed be ones that avoid understating the risk so that you make sure to err on the side of safety. We urge that you take care in making quantitative risk assessments since synergism of other environmental factors make these imprecise.

The initial generic clean-up requirements for listed carcinogens represent a low-cost, low-technology housekeeping approach that makes good sense. These controls are needed especially in this area where the enormous hydrocarbon emissions contribute to the small particulate haze so that the respirable particulate here are likely heavily laced with carcinogens.

These controls should be at least as stringent as the ones required for ozone

3-b

control, including things like floating roofs with double seals, better pump seals, and more strict monitoring of leaks.

Careful scrutiny of sitings suggested is important to avoid a concentration of industries which would increase carcinogenesis by synergism or endanger large numbers of people.

In the case of existing industries concentrated in one area as found in Houston, stricter standards need to be set because of the additive effect of the multiple plants. The consideration of alternative sites has been all but ingnored in Texas up until now, and it is time that surrounding residents be given some real consideration.

In the question of offsets, we urge you to take special care not to allow air quality to deteriorate through a number game. We urge you to look at the actual versus the permitted emissions -- where the acutal are often less than permitted, so that in the computation of the offset the air would become more toxic, which has happened in the past.

We agree with the principal of using single animal studies to list carcinogens

34-b

for regulation. Since the first phase of regulation is simply better housekeeping, these requirements will be relatively inexpensive, and further studies for verification can be made as more effective controls are designed.

While some people have made light of animal studies, we should be reminded that people may be 60 times as sensitive as animals to a toxic substance as in the case of Thalidomide. So here again the EPA must lean toward the side of safety in its decisions.

We agree that little is to be gained by setting up an outside screening panel for evaluating carcinogens, since industry-experienced researchers and environmentally-concerned researchers would quickly come to loggerheads over interpretation of data. EPA must make these decisions, not Industry or environmental activists.

There are some parts of the proposal which give us concern. Much is made of balancing costs of controls with the benefit of the substance regulated and consideration of plant closures. Indeed, plants may need to be closed when the hazard to human health is too

great.

It appears that the EPA may be overly generous in its concern for old plants with granting waivers for compliance. It is too difficult to assess the value of health and life, and the EPA must truly protect health in these decisions.

A re-evaluation of your priority approach to carcinogenic agents that are supposedly present in small quantities would be in order at this time. These should be evaluated carefully since they may pose a larger than expected hazard because of nearby residences or synergism with other pollutants.

In your measurements of exposure, it would be well to consider people working ourside or exercising outside as well as the susceptability of young children. We may be setting 10- or 20-year time bombs in our children who live near petrochemical plants.

We feel the EPA should reconsider the possibility of using unannounced spot checks of facilities to check compliance.

We urge you to move as rapidly as possible to control airborne carcinogens and

36-b

establish a list of high-priority substances to be regulated without delay and to establish a further list of substances to be studied on an accelerated basis.

Thank you for this opportunity to comment on these proposals. We hope for your careful consideration and rapid control of carcinogens in our air.

CHAIRMAN PADGETT:

Thank you.

MR. SMITH:

Thank you.

CHAIRMAN PADGETT:

Any comments?

(There was no response.)

CHAIRMAN PADGETT:

Thank you.

CHAIRMAN PADGETT:

G. W. Fuller? Is G. W. Fuller in the audience?

(There was no response.)

A representative from the Texas Air Control Board?

(There was no response.)

Okay. We'll come back to him.

W. L. Senn?

37-b

STATEMENT OF W. L. SENN

MR. SENN:

Mr. Padgett, members of the hearing panel.

I appreciate the opportunity to express my views on EPA's proposed policy on airborne carcinogens.

My name is Bill Senn and I appear before you on behalf of Exxon Chemical Company, U.S.A. in my capacity as Manager of our chemicals manufacturing operations in Baytown.

Two additional facts that may help you in evaluating my comments are, first, I am Chairman of the Environmental Health Committee of the Texas Chemical Council; and, secondly, I reside in Baytown, less than a mile from the Exxon Chemical Plant. And my family and I are directly affected by the air quality of the community in which we live.

Exxon Chemical recognizes the benefit of identification, assessment and regulation of carcinogenic risks, including any associated with industrial activities, when a valid need has been demonstrated.

In my opinion, EPA is premature

-b

in proposing this policy in the absence of a substantiated need. To this end, I am supporting and we are supporting totally the position and provisions adopted by the American Industrial Health Council.

Furthermore, we feel that adequate protection of air quality is already in place under other provisions of the Clean Air Act and is assured by in-plant controls, based on current industrial hygiene science. Nevertheless, this issue that we're addressing here today should be approached with caution and priorities should be established to address specific problems.

We believe that EPA's proposed policy shows an unrealistic perspective of the incidence and causes of cancer and it overstates considerably the potential role of airborne industrial chemicals in causing cancer. The facts confirmed by Government data are that the incidence rate of cancer has declined somewhat since 1947 and without the increase in lung cancer, which is attributable by most scientists to cigarette smoking, the cancer mortality rate would be declining. Thus, I feel the EPA is in the unsupportable position of acting on the basis of

39-b

speculation.

Not only does this approach cause inflationary pressure and financial disservice to taxpayers, but it clouds the negative role that factors such as smoking, diet and alcohol consumption play in cancer causation.

Lest there be any doubt about Exxon's commitment to clean air, clean water, and the control of toxic substances, you should know that Exxon has spent 2.8 billion dollars on environmental conservation in the U.S. since 1965.

At the Baytown Chemical Plant alone, we expect to spend over 50 million dollars on environmental conservation over the next three years.

In conclusion, Exxon Chemical U.S.A. recognizes its responsibility for the environmental impact of its operations and products. We do not rely on regulations in pursuit of that policy, nor do we oppose expenditures when we are justified.

I assure you, that further, of my concern for environmental conservation as a private citizen residing with my family in our Baytown Chemical Plant community.

Thank you, Mr. Padgett.

CHAIRMAN PADGETT:

Thank you.

Any comments?

MS. ANDERSON:

Dr. Senn, with regard to your statements on the fact that the incident rate of cancer has declined somewhat since 1847 and the mortality rate is also declining, we have heard testimony and in fact have it in writing from Dr. Marvin Seiderman (phonetic), of the National Cancer Institute, a different opinion on this, that the incident rate is increasing and has steadily been increasing where we have data to show this and also the mortality rate, when adjusted, has also been increasing.

Are you aware of these differences in opinion about these data?

MR. SENN:

Yes. My comments were based primarily on the findings or testimony of Dr. Robert Morgan, whom I think testified earlier in Washington this week.

But I am aware that there are divergent views on the interpretation of the

41-b

statistics.

CHAIRMAN PADGETT:

Anything else?

MR. JOSEPH:

Just one question, Dr. Senn.

Given the divergence of the testimony in these hearings, as illustrated on whether epidemiology is a sensitive-enough tool to tell us whether some -- some number less than epidemic proportions of cancers are being caused, or are being contributed to, by air pollution, emissions of carcinogenic substances, given the divergence on the interpretation of what data do exist, if EPA were to come to the conclusion that it is impossible at this point to draw reliable conclusions from the epidemiological data, what would you have the Agency do?

MR. SENN:

My first step would be to have the Agency embark on a very thorough study to sort out and determine, on a sound scientific basis what true epidemiological information exists and why that is a sound scientific basis; and then take your action off of that basis.

MR. JOSEPH:

2-b

What if, after evaluating all the possible epidemiology on a basis that you would consider sound and scientific, the conclusion were that it didn't tell us the answer?

MR. SENN:

Then I think you have to step back and ask them to tell you their problem.

MR. JOSEPH:

Thank you.

CHAIRMAN PADGETT:

Dr. Anderson?

MS. ANDERSON:

As a follow-up to that last question, does this mean that you think the Agency should then not take action under the Clean Air Act until we do have positive evidence, that is, I guess what is generally regarded as positive evidence that people are getting cancer from air pollution?

MR. SENN:

I think that is right. I think that we need to determine not that they are getting cancer, but that an exposure at certain levels might produce cancer in those individuals.

I think the exposure of those

43-b

individuals to airborne carcinogens is separate from whether those materials cause cancer in the people.

MS. ANDERSON:

We've certainly heard testimony on this problem. Several epidemiologists who have -- all have indicated that when you start to see this kind of positive evidence, that really would indicate a large problem. Do you have a comment on that?

MR. SENN:

No really. I have been exposed to some epidemiological studies; I am not an epidemiologist, per se.

If you're talking about the long-term latent effects before you begin to notice it, I think there is a big body of knowledge out there right now that you could devote your activity to acquiring and coming down on what the specifics are and then working with specific problems as they occur.

CHAIRMAN PADGETT:

Mr. Kellam?

MR. KELLAM:

Dr. Senn, on the first page

of your testimony, you state, and I quote:

"We feel that adequate protection of air quality is already in place under other provisions of the Clean Air Act."

Just as a point of clarification, it is not clear to me whether you mean that we currently have sufficient authority under the Clean Air Act or whether you feel that, indeed, no further regulation of air pollution is necessary?

MR. SENN:

No, that's not what I said. What I said was, we believe there is adequate protection of air quality already in place, either under the Clean Air Act or by in-plant controls; so there is really more than just the Clean Air Act.

By the in-plant controls, we monitor inside the limits of our plant the levels. We monitor exposures. We follow the health of our people.

I guess I have a little hard time if we are controlling things within the

45-b

plant, why outside the plant that it is critical to move this rapidly without going and getting the scientific data and making a rather exhaustive study.

MR. KELLAM:

I understand your point.

But isn't it true that a lot of the techniques that you would use in your plant to control or limit the exposure of your workers indeed may vent through the roof and into the ambient air?

MR. SENN:

Not necessarily.

MR. KELLAM:

I'm not saying exclusively, but --

MR. SENN:

You are talking about venting? Vents? Flares?

MR. KELLAM:

You say, using current industrial hygiene science; and I assume that those are steps that you take to protect the workers?

MR. SENN:

That is right.

MR. KELLAM:

I think you have answered my question. Thank you.

CHAIRMAN PADGETT:

Any other questions?

(There was no response.)

CHAIRMAN PADGETT:

Thank you.

MR. SENN:

Thank you.

UNIDENTIFIED SPEAKER:

Mr. Chairman, with respect to the information that Dr. Anderson raised regarding Dr. Sneiderman (phonetic), is that information received in the last 48 or 72 hours? Or when was that information made available? Because I think Dr. Albert (phonetic) referred to that on Monday.

MS. ANDERSON:

These same comments were made in the OSHA hearings. He has made them many times; many places.

I happen to have a letter dated October 25, 1979, where he has made these comments in writing. So I have to get a copy of it.

47-b

CHAIRMAN PADGETT:

All right.

Meg Titus?

8-b

STATEMENT OF MEG TITUS

MS. TITUS:

My name is Meg Titus, and I'm speaking on behalf of the League of Women Voters of Texas, because our organization believes that our goal of promoting an environment beneficial to life is well served if any toxic substances can be controlled at the outset rather than going down the sewer, into the dump or up the smokestake, we support adoption and implementation of policies which will provide effective controls of carcinogenic air pollutants.

It is generally agreed that one in four Americans will contract cancer, that the majority of these cancers are preventable and that stationary sources contribute a substantial fraction of the cancer causes, and I will site some World Health Organization factors.

The World Health Organization and assorted scientific groups have estimated that 60 to 90 percent of human cancers are associated with environmental factors.

It is also generally recognized that Section 112 of the Clean Air Act Amendments of 1977 which contains the Congressional mandate

49-b

relating to controlling airborne pollutants as well as airborne carcinogens has not been effectively implemented to date as only four of th hundreds of hazardous air pollutants have standards.

Policies and procedures for controlling potential carcinogens must somehow greatly accelerate the pace of implementation of Section 112 to adequately protect the public health.

We find the counties with the highest cancer rates in the country in our own Gulf Coast area. Many studies indicate that cancer of the liver, lung, brain, nasal cavity, larynx and eye as well as melanomas can be largely attributed to the environmental hazards surrounding the petrochemical industry.

It is estimated that 70 to 90 percent of these cancers are environmentally related -- R. Doll, "Prevention of Cancer", 1967; Higginson, "Environment and Cancer", 1972, Pages 69-89.

The petrochemical industry itself can no longer cope with the risks of its own operations, due to the industry's skyrocketin

-b

insurance premiums with renewals sometimes 50 times higher than their older rates.

In addition, we are just beginning to realize the profound effects these substances may be having on future generations. Many substances which are carcinogenic can also produce mutations and/or abnormalities in the development of the fetus if the pregnant mother is exposed.

The gravity of this situation is profound -- the effects irreversible and may effect the lives of innocent people for generations to come.

As an example of this sort of toxic airborne emission, let's look at Benzene -- one for which a standard has not yet been set. Production of Benzene has increased about five percent per year for the past decade, with total 1977 production at about 11 billion pounds, some 90 percent of which was produced in petroleum refining and petrochemical industries. Some of its end-product uses are as an octane booster in gasoline, nylons, pesticides, adhesives, coating, inks, paints, varnishes and moldings. Nearly 55,000 full-time workers are exposed to

51-b

Benzene, of whom 55 percent work at facilities that have no engineering controls or protective equipment.

NIOSH estimates that about two million workers are now exposed to Benzene.

The Sanford Research Institute estimates that the general population is exposed to lower but unregulated exposure amounts. This study further documents that these estimates have been confirmed by limited industry monitoring including that by the American Petroleum Institute. The study also documents that over half the Benzene supply in the United States comes from a small number of petroleum refineries in Texas, California, Louisiana and Illinois.

It is further estimated that more than six million people who live within the vicinity of these refineries are being constantly exposed to Benzene emissions in the .1 parts per billion range. A wide range of chemical manufacturing plants through the U.S., but particularly concentrated along the Gulf Coast, leak substantial quantities of Benzene into the atmosphere. Another source of Benzene exposure are gasoline stations of which there are

about 200,000 in the United States.

With the phasing out of lead additive, Benzene use as an octane booster has doubled over the last four years to current levels of from 1 percent to 2.5 percent in most brands. This is mostly liberated during fill-up from the displacement of gasoline within the gas tank producing recent Benzene levels averaging 250 parts per billion immediately adjacent to the gasoline pumps.

Estimates of average Benzene levels from these sources range from 1 to 4 parts per billion in downtown Dallas and other cities across the country -- Ibid., page 87.

For documentation of Benzene as a cancer-causing agent and as the cause of other occupational diseases, such as aplastic anaemia and chromosomal effects, I refer you to The Workplace, Case Studies in The Politics of Cancer by Mr. Epstein, 1979, pages 132 to 137.

An emergency standard was granted May 29, 1979 after a petition by the AFL-CIO but was strongly protested by the API and the Federal Court of the New Orleans Fifth Circuit granted a stay of the emergency standard

53-b

of 1 part per million. The League of Women Voters of Texas urges the EPA to do everything possible to move more rapidly toward regulation of Benzene and the hundreds of other potential carcinogens than it has since the passage of the Clean Air Act of 1970.

Protection of public health is the issue and the present standard of 10 parts per million is not adequate protection of the public health.

We agree with the following conclusions found in the proposed policy and procedures for Regulation of Airborne Substances Posing a Risk of Cancer as set out in the Federal Register, Volume 44, October 10, 1979. We agree that the public has frequent exposures to potential carcinogens from stationary sources. We agree that no safe level of a carcinogen has been identified. We agree that an increasing number of persons can be expected to develop cancer from even low levels of exposure. We agree that positive results from either human-epidemiological or animal-toxicological studies are adequate to establish the carcinogenicity of a substance. We agree that

54-b

any proposed national emissions standards for each source category should be based solely on potential health effects.

The Texas League commends the EPA's strong acknowledgement that airborne carcinogens do pose a major public health problem which will require tough emissions controls to prevent serious illness and deaths. We also commend the EPA for planning to list and regulate many more potential carcinogens, for urging industry to search for substitute processes that may eliminate carcinogenic emissions altogether from the workplace and the ambient air, and for insisting that new plants develop strong emissions controls.

We believe, however, that current epidemiological methods are insufficiently reliable to provide an adequate and complete assessment of the impact on public health of multiple carcinogens and their potential synergistic effects.

Airborne carcinogens are still another incremental hazard to add to the many other exposures we all receive daily. We also believe that 10 years has been an inexcusably

55-h

long time for the EPA to have spent in addressing Section 112 which states that within 360 days of placing a substance on the Hazardous Air Pollution List, EPA must set standards to protect the public health with "an ample margin of safety." Section 112 (a)(1), (b)(1)(A)(b)(1)(B).

You have scarcely begun the task as you have listed only six hazardous air pollutants up to this time and standards, some of which we feel are inadequate, have been set for only four. The League urges you to begin immediately to list and regulate a specific number of potential carcinogens and we support the twenty per year proposed by the Environmental Defends Fund, and this this be done on a scheduled priority basis with adequate publicity about the listing so that Industry will be certain to know that regulation is imminent and will be based on health not economic factors, and also so that the public can be certain of protection.

If further financial resources are required for the EPA to make this commitment the League in Texas can be counted on to support your efforts to obtain them.

We believe the EPA should make

-b

every effort to facilitate the listing and regulating process by avoiding the rehash of such matters as the validity of animal studies or the concept of "no safe dosage." Much time could be saved in this process if the EPA would accept and make it known that it would adhere to the following statements contained in the HEW document entitled, "Estimates of the Fraction of Cancer in the U.S. Related to Occupational Factors," September 15, 1978. They are:

The estimate that only one to five percent of total cancers in the U.S. are attributable to occupational factors have not been scientifically documented and have little meaning for estimating even short-term future risks.

Most cancers have multiple causes: It is a reductionist error and not in keeping with current theories of cancer causation to attempt to assign each cancer to an exclusive single cause.

Because cancer incidence is strongly dependent on age and duration of exposure, and because most cancers occur late in life, any industrial epidemiological studies detect only a

57-b

small fraction of cancers, that is, those developing early.

Past exposure to asbestos is expected to result in up to two million excess cancer deaths in the next three decades; this woul correspond to roughly 13 to 15 percent of the tota cancer mortality expected in that period.

Reasonable projections of the future consequences of past exposure to establishe carcinogens suggest that at least five of them -- Benzene, arsenic, chromium, nickel oxides and petroleum fractions -- may be comparable in their total effect to asbestos.

These projections suggest that occupationally-related cancers may comprise as much as 20 percent or more of total cancer mortality in forthcoming decades. Asbestos alone will probably contribute up to 13 to 18 percent and the data on the other five carcinogens suggest at least 10 to 20 percent. These data do not include effects of radiation or effects of a number of other known chemical carcinogens.

Although exposure to some of the more important occupational carcinogens has been reduced in recent years, there are still many

unregulated carcinogens in the U.S. workplaces. A number of occupations are characterized by excess cancer risks that have not yet been attributed to specific agents.

There is no sould reason to assume that the future consequences of present-day exposure to carcinogens in the workplace will be less than those of exposure in the recent past.

Patterns and trends in total cancer hypothesize that occupationally-related cancers comprise a substantial and increasing fraction of the total cancer incidence.

The conclusion that a substantial fraction of cancers in the U.S. are occupationally-related is not inconsistent with conclusions that a substantial fraction of cancers are also associated with other factors such as cigarette smoking and diet (sic).

Occupationally-related cancers offer important opportunities for prevention.

The League of Women Voters of Texas believes that EPA, OSHA, NIOSH, the National Cancer Institute and the International Agency for Research on Cancer all should use the above as the basis for future action to eliminate

59-b

future debate on these widely-accepted principles.

Our organization also believes that the EPA proposal to use a quantitative risk assessment for each chemical to decide if risk exists even after the use of BAT flies in the face of Section 112. That section requires standards which provide an ample margin of safety for airborne pollutants. We find no statutory license for accepting any amount of residual risk as you propose to define "unreasonable risk."

We agree with Senator Muskie's statement, and I quote:

> "The bill provides the Secretary with the authority to prohibit the emission of hazardous substances. The Committee was presented with strong evidence that any level of emission of certain pollutants may produce adverse health effects that cannot be tolerated.

It seems to us that the EPA is proposing to accept a certain number of deaths as a result of not being able to identify a threshold for carcinogens. We believe the Senate

Committee did not accept that concept, nor do we.

We believe that in order to provide the greatest possible incentive for Industry to move quickly to reduce risks to the public from carcinogens, EPA should require that one year after a standard is set either the emissions goal should be zero for known carcinogens, or a substitute should have been found, or documentation should be presented by Industry that no available technology could attain zero carcinogenic emissions.

We read Section 112 as an important technology-forcing portion of the Clean Air Act Amendment with the burden of proof on Industry, not on the EPA, for not meeting the mandate of the law. Further, an offset policy should be developed to assure continued emission reductions.

We believe that dispersion approaches such as the risk avoidance criteria and the proposal for providing waivers will encourage an increase in carcinogenic emissions in areas of low population and we did not think that was the intent of the law.

The League of Women Voters of

61-b

Texas is also concerned that quantitative risk assessments when dealing with carcinogens are unrealiable and, therefore, unwarranted. All current knowledge in this area is related to qualitative analysis and, given the factors of long latency periods and unknown or unmeasured exposure levels, we believe quantitative risk assessment to be not only imprecise but unacceptable, as no portion of Section 112 suggests its use or suggests that balancing risks and benefits can be considered under this portion of the law.

Under a separate rulemaking notice entitled, "National Emission Standards for Hazardous Air Pollutants: Advance Notice of Proposed Generic Standards", EPA sets out a group of housekeeping standards and requirements for sources to use in controlling carcinogenic emissions. We support the concept of such requirements as a quick method for reducing fugit: emissions. However, some of these proposals seem to be less stringent than RACT, reasonably available control technology, for hydrocarbons. We urge that these be strengthened not only to reduce health risk but, judging from previous

industry actions, they may reduce industry costs.

A single rulemaking to apply to all pollutants in this category could save a great deal of time as opposed to separate proposals for each chemical as it is added to the list to be regulated.

We also support housekeeping requirements for storage, pumping and processing these potential carcinogens, as well as for their production. For example, as the Court was drafting its final decision, a study was released for the Manufacturing Chemists Association showing that control of process vents and Benzene storage tanks could achieve 95 percent reduction of all emissions for considerably less cost than previous estimated.

Both Government and Industry resources should quickly focus on these generic housekeeping measures to reduce carcinogenic emissions as soon as possible.

Out state air quality position as well as our national position requires us to urge the above outlined measures relating to rules, policies and procedures for identifying, assessing and regulating airborne substances posing a risk

63-b

of cancer be implemented rapidly. We also urge that the final rules be drafted in such a manner as to encourage voluntary compliance.

Thank you for the opportunity to present our views.

MR. PATRICK:

One of the important things at these public hearings is to find out -- where things are being misinterpreted.

A perfect example of that is our housekeeping requirements are being interpreted by you as being less stringent; and Mr. Krohn determines them as being more stringent

And it seems like we've got to do a little bit of rewriting on that.

CHAIRMAN PADGETT:

Dr. Anderson?

MS. ANDERSON:

On the use of quantitative risk assessment, to look at residual risk, the thrust of your comments presumed the use of this tool essentially would -- from the Agency's point of view -- permit a certain amount of cancers to stay out there after the application of the best available technology.

Looking at it another way, suppose we had applied best available technology and we didn't take into account potency -- which seems to vary widely amongst the carcinogens -- and that there are two determinations; whether or not something can cause cancer and then how potent it is.

Suppose that the residual risk there from a chemical as potent, say, as dioxin, if we didn't take any account of this, we wouldn't have any way of knowing.

So saving from two to zero in the next five years would leave us really not fulfilling a major public health responsibility.

Don't you think that maybe rethinking might lead you to think that it really is worth taking a look at this residual risk application of best available technology?

MS. TITUS:

Possibly. But we still feel some concern about using quantitative analysis.

MS. ANDERSON:

Just to make the point: I think if we don't look at it, it means that we treat all chemicals as if they have precisely the

same ability to affect public health -- which we know isn't true.

MS. TITUS:

Yes; I know.

CHAIRMAN PADGETT:

Sort of into the same area: On page 6, you state:

> "...EPA should require that one year after a standard is set either the emissions goal should be zero for known carcinogens, or a substitute should have been found, or documentation presented by industry that no available technology could attain zero carcinogenic emissions."

Assuming that Number three is the course of action, then, is it your statement that that would be a sufficient standard or --

I am not sure exactly what you have said here.

MS. TITUS:

Yes. I can see why there might

be some confusion on that.

I think that our position would be that if there were no method available for reducing those carcinogens, then further search should be made for a substitute. They should simple not be allowed to be emitted into the air.

CHAIRMAN PADGETT:

But in the meantime, they would simply live with the best available technology.

MS. TITUS:

Until a substitute -- I suppose that would be rather inevitable.

CHAIRMAN PADGETT:

So you are saying there is no potential alternative for more stringent action in the case of particularly strong --

MS. TITUS:

We would like to see the EPA take the strongest possible option for controlling them under any circumstance.

We feel the option should be chosen which would be most likely to reduce carcinogenic emissions and come closest to attaining a zero emission.

67-b

CHAIRMAN PADGETT:

Any other questions?

(There was no response.)

CHAIRMAN PADGETT:

Is D. W. Fuller in the audience now?

(There was no response.)

CHAIRMAN PADGETT:

How about someone from the Texas Air Control Board?

(There was no response.)

CHAIRMAN PADGETT:

Our next speaker, then, is Jim Mullins.

STATEMENT OF JIM MULLINS

MR. MULLINS:

Good afternoon, Mr. Padgett and members of the panel.

I am a Senior Staff Engineer with the Shell Oil Company Environmental Affairs Department.

My purpose today is to provide a summary of Shell's written comments on both the proposed rulemaking regarding the policy for identifying, assessing and regulating airborne substances posing a risk of cancer, and the proposed rulemaking regarding generic standards under the NESHAPS program.

With me is Mr. Brynn Aurelius of Shell's legal organization who, with myself, will be glad to respond to questions the panel may have following my presentation.

The proposed policy appears to be based on the premise that industrial airborne substances are known to be responsible for a significant proportion of the cancer that exists today. In this respect, the proposal reiterates a statistic that has been repeatedly misunderstood: Namely, "60 to 90 percent of all human cancers

69-b

may be due to environmental factors." Although it is further stated in the proposal that the term "environmental factors" must be understood to include chemical exposures from smoking, diet, occupation, drinking water, air pollution, various forms of radiation, including sunlight, and some forms of physical irritation, the conclusion which has been reached by EPA creates the impression that industrial airborne substances present a great risk of cancer.

EPA has not presented data, and we are not aware of any data, whoch would support this conclusion. In fact, there has been previous testimony at an earlier procedure (sic) which actually supports a conclusion of no known effect

Without adequate data to support this Agency position, there is no justification for the broad-based generic regulation that has been proposed. Furthermore, this new policy is not needed because the Agency already has the authority to regulate hazardous airborne pollutan

Even more inexplicable is the Agency's proposal to abandon its previous policy of separation of scientific issues from regulator issues. The "Interim Guideline" under which the

-b

Agency now operates, and indeed parts of the proposed rulemaking, take cognizance of this principle.

The preamble to the proposed rulemaking states that judgments concerning the probability of human carcinogenicity, a scientific issue, are made based on the quality and weight of evidence. This implies that the Agency wishes to address scientific issues separately from regulatory issues. Unfortunately, this logical process is contradicted by the proposed rule.

The net effect of the proposal is that we are faced with a procedure that prescribes listing and an arbitrary degree of control, best available technology, prior to any significant assessment of the risk. It is not reasonable to regulate a substance if there are no data to indicate that the substance poses a significant risk.

It is even possible that there will never be a quantitative risk assessment of the type proposed by the Agency since the policy states that one will be made after the imposition of BAT only if possible.

This situation has been created

71-b

because the Agency has not adhered to its stated principle of separation of scientific and regulatory issues. EPA has instead chosen to use rigid, fixed criteria and automatic classification

This action results in an approach to zero-risk because it is a de facto attempt to eliminate all risks from airborne carcinogens. Under the proposal, substances could be listed under Section 112 of the Clean Air Act if there were a single mammalian study demonstrati the induction of certain benign tumors under severe conditions of high-dose exposure.

Under the proposed criteria, it is evident that the proposed policy is an indiscriminate mixture of scientific and regulatory issues. Generic regulations, while ostensibly offering regulatory agencies a means to speed up the promulgation of regulations, in the long run will do the country harm because they compromise complex scientific issues and lead to poor utilization of the resources of this country.

Because of the minimal requirements that must be met to classify a substance as a "high-probability" carcinogen, and the undefined "significant-exposure" level,

-b

substances will be regulated without benefit of a quantitative risk assessment of the type detailed by EPA.

If we are to gain the maximum benefit from our country's resources, it is essential that the quantitative risk assessment be conducted prior to, and used as a basis for, listing a substance as a hazardous air pollutant.

Turning to another concern, we believe the proposed policy thwarts the requirement of Section 112 of the Clean Air Act to provide for public review and comment on a decision to list a substance as a hazardous air pollutant.

Under Section 112, the Agency is required to conduct a public hearing regarding the decision to list a substance within 210 days of that listing. The proposed policy fails to provide this required step in the rulemaking procedure.

We believe that the Agency must provide for public review of the decision to list as well as all the evidence used to make that decision. An opportunity must also be provided at such a hearing for the presentation of

73-b

information which is relevant to the listing decision. It is only after such a hearing that the Agency may proceed to regulate under Section 112.

We also believe that the propose requirement to regulate a substance to the level of best available technology, or BAT, as a minimur in addition to its wastefulness of resources, goes beyond the requirements of Section 112. Witl this approach, the Agency has pre-determined that nothing less than BAT will provide an ample margi of safety to protect the public health. Without benefit of a quantitative risk assessment, it is impossible to judge such a margin of safety. To regulate at the BAT level, without such a demonstration, is simply not authorized by Section 112.

Another issue of concern is the Agency's conclusion that the proposed policy does not meet the criteria contained in Executive Order 12044 for requiring a regulatory analysis because, and I quote, "The policy does not impose regulatory requirements on any emission source." This conclusion is inconsistent with both the title and thrust of the proposed rulemaking.

Simply because the Agency chooses to call the regulation a "policy" does not relieve the Agency from the requirement for a regulatory analysis.

The Policy describes very specific regulatory actions for substances that meet very rigid criteria. Only the names of the substances are missing. And even here, the Agency has already identified, but not accounced, 40 substances for which carcinogenicity determinations and preliminary-exposure estimates are underway. The Policy will have sharply defined results which can be measured and quantified. Under the policy the Agency will be able to list a suspected carcinogen and trigger all that must follow under Section 112, before the required regulatory analysis is conducted.

At this time, I would like to comment on the Advance Notice of Proposed Rulemaking for Generic Standards under the NESHAP program. Our initial concern here is that the proposed generic rules appear to put the cart before the horse. The concept of regulating very minor sources prior to preparation of a quantitative risk assessment or consideration of other routes to reduce exposure is wasteful of

75-b

limited resources and clearly not an effective way to deal with the problem of control of hazardous air pollutants.

It a regulation for control of fugitive emissions is ever justified, we believe the rules proposed here are too rigid and potentially ineffective. The Agency states it has considered three alternate approaches for these controls.

It has rejected the approach of requiring specific performance levels since it claims that there are insufficient data available to set performance levels for the type of emissior being considered. We agree that this approach would be very difficult.

We do not agree, however, with rejection of the second approach -- that of individual plant systems developed from EPA-issued guidelines. This type of system has been adopted by EPA in its current NESHAP standarc for vinyl chloride and in our opinion meets or exceeds the level of control contemplated by EPA's actual proposal.

In our written testimony we have presented data which indicate that a system

utilizing fixed-point monitors is extremely effective in controlling fugitive emissions.

Leak frequencies of less than one percent for equipment such as flanges and valves have been demonstrated. We do not advocate fixed-point systems as the mandatory regulatory scheme, however, since circumstances differ at each facility. We believe that each source should be allowed to adopt a leak-detection and repair program that is compatible with its design and operating characteristics while meeting certain guidelines provided by the Agency.

In the area of recordkeeping and reporting, the proposal is inconsistent with the recordkeeping and reporting requirements already in place under NESHAP for vinyl chloride controls. This will be confusing to Industry and serve no useful purpose.

In closing, we recommend the following:

- The Agency should revise its current conclusion that industrial airborne substances present a significant risk of cancer to the public. The available data simply

77-b

do not support such a position.

A generic type regulatory policy, such as proposed, is not needed.

- If a new regulatory policy is to be promulgated, the Agency should maintain its philosophy of separating scientific policy from regulatory policy, as described in its "Interim Guideline."

- The Agency should recognize that a rigid generic classification system without quantitative risk assessment will expend this Nation's limited resources without obtaining maximum benefit.

- Quantitative risk assessment of the type detailed by EPA should be used prior to, and as a basis for, listing a substance under Section 112.

- The adoption of this, or any similar policy, cannot substitute for the requirement to provide for public hearing and comment on the decision to list a specific substance.

- The requirement that Best Available

Technology will be the minimum level of control is not consistent with Section 112 requirements. The level of control must be that which provides the "ample margin of safety" and no more.

- A regulatory analysis of the proposed policy, as required by Executive Order 12044, can be and should be made.

- The use of the generic-type fugitive emission control for the initial regulation step is not cost effective. All types of control should be considered, and only those that meet the economic and "ample margin of safety criteria" should be promulgated.

- Any fugitive emission control scheme that is adopted should be in the form of guidelines which will allow each source to utilize control procedures that best fit its particular circumstances.

Our written testimony discusses

79-b

the points I have made today more fully and also presents other concerns which we have. I appreciate the opportunity to appear here today and will be glad to respond to questions the panel may have.

MR. PATRICK:

Jim, just a couple of quick things.

You're advocating, really, a guideline-type approach that is something we talked about in Washington.

You also stated on page 7 that the standards for vinyl chloride met or exceeded the level of control contemplated by EPA's actual proposal.

Do you regard those requirements to be a good basis or sufficient from the standpoint of emission control --

MR. MULLINS:

Well, in the case of fugitive-emissions control data for vinyl chloride through leak detection, I was talking about a program established and approved by EPA; that's the guideline I am talking about.

MS. ANDERSON:

I think perhaps something else isn't coming through clearly in the Policy. I wonder why you read the Policy and determined that EPA is going to depart from its stated policy in the interim guidelines separate from the regulatory decision?

In other words, I'm wondering why it's coming through to you regulatory policy and thus is not following the Agency's guidelines in assessing carcinogen risk.

MR. MULLINS:

I believe that is a regulatory decision that has mixed science and the regulations.

I think that science should determine what is a carcinogen and what is the level of risk and the confidence levels that scientists have in that level and then regulatory decisions are made after that determination to decide what levels of control we will go to.

MS. ANDERSON:

I think it's unfair to say that neither of these two points deviate from the interim guidelines that were published in May of 1976.

81-b

Were you here earlier when they talked about the significance of the single study?

MR. MULLINS:

Yes, I was.

MS. ANDERSON:

But I just wonder -- I don't think that it should be read and I think this is an area where we probably will need to do some work, because I don't think that the Policy is intending to say that a single study that is very flimsy and border-line and poorly conducted and so forth all by itself is being used to list something as a cancer risk under any one of EPA's seven laws.

But rather than in some cases it certainly does make sense to regard information from a single aminal test as such examples that I gave this morning were, for example, the aflotoxin situation and I wondered if you have any feelings on using single-animal tests and certainly looking at everything else we have all the other related information.

But do you regard this as a reasonable use of a single-animal test?

-b

The aflotoxin data being that aflotoxin was tested and the mouse was negative and the rate positive and there are a number of chemicals tested this way and then we'll have an opportunity to get human epidemiological data. We often can confirm that indeed what is expected is demonstrated in human population.

Do you think the Agency should ignore results of this type in single-animal species?

MR. MULLINS:

I don't think it should be ignored. I think efforts should be made to confirm them. I think other types of studies should also be looked at, both positive and negative rather than using just the one.

I think as I stated, there are in the preamble to the proposed policy much of the statements which you have just made and it would appear that use of the interim guidelines might be the type of thing that's being proposed. But when you get to the acutal Appendix C that is being proposed, a lot of that does not come through.

MS. ANDERSON:

I think that's the idea of the

83-b

interim guidelines. You mean --

Notice taken that these guidelines would apply to seven or six, at the time I think, toxic substances.

MR. PATRICK:

I thought of one other thing.

You made a statement that the requirements for BAT as a minimum was not consistent with 112 and its language about ample margin of safety.

I think the thought there was when you can't define a threshold, how do you define ample margin of safety?

And it has been, I think, a...BAT concept really fit that better and then assigned BAT as a minimum and then look for residual risk going above that. And we see that as consistent with the BAT concept in 112.

Do you -- You apparently have a different interpretation of that when you have under the assumption of no-threshold. Do you still see smoe more individualized level of determination of what's the adequate controls?

MR. MULLINS:

It is indeed true that best

available control technology must be -- will be the minimum. There may be cases where that is indicated.

MR. BAUMAN:

On page 5 of your testimony, the second paragraph, you make some remarks about the public participation in both the decision and the evidence.

And I gave my views earlier this morning...

To your testimony I do feel the policy does speak to that issue.

I do have a question, though, with regard to your statement on page 4. You say that:

> "...substances will be regulated without benefit of a quantitative risk assessment of the type detailed by EPA."

And my question to you is, what do you mean by regulation or what do you mean -- How do you define the term "regulation"?

Are you referring now to the emission regulations for the BAT or what?

MR. MULLINS:

85-b

I am referring both to BAT and the generic standards. The Policy seems to state to us that the generic standards and best available technology will be mandated as the minimum level of control and the risk assessment will be used only to determine if we should go any further.

It seems to me that if that risk assessment is made after those controls have been imposed, it is too late. We have already spent the money and put it in.

Indeed, the risk assessment for any given substance may show that BAT went further than we need it to.

MR. KALLAM:

Mr. Mullins, on page 3 of your testimony, you indicated, as other witnesses have, that you feel that the policy suffers from its use of rigid fixed criteria and automatic classifications.

My first question is: Do you feel that -- Do you mean by these criteria, the listing criteria that we use?

MR. MULLINS:

Yes.

MR. KALLAM:

On the following page, you refer to the " ...undefined 'significant-exposure' level."

That is also one of our criteria for listing. Am I to understand that as far as exposure is concerned, you are more worried about--

MR. MULLINS:

Yes. I am concerned that the EPA will list the substance if it determines that there is a significant exposure. But there is no guideline given as to what is a significant exposure.

MR. KALLAM:

Would you then prefer us to have fixed, rigid criteria for exposure?

MR. MULLINS:

I think it ought to be a guideline. I think each substance has to be evaluated or the exposure of each substance has to be evaluated; what you need a guideline on is what is significant in relationship to other substances that we are looking at.

If you look at one given substance this year and find an exposure level

87-b

that is considerably lower, you may consider that that is significant. There doesn't seem to be any guideline for saying -- relating the significance of the exposure between chemicals.

MR. KELLAM:

I think that's the conclusion that we reached. Thank you.

MR. PATRICK:

I had one question from the audience concerning that statement about fixed-point monitoring systems.

(Addressing the audience:) If you will see me after the meeting, I will give you the names of the people you can talk to to get more information on that.

CHAIRMAN PADGETT:

Dr. Walker was listed to speak this evening. He asked to be moved up.

There are several times where I have called out the names of a couple of people who have been listed to talk and they have not been here.

Let me just ask a general question: Is there anyone in the audience who thinks that they were listed to speak this

1-c

STATEMENT OF FRANCES B. SMITH

MS. SMITH:

Thank you, Mr. Chairman, for this opportunity to comment on the EPA proposed rulemaking on emissions of cancer-causing substances into the air.

I am Frances Smith, representing the League of Women Voters of Houston, which has a deep concern for public health, and has had an active interest in air quality in general and airborne carcinogens in particular, for several years.

In 1977, the League of Women Voters of Houston, and the Texas League, sponsored in conjunction with the University of Texas Health Science Center at Houston, and Tenneco Chemicals,, Incorporated, a Conference on Environmental Cancer.

This conference focused on several aspects of the problem, including airborne carcinogens. The concern, which prompted this conference, grew out of the awareness that proper control of carcinogens in the present may reduce cancer rates in the future, and that current cancer rates reflect exposures which pre-date the

increased production and use of chemicals which has occurred since the early 1960's, because of varying latency periods.

We are aware of the work of Hoover, Mason and McKay, and also Blot and Fraumeni which show that lung cancer rates are higher in highly-industrialized counties than non-industrialized counties in the United States. And Enstrom, as noted in a letter in Science, reported last year that there has been a significant increase, since 1935, in the lung cancer rate among non-smokers. Therefore, as residents of an industrial area, we urge you to control the hazards from airborne carcinogens as rapidly as is feasible.

We note that three carcinogens are now listed under Section 112 of the Clean Air Act Amendments. We support your efforts to control now some of the airborne carcinogens through the use of generic standards for source categories. We would expect that more of these will eventually be listed under Section 112. We urge your continued evaluation of the twenty-six chemicals termed known human carcinogens by the International Agency for Research on Cancer.

3-c

We realize that it is difficult to determine a threshold for carcinogens, if indeed there is one. We realize also that neither zero-risk nor zero-emissions are probably attainable in all cases. However, these facets of the control problem do not diminish at all the argumentthat carcinogenic emissions should be reduced to the lowest feasible level to reduce the hazards to the general public.

We recognize the need for risk assessment, but only as a means of setting priorities. Qualitative, not quantitative, inferences can be drawn from evaluation of the extent of general public exposure and evaluation of carcinogenicity. Given the complex organic emissions from highly industrialized areas, such as ours, adequate risk assessment is difficult. Will the increments of each carcinogen be considered additive or synergistic? Surely they should not be considered entirely separately.

Some flexibility may well be desirable in the screening and classification systems. We agree that some generic classificati system would enable a more rapid control of airborne carcinogens. But we urge you to careful

consider new approaches, should a more reliable and workable classification system emerge from current research on chemical reactivity.

Thus, we support your approach in reducing airborne carcinogens quickly through generic standards, and urge you to proceed as rapidly as possible to list additional substances under Section 112. We believe that an ample margin of safety should be preserved for the protection of the general public.

The League of Women Voters of Houston is aware that there is much debate in the matter of airborne carcinogens, but believes sufficient knowledge exists to permit us to proceed. Debate is healthy, but the public health demands that such debate not be permitted to delay protection of that public.

Thank you.

CHAIRMAN PADGETT:

Thank you.

What comments do you have relative to siting of new sources?

MS. SMITH:

We do not choose to comment on that.

5-c

CHAIRMAN PADGETT:

Thank you.

Any questions?

(There was no response.)

CHAIRMAN PADGETT:

Thank you very much.

Dr. Walker?

STATEMENT OF HARRY M. WALKER

MR. WALKER:

Thank you, Mr. Padgett.

Today I am speaking not in my official capacity but strictly as a concerned citizen of Dickenson, Texas.

I am Dr. H. M. Walker of Dickenson, Texas. I am an atmospheric chemist and am a professional in the field of air pollution. The remarks that I am about to make regarding the subject of this hearing represent my personal and professional views as a concerned citizen and as a professional in the field of air pollution and regulatory affairs.

My great concern regarding today's subject is that it represents a major escalation of the regulatory process in the United States. Today, when the newspapers, the politicians, the scientific community, and the business community have virtually reached a consensus that over-regulation is seriously damaging our nation, our economy, our level of innovation and our ability to mount any national program of consequence, we have before us a sweeping new regulatory proposal of almost

7-c

unlimited potential for interference with the activities of citizens in all walks of life.

Consider this -- the air pollution program which has, over the past ten years, had vast negative impact on the economy, which has contributed significantly to the nation' inability to resolve its energy crisis and which has in many respects yielded only very questionable benefits, deals only with the regulation of a mere six criteria pollutants plus four additional materials under the NESHAPS program.

The program proposed today seeks to control 40 or 140 or 600 of thousands of materials depending upon which sentence in the proposal document one chooses.

Let us clearly recognize that the program under discussion does not seek to control materials which are known to cause human cancer by virtue of their being present in the ambient atmosphere. It seeks to control any material which, by laboratory animal testing, can be shown to merely preturbe the natural rate of formation of tumors, both malignant and non-malignant in groups of animals specifically

selected because their natural tumor rate is very high -- or which proves mutagenic in a synthetic test tube procedure such as the Aimes test. Or which becomes epidemiologically associated with cancer in any situation, almost certainly one not involving ambient air exposure.

I inject the latter observation because I am totally unaware of any epidemiological association of any specific material with cancer among any population where the only exposure was ambient as this is as contrasted to workplace air.

In other words, the policy proposed permits the regulation of materials in the ambient air, not based only upon firm showing that their presence has caused human cancer but merely on subjective judgment about the weight of evidence where the evidence will be almost entirely on such indirect sorts.

Also of great concern to me is the total absence of any weighting to be assigned to the potency of any carcinogen, which has been mentioned previously, several times today. Thus it would appear that perhaps benzidine and saccharin may merit equal priority in the pending regulatory campaign.

9-c

With the background that dozens and perhaps hundreds of the essential materials of civilization are likely to be involved in the program, the correlatory postulate advanced -- namely that the only acceptable level for such materials will be zero is indeed frightening.

In these days when the triumphs of analytical chemistry have rendered commonplace the measurement of materials at levels of just a few parts per billion or even just a few parts per trillion, zero is seldom an attainable number.

With such premises it seems obvious to me that in most cases the regulatory approach will become simply an absolute ban. A policy of loose criteria plus a zero objective in the hands of an over-zealous regulator has the potential, for starters, to remove from the benef: of mankind, the diesel engine, coal, heavy-fuel-oil combustion, most pesticides, most chlorinated solvents, most dyes, most plastics, many minerals, chemicals, drugs -- in short, a significant portion of those materials which provide the basis for our standards for human confort and living in the United States today.

It has the potential for the

disruption, if not in some cases the elimination, of industries and activities which, and I quote from your document, "fall into six broad groups; one, mining, smelting, refining, manufacture and end use of minerals and other inorganic chemicals; two, combustion; three, petroleum refining; four, synthetic organic chemical industries and end use application and waste disposal;..." and some others I won't mention. In short, most of the major essential industries of America are to be further seriously regulated.

Now, of course, this is not really going to happen. Neither the EPA nor any other governmental body can ban many materials of such major benefit. Just as the FDA found that it could not ban saccharin in the face of an obvious public willingness to accept the material on the basis that its benefits outweighed its risks and this latter consideration, I note, seems to be entirely missing from the proposal under discussion today.

What would take place would be a very selective enforcement effort under such a sweeping policy. In effect, whatever is regulated, whatever is banned or whatever is ignored will be

11-c

determined by arbitrary decision of the regulators working under a policy so sweeping that it constrains them not at all.

The Policy, in practice, will be a vehicle for government by men, not by laws -- totally incompatible with our American system.

I strongly recommend that you wh are judging this issue recognize the enormous potential for over-regulation inherent in this policy, as written, and also take cognizance of the fact that the pendulum has turned, that the nation is in no mood for any new escalation in the level of arbitrary interference in the economic system or in the lives of citizens, for alledged benefits which are hypothetical and tenuous at best.

I, therefore, recommend that the policy be revised to require:

1 - Unequivocal levels of proof as to real human carcinogenicity before the qualification of any material.

2 - That carcinogenic potency be given serious weight in such qualification.

3 - That risks versus benefits be similarly given major consideration.

4 - That target abatement levels shall not be zero but shall be reasonably related to levels and exposures of demonstrated carcinogenesis.

Such a policy should provide clear guidance and leave little leeway for arbitrary regulation. Certainly it should prove far more desirable from the standpoint of the economy, of the nation and even of EPA and should avoid the regulatory chaos which would be inevitable if the proposal is adopted without significant improvement.

And I thank you for your attention.

CHAIRMAN PADGETT:

Before we start, I have one question from the floor, which you can either answer or not answer.

"Please declare your employer for financial interest in regulation of cancer."

13-c

MR. WALKER:

I have no financial interest in the regulation. My employer is MOnsanto Company, and I do not speak for Monsanto Company. And I speak because I have a serious concern, myself as a citizen, with some knowledge into the matter.

CHAIRMAN PADGETT:

Thank you.

Relative to your first recommendation on the last page of your write-up:

"1) Unequivocal levels of proof as to real human carcinogenicity before the qualification of any material."

Do you mean through epidemiological studies?

MR. WALKER:

Yes sir.

I feel the workplace, epidemilogically, is an excellent testing point; if you have a negative epidemilogical one, then the chances to have any situation of consequence outside the workplace where the levels will be severalfold lower is almost of no concern at all.

CHAIRMAN PADGETT:

Without getting into a real long discussion on this, because that is really not our purpose here, in my understanding of epidemiology, from several days of testimony, from the various questions, first of all it is a fairly imprecise tool.

We have heard estimates, such as the best it can do is indicate when there is a 50 percent increase in a particular type of cancer; it will tell you that. But that's really about the best it can do.

The second thing is that it requires a good ten, to twenty, to forty years to work, depending on who you ask; some say ten to thirty and some say twenty to forty.

So we're talking about that much of a lag time.

Now, are you saying that there should be that lag and reliance on that imprecise tool before any consideration should be given to control of a particular chemical?

MR. WALKER:

I agree that a lifetime in many cases is very long. Certainly many chemicals who

15-c

will become candidates for consideration under this regulation have also been here equally long and if problems have not surfaced in that time then that would be evidence that there is not a problem.

CHAIRMAN PADGETT:

But you're suggesting a fixed approach, inflexible approach, if you will, that would require this or -- I'm not sure --

Because, you see --

There are chemicals that are relatively new and many chemicals have not been around in sufficient quantities.

MR. WALKER:

That is true; that is true; I feel like people can always come up with a perhaps-this-is-a-problem sort of analysis. Perhaps, because it's something like something else that was going to be a problem, could be a problem.

But I think the issue is far too important to proceed that arbitrarily. And I feel that these tests -- the Aimes Test, the animals studies and so forth should be done. But each one should represent simply a screening step

to move to the next higher level.

But there is certainly no one-to-one correspondence between a few positive animal tests and human cancer. Invariably, the animal tests are done in such high concentrations that that alone is one of the reasons you don't have a true applicability.

CHAIRMAN PADGETT:

Again, your feeling is that you should wait until you get that unequivocal, true epidemiology?

MR. WALKER:

I would say in the majority of cases -- Now that's where possibly you could introduce the thought of potency.

CHAIRMAN PADGETT:

Okay. Thank you.

MS. ANDERSON:

In mentioning the saccharin case, I gather that you read this policy as being virtually the same as the Delaney Clause -- which of course, I'm sure you know, is unique in all the Federal regulations in that it establishes an absolute ban on the chemical which has been shown to be associated with the induction of

17-c

cancer in humans or animals.

And of course, when the FDA took its action on saccharin, it was taking action that Congress said it had to take and it was because Congress essentially changed the law of saccharin that's still on the market.

MR. WALKER:

Yes.

MS. ANDERSON:

So I'm not sure I see that as relevant to this topic, and I'm wondering how you read this Policy to imply the same thing that the Delaney Clause dictates to the FDA --

MR. WALKER:

Actually, with the factors you list there, you have a more sweeping ability under this policy to condemn material that isn't under the Delaney Clause. So I think if I recall correctly, the Delaney Clause was confined to animal testing --

MS. ANDERSON:

The Delaney Clause is animal or human --

MR. WALKER:

Oh --

MS. ANDERSON:

It says as soon as you find an association, that the substance can no longer be intentionally be added to food which is an absolute ban.

MR. WALKER:

Yes.

MS. ANDERSON:

I don't think there's any intent of this policy and I'm wondering how you read in this policy that as soon as there is any association the EPA would absolutely ban certain substances. I don't see the --

MR. WALKER:

You list a lot of criteria, some of which are less demanding, like the Aimes Test, and so forth as possible causes for listing and let me -- zero allowable concept would lead you, I think, rather rapidly --

Now, this may not be your intention now -- but I think inevitably with that line of logic it's going to -- the retreat will be in that direction. "When in doubt, ban."

MS. ANDERSON:

I think -- I brought that up

19-c

simply because I think we see this policy being interpreted in the extremes in both directions and I think this certainly is a very extreme interpretation of the policy and I don't believe it's written --

MR. WALKER:

No. I would agree it isn't written exactly that way but just the discussion c zero implies that I think leaves the door open for that.

CHAIRMAN PADGETT:

Mr. Joseph?

MR. JOSEPH:

Dr. Walker, I was just wondering if you had the opportunity to read the extended discussion and the supplemental statement basis and purpose at the end of this Federal Register publication, which discusses at considerable length why the Agency does not belie that zero emissions are required by Section 112?

MR. WALKER:

I did not dwell on that tailend of it in particular detail.

MR. JOSEPH:

You might find some comfort in

that.

CHAIRMAN PADGETT:

Thank you very much.

Once again, now, let me ask: Is there anyone -- Let's make sure I don't miss anyone.

Is there anyone here who was scheduled to speak or who wants to speak in this afternoon's session? Anyone that I missed?

(There was no response.)

CHAIRMAN PADGETT:

We have the evening session scheduled to begin at 7:00 p.m. At this point, we have five individuals, I believe, who will speak at that session.

So if there are no further speakers, then we will adjourn.

I would remind you that the record will be held open for 30 days from today for the submission of additional, supplementary information and comments into the record relative to this hearing.

The hearing is adjourned, then, until 7:00 p.m.

(Whereupon, at the hour of

21-c

3:10 p.m., the hearing in the above-entitled matter was adjourned, to reconvene this same date, Thursday, March 13, 1980, at 7:00 p.m., at the same location.)

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E V E N I N G S E S S I O N

(7:06 p.m.)

CHAIRMAN PADGETT:

I want to welcome you to the continuation of the informal public hearing on EPA's proposed airborne carcinogen policy and the advanced notice of proposed rulemaking on draft generic practice and operation standards.

My name is Joe Padgett. I'm the Chairman of the session. And very shortly, I will introduce or call out the names of the other panel members.

This proposed policy was published in the Federal Register October 10th. There are copies of the Policy back on the back; and I think most of you have copies of it.

The public hearings have been held in three places -- two days, Monday and Tuesday in Washington; Wednesday in Boston; and today, here in Houston.

We had a session today. We adjourned about 3:00 o'clock and we are reconvening now at approximately 7:00 o'clock.

The hearing is being reported and so your comments will be put in the record.

23-c

And we are holding the public record open for 30 days until April 14th for submission of any other comments, written comments, thatn you would like to make in response, to supplement or rebut anything, that you would like to submit as a resul of information received here at the public hearing.

Basically, each person will be asked to speak; and the nominal time is approximately ten minutes or so for your remarks.

Following that, we will have questions -- if the panel has any questions of you -- for the purpose of understanding better what you have said and clarifying your comments -- not for the purpose of particularly arguing or defending.

The transcript for both this hearing and the other hearings that we have had will be available for inspection and copying at the various EPA Regional Office libraries -- the nearest one is in Dallas -- and also at the EPA Central Docket Section in Washington, D.C.

We have, I believe, four witnesses whom we will be calling in the order in which they are listed, unless there is some reasor

why a witness would like to change the order.

The panel members: On my far left is Bob Bauman. And next to him, Bob Kellam, both of the Air Programs office.

I am also in the Air Programs Office.

Todd Joseph is on my immediate right. He's with the Office of General Counsel.

And next to him is Dr. Anderson, who is with the EPA office of Health and Environmental Assessment.

And on my far right is Dave Patrick, who is also in the Air Programs Office.

Unless you have any questions, we will proceed with the calling of the first witness.

The hearing record will remain open for 30 days, until April 14th.

First on my list is Judy Martin.

25-c

STATEMENT OF JUDY MARTIN

MS.MARTIN:

I appreciate EPA offering citizens an evening hearing that we have have the opportunity to present comments on the proposed policies for controlling the emissions of cancer-causing substances in the air.

As a member of several groups concerned about air quality in the Houston area, I have become aware of the difficulties EPA faces in proposing pollution control strategies which satisfy the public's concern for environmental protection, which adequately implement Congress' legislative intent and which are acceptable to Industry and feasible to implement.

The proposed rules regulating the emissions of airborne carcinogens seem to strike a balance among the contending interests EPA must respond to. The rules incorporate a concern for the public health impact of carcinoge by establishing testing and identification procedures and an ample margin of safety in the consideration of emission standards.

They also recognize Industry's need for rapid responses to fugitive emissions

without costly equipment purchases, but rather through generic, broadly applicable standards which emphasize improved work procedures to detect and repair leaks.

Since the number of substances which EPA might investigate is large, it seems necessary to focus on indentifying the most dangerous ones which have a high probability of human carcinogenicity and thus are a significant cancer risk. Listing under Section 112 as a hazardous air pollutant immediately is a good first step. And the subsequent imposition of generic standards on all industries possibly emitting or producing such substances in a logical second step. And the further step of a quantitative risk assessment on all high probability carcinogens is necessary to establish the need for further regulations based on level of carcinogenicity and exposure of the public.

The risk assessment procedure should probably be carried out on some of the lower probability carcinogens as well so they are not overlooked as substances needing regulation. I would hope that the process of quantitative assessment would not ignore the real-life impact

27-c

of low-level exposure of humans over a long period of time.

I agree that there is no safe threshold for exposure to carcinogens and that human exposure should be as low as feasible. The screening and ranking procedure is thus necessary to give us a better understanding of which substances must be most rigidly controlled.

I am very much in favor of dealing directly with the sources of excess emissions in a timely manner by requiring leak detection and repair. Relying only on ambient monitoring to expose fugitive emissions is inadequate because of dilution of carcinogens in the general atmosphere and the time delay in recovering data on monitored excesses. Preventin fugitive emissions is a much more satisfactory program.

The generic standards which rel on tightened procedures by plant personnel on a regular basis that specifies proper maintenance rather than high capital expenses is a low cost control strategy which should be agreeable to Industry.

Emission standards and further

control strategies must be based on the protection of public health. Dealing with new sources on a case-by-case basis may be effective as long as emission standards and BAT are followed and the question of new plant siting is thoroughly explored. There are too many variables to be considered by EPA in waivers or granting alternate emission standards.

Thank you.

CHAIRMAN PADGETT:

Thank you.

29-c

STATEMENT OF BRANDT MANNCHEN

MR. MANNCHEN:

My name is Brandt Mannchen. I'm representing the Houston Sierra Club.

Concerning page 58642 of the summary of this document, it is stated that "Listing under Section 112 would be accomplished, where applicable, by the proposalof generic standards for source categories producing or handling significant quantities of the substance." The "where applicable" should be removed. If the source is listed under Section 112 then there must be generic standards for its control.

The whole purpose of such standards is to reduce immediately at least some of the tonnages of carcinogenic materials being emitted into the air until such time as further study determines what the ultimate emission reduction mechanism is to be.

At the very minimum the generic standards should be used even on dispersed, hard-to-control, or small sources to reduce the overall ambient concentrations of carcinogens.

We fully support the concept of a no-threshold level for carcinogenic

substances. That is why it is so very important to reduce to the maximum possible all carcinogenic emissions whether by particular control equipment or substitution. In fact, we favor substitition wherever possible as the best way to completely eliminate carcinogenic risks.

We are very distrubed that these regulations do not include mutagenic or teratogenic substances. These are at least as harmful as carcinogens and need to be regulated as well. Their effects, like carcinogens, are hard to detect and have a long residence time before they make themselves known.

When referring to the known threshold level, I would like to make a comment concerning Industry's claim that there is indeed a threshold level for carcinogens. If these claims are valid, then the only way they can gain credence of acceptance is by publishing them and their supporting data in accepted, reputable scientific journals, like Nature or Science, where they can undergo rigorous peer review.

When putting possible carcinogens in one of three groups; high-substantial evidence, moderate-suggestive evidence, or low-ancillary

31-c

evidence, page 58647, EPA must be careful not to simply leave the chemicals in these groups with no further data being gathered, analysed, or tested. Any chemical put in the low or moderate group simply because enough data has not been produced must be put on a testing schedule which will produce results quickly so further verification of the proper classification of the chemical can be made.

On page 58647(b) Preliminary Evaluation of Ambient Exposure, if sampling data is not available then EPA must have a mechanism whereby it will be gathered as quickly as possible to clarify what the ambient levels are.

Also, some substances may be emitted in significant amounts but only or mostly in conjunction with other pollutants. Therefore, not only should specific sources of the pollutant be sampled but also those which include the chemical as a by-product, a major component, or a less-than-major constituent of the emissions.

One aspect to take into account is if or how quickly the carcinogens degrade or break down in the environment.

It is alarming the synergistic

effects are ignored. In conjunction with a sampling program an ongoing program of synergistic testing needs to be done to find out about these mechanisms and at what, if there is a concentration minimum, do these reactions not occur. Indeed, known substances with synergistic effects or suspected effects must be regulated much more stringently than those without them.

On page 58655, even if the new source meets the requirements of the Risk Avoidance Criteria for the applicable source category, it should not automatically be permitted to meet the BAT standard instead of the National Emission Standard. One reason for this is because there is at present no mechanism which prevents residential building around the industrialized areas and thus, increasing the density in the area and the number of people exposed.

In addition, the possibility that even small levels of carcinogens may be cumulative in their effect and the fact that many of them may be carried far away from their place of emission could cause an unnecessary risk for people living beyond the EPA stipulated distance criteria.

33-c

Concerning the proposed Generic Standards, EPA must be required to make periodic inspections of plants for fugitive emissions leaks so that the companies' maintenance programs will be adequately monitored to ensure compliance.

The concentration value which constitutes a leak should be 1000 parts per millic and the number of days to fix the leak should be seven working days and the standards should effect equipment which comes into contact with a liquid mixture containing one percent more by weight or volume of organic chemicals listed by EPA as carcinogenic air pollutants.

For storage equipment of greate than 40 cubic meter capacity, the chemical storag regulations should apply. We support the use of 8-hour limit for liquid spill clean-ups but, if the spill is larger than a certain size, it may take longer to clean-up, so perhaps there should be a size limit included here for the 8-hour clean-up.

We have listed a variety of carcinogens which we are concerned about, and there are about 20 or 21 of them; and I won't go through all of them. But these are the ones

that we are particularly concerned about. This is by no means an exhaustive list but these are at least some of the specific compounds and/or sources which emit these compounds which need to be regulated. Some of these are already regulated but there is a need to keep emissions as low as possible because of the no-threshold level, so we want as stringent controls as possible.

As far as mutagens and teratogens, we have a few of those listed also, to be looked into, as far as testing.

We appreciate the opportunity to comment and anticipate your final decision.

CHAIRMAN PADGETT:

Thank you.

I'd appreciate it if you'd read the list.

MR. MANNCHEN:

1) Arsenic

2) Beryllium

3) Asbestos

4) Benzene

5) Nitrosamines

6) Various pesticides

(2,4,5T, et cetera,)

7) Cadmium

8) Nickel Carbonyl

9) Radiation

10) Coke oven emissions

11) Chromium

12) Diesel Exhausts

13) Vinyl Chloride

14) Selenium

15) Carbon Tetrachloride

16) Polycyclic Organic Matter, which includes polycyclic aromatic hydrocarbons like:

- Benzopyrene
- Idenopyrene
- Benzacephenanthrylene
- Benzofluoranthene
- Dibenzopyrene
- Polynuclear imino-Heyerocycli

compounds, and Polynuclear aza-heterocyclic compounds like Dibenzacridine

- 7, 12 Dimethylbenzanthracene
- Benzophenanthrene
- 3 Methylchlolanthrene

17) Toluene

18) Chloroform

19) Methyl ethyl ketone

20) Catalytic cracking of crude oil.

(There was a pause in the proceedings.)

CHAIRMAN PADGETT:

Do you have all that (addressing the Reporter)?

THE REPORTER:

More or less, I believe.

MS. ANDERSON:

Do you have the data? Could you give us some references, say, for Toluene?

MR. MANNCHEN:

I -- I could go back and look. I took this out of several source books. One of them happened to be Politics of Cancer, Malignant Neglect.

Another one had to do with Health Effects of Air Pollutants (sic) by George Walbott. These are mainly --

MS. ANDERSON:

Most of -- most of them -- now, I know about ....

MR. MANNCHEN:

Okay.

But those are essentially the source books which I got most of these out of.

CHAIRMAN PADGETT:

Dave, do you have any comments?

MR. PATRICK:

Really, my only question would be, you made a statement that the generic fugitive or the generic standards that we are -- to be listed as advance notice should not be on a where-applicable basis, but really, I gathered, in every case whenever we had a listing for a hazardous pollutant or for chemical carconogen, there should be generic standards; you don't leave any sort of flexibility.

Now, I presume by that you mean that there just should be some tpes of generic standards that are -- that deal with the kinds of housekeeping problems that we listed here.

These particular ones happen to deal more with very volatile kinds of chemicals

MR. MANNCHEN:

Right.

MR. PATRICK:

You weren't -- I'm assuming that you weren't indicating that these should be applie across the board to even unvolatile or less-volat materials?

MR. MANNCHEN:

Just whatever you list in 112.

I think there should be generic standards for them. Yeah.

CHAIRMAN PADGETT:

Do you have any comments?

MS. ANDERSON:

Just one other comment.

I think I understand what you're saying about the no-threshold limit. And perhaps that is certainly a valid way to base that policy.

You're saying in specific cases where something other than a no-threshold shape-to-the-dose-response curve is to be applied that it should be based on data that has been published and subjected to peer review, on a case-by-case basis?

MR. MANNCHEN:

When I'm referring -- Are you referring to the statement I made about industry's comments? Is that what you're talking about?

MS. ANDERSON:

Well, earlier in your statement, you said --

MR. MANNCHEN:

Okay. I was referring to that

simply because we seem to have this -- these two sides.

One says there's a threshold one says there's not a threshold. As far as I've been able to determine, all the things I've seen said there's no threshold. No one's been able to determine threshold on any carcinogen.

So if industry says there ins't a -- I mean, there is a threshold, then it' up to them to bring forth the data and bring it out in respectable scienctific journals and let it stand peer pressure and review and everything. And if it's good data and everything, it'll stand up. Tha's all I'm saying.

MS. ANDERSON:

Thank you. I think that's what we say in EPA guidelines for assessing carcinogencity risk and also in our Federal docum which establishes a scientific basis and that is if you find a situation where you can identify a threshold, then present new information .....

MR. MANNCHEN:

All right.

MS. ANDERSON:

Thank you.

CHAIRMAN PADGETT:

How do you see the goal of risk assessment in -- in control of carcinogens?

MR. MANNCHEN:

I'm not real keen on risk assessment myself.

I personally -- just my own feelings are just that, you know, carcinogens are real tough, mutagens, teratogens.

It would just be smart policy to keep the emissions as low as possible, control as many sources as you can; and that's why I mentioned substitution, because that way, you get rid of the carcinogen completely. If there's any way, I think that would probably be the best route to go.

I would also like to mention, you asked Judy Martin before about siting. Especially in Houston, we have no zoning in this area, and I think it is extremely bad when you can see -- I won't name any particular plant -- but you can see an oil refinery here and right nextdoor is a residential area and you know that those emissions are going into the air and you don't know what's happening to those people; you don't know if they're

being affect by possible carcinogenic emissions or others.

And it's kind of a really deplorable situation when something like that occurs. And it may get to the point where some sort of land-use controls are needed because I just don't think you should be siting either way, either industrial plants in residential area or residential areas near industrial plants.

Maybe, you know buffer zones or -- oh -- what do they call them -- just areas just strictly for plants, industrial parks, et cetera, et cetera, should be the types of things that we should more toward.

But I just can't see mixing the two, because to me they are incompatible when you've got hazardous substances in the air.

CHAIRMAN PADGETT:

Thank you.

Can you give us a copy of your speech --

MR. MANNCHEN:

Yes. I was going to, anyway.

CHAIRMAN PADGETT:

That would help with the

spelling of some of those chemical terms.

MR. MANNCHEN:

I'm not sure they're exactly spelled correctly.

MR. KELLAM:

Mr. Mannchen, I just wanted to pursue one of the comments that you made that had to do with your preference for the substitution of -- of other types of substances for airborne carcinogens.

MR. MANNCHEN:

All right.

MR. KELLAM:

One of the things that we've come across in looking at substitution as an alternative is that in many cases we know less about the substitutes than we know about the chemicals we're trying to regulate.

MR. MANNCHEN:

Right.

MR. KELLAM:

Would you have any suggestions for houw we would "clear" or in some say render innocent a substance before we use it as a substitute?

MR. MANNCHEN:

Well, it's obvious you shoul go ahead and take a substitute for carcinogen without it having been tested. I think that's -- That's not the way to go, because like you said it could be worse if you find out later that this might be even a worse carcinogen than the other thing.

I think if you're going to substitute something, you've got to know what it is and how it affects people and that means carcinogenicity, it means mutagenicity, that mean teratogenicity, that means chronic or acute poisoning -- whatever, I mean, you got to know about, because you don't want to go ahead and put something worse in than what you've got.

MR. KELLAM:

Secondly, you mentioned that as far as pollutants which have demonstrated synergism --

MR. MANNCHEN:

Yes?

MR. KELLAM:

-- or potentiation of carcinogenic effects should be regulated more

stringently, in some cases I think such things as co-carcinogens may not directly induce cancer but only in combination with another agent.

Would you have any comments on how the Agency should view such things as co-carcinogens or potentiating agents that are not themselves direct cancer inducers?

MR. MANNCHEN:

I see. Okay.

Well, again, since these potentiators seems to be such integral with the carcinogen itself, I would say you might have to go ahead and regulate those, too, as much as possible.

I would personally be in favor of it.

MR. KELLAM:

One final question, just a follow-up on Dave Patrick's question.

I -- the generics that we currently have that are published separately, but really incorporated in this Policy, really apply to the synthetic-organic chemical manufacturing industry -- and the reason we call them "generic" is that they're a great deal -- there are many

similar processes in that industry that lend themselves to a generic approach.

MR. MANNCHEN:

Right.

MR. KELLAM:

Is your suggestion that these generics should be expanded, or modified, in some way so that they would apply across not only this industry but also smelting and refinery or other industries that are very dissimilar, I think, in many ways.

MR. MANNCHEN:

Okay.

Those particular generic standards you've got there may not apply to other industries; but that doesn't mean you can't make generic standards for each industry, like smelting, for instance.

You can make maybe some simple generic standards -- if there are any; I don't know but to go ahead and cut down the amount now until you can get your long-range policy into effect to where you can deal with it more directly.

But I think that it's real crucial that we go ahead and cut down on the amount

of carcinogens in the air right now as much as possible and it seems a good idea that generic standards are a good way of doing that.

MR. KELLAM:

Thank you.

MR. MANNCHEN

Thank you.

CHAIRMAN PADGETT:

Janet Maier?

STATEMENT OF JANET MAIER

MS. MAIER:

I'm Janet Maier and I'm speaking as an individual.

I feel that the policies proposed by EPA and its information here offer a reasonable approach towards reducing the risks associated with airborne carcinogens.

The plan, I think, should be implemented as soon as possible. But there are some suggestions that I have regarding areas that I don't think were adequately addressed.

I think we cannot ignore syng- synergistic effects, as Mr. Mannchen was discussing with you.

Also, I think that the effects of mutagenic and teratogenic substances cannot be overlooked if you look at the cost in both dollars and psychological anguish that these bring. It is something that is too significant to ignore

I support the Sierra Club's position of Houston, Texas on this issue and I also would like to emphasize the emphasis of the no-threshold level for carcinogens and encourage implementation immediately of the generic standards

for maximum, short-term protection until we have the long-term into effect.

I was one of the people that wrote in and specifically asked for an evening hearing and I'm really glad that this has happened.

I guess what concerns me is when is the average working person expected to have the chance to speak.

This is my first time speaking at a hearing. I'm kind of new at this business. But I guess I have a fair education and a fair awareness of what is going on.

But I think that the average citizens do not have adequate awareness of a hearing such as this. Industry can sink millions of dollars into research, hire health experts and present a well-organized front -- of course, individual industries, I'm sure, and perhaps some professional groups together.

But I think the average person has a poor chance of being represented here. They do have a huge investment in their health. I was wondering like how many people are here tonight are not with an industry of some kind.

Probably not very many. How

many people are here?

[Laughter]

How many people know of the Federal Register on the street? I never knew of one until I became interested and worried about the air pollution here in Houston.

Let's see.

I'd like to see more of the efforts on your part to publicize these things and I realize a lot of it's technical and the average person would not understand some of the things -- the technical details going on. But I think it can be brought down to a lay-person's level with some effort and some investment in the cost that that would take.

But I think it's terribly important. I'd love to know how many people, you know, bodies, are represented in the people you have heard in the last few days in comparison to the average person on the street.

Is that clear?

The number of people -- I don't know the statistics, but I'd like to know how may people are involved, either by job or by stockholding, in the companies that will be involve

in controls on carcinogens as compared to the number of people in the country at large.

Virtually every person in this country will be breathing the air which carries the carcinogens, teratogens and mutagens. And that's something that I think would be of importance to everyone if it was explained on their level so they could understand that.

I think we've seen some of our mistakes in the past in emissions which turned out to be carcinogenic, not only airborne but other kinds. And I think it is time now to act very strongly to stop that until we can catch up with our awareness of the effects of all this so we can control that.

And I think it is interesting that this hearing deals with cancer, in particular, because it's my understanding that cancer is uncontrolled growth on the cellular level and I think maybe in this country we have a bit too much uncontrolled growth economically or industrially and it can be very devastating to us in the form of a cancer also if we don't control it. And that is how you control growth and that's part of the backbone of this country. But just as growth in the

human being starts out as necessary and it has to get to a certain point to be an adult, and then there's a level of growth that's necessary to maintain that.

But if it gets out of hand, it's fatal. And I think EPA can use the power to control that.

CHAIRMAN PADGETT:

Thank you.

(The speaker prepared to leave.)

CHAIRMAN PADGETT:

Wait a minute. Before you leave --

MS. ANDERSON:

I think we all find it very refreshing that you all come out tonight and on behalf of the panel, we thank you for coming.

You were wondering how many private citizens have spoken to us. And just to give you some feel, I've looked back through the speakers who came to the panel here at Boston yesterday -- and roughly -- there are quite a few; in the neighborhood of about 15 or so out of 25 represented individual neighborhood groups.

I think we found it very

refreshing to hear these statements from people who, I think, someone said earlier -- the statements have not been necessarily grilled by their attorneys --

[Laughter from the audience obliterated several words]

MS. MAIER:

I work in a very poor area and the City, probably the lowest-income school in Houston, according to statistics.

And as I mentioned before, there are no joining, quote-unquote, areas here and there's industry all around.

And I think it's just vital that these peoples' interests be kept in mind even though they're not here to speak and probably aren't very aware of what's going on.

CHAIRMAN PADGETT:

Thank you.

The next speaker I have listed is Sylvia Grickle (phonetic).

Is Sylvia here?

(There was no response.)

Anybody from the Union?

(There was no response.)

Was there someone else who

wanted to speak?

MR. JOHN FAFOUTAKIS:

Yes, sir.

I'm a private citizen.

CHAIRMAN PADGETT:

May we have your name.

MR. FAFOUTAKIS:

I'm John Fafoutakis. I signed the sheet out front.

CHAIRMAN PADGETT:

How do you spell it?

MR. FAFOUTAKIS:

Okay.

Make a lot of room for the last.

[Laughter]

MR. FAFOUTAKIS:

F-a-f-o-u-t-a-k-i-s; first name is "John."

TESTIMONY OF JOHN FAFOUTAKIS

MR. FAFOUTAKIS:

First of all, I want to thank the EPA for coming to Houston and taking public comment.

Secondly, I wish to publicly chastize the news media in Houston for giving your arrival such very poor advance notice. Virtually no advance notice was given of your arrival to allow the general public, as well as industry, to come up here to give good general input, both the pros and cons, about these emission regulations.

The television media did virtually nothing to announce your arrival. In the Houston Chronicle, a very, very small article was listed in yesterday's paper announcing your arrival.

And I think this is very poor because the people do not know what is in effect just around the corner with the EPA. They don't know what you are proposing because they're not being informed by the media. The media has done a very poor job and it's quite understandable with their past performance.

One of the things that concerns

me is the threshold level for pollutants and carcinogenic materials that have been discussed thus far this evening, when we really look at virtually every substance -- both carcinogenic and even so-called harmless substances have at one point or another some sort of a tolerance level.

Even water, for instance, just clean, pure water; one person's body can absorb just so much of that water before their cells literally drown in it.

So in order for industry or the Environmental Protection Agency or anyone to try to discern any specific tolerance level is a virtual impossibility I believe because what may be a threshold for one particular individual -- someone, let's say --

I, for instance, can tolerate only a certain amount of percentage, a certain percentage of carcinogenic material; perhaps another individual can tolerate a lower threshold level and yet another individual can tolerate a much higher level.

So to try to set any arbitrary standard, any arbitrary threshold level would be

very, very arbitary indeed, because you cannot do it, you cannot set a general standard and accept everyone -- "expect" everyone to be able to somehow hopefully comply with that standard.

One of the things that I'm concerned about, too, having lived in the Denver, Colorado area, the EPA has done quite a bit of -- well, you might say, work in the Denver area in trying to clean up their very obvious pollution problem that they're having up there.

And one of the solutions that they're coming up with is actually something that I vehemently disagree with and that's the forcing you might say through mandates, forcing the reduction of vehicular miles travelled by drivers, by automobile drivers.

And this was also one of the EPA's proposals that we had given to us in the Houston area back in around 1973-74, if you recall.

I was wondering if such proposal, since I haven't had the time coming in here this evening to fully read your proposal, are these proposals under consideration for the Houston area, for reduction of let's say vehicular

miles travelled or anything like that?

MR. JOSEPH:

This proposal deals only with the emission of --

MR. FAFOUTAKIS:

-- stationary sources?

MR. JOSEPH:

Right.

Carcinogenic compounds from stationary sources.

MR. FAFOUTAKIS:

Okay.

But if, let's say, the stationary sources are reduced to a certain level, whether it's an EPA level or just the quote "the lowest possible level," and yet pollution continues to be a problem, would then the automobile somehow take the blame?

Because one of the things I was distressed to see when I was living in the Denver area is although automobiles up there were being increasinglu subject to more stringent pollution inspections and things like that and they were, as a matter of fact, being targeted by EPA and in particular by the Colorado Air Resources

Board, in being the main cause of pollution.

It was in fact industry which was causing the bulk of Colorado's pollution. If -- I don't wish to start deviating and go over to Colorado, but I just want to give you this as an example.

One short drive down a little stretch of Interstate 225 in northeastern sections of Denver, Colorado will show you very readily the copious amounts of air pollution being emitted from several industrial stationary sources whereas those individual sources were polluting the air let's say thousands of times more than any particular bus, or truck, or automobile could. They were not the ones being penalized; the ones being penalized were the everyday people who were just trying to drive theircar to and from work, being told that possibly some sort of a reduction in vehicular miles travelled was going to be mandated upon those people and I'm concerned that these controls will be placed upon the American public unfairly.

And as an example to show what industry has done, let's say the automotive industry has done, to reduce vehicular emissions, I have with

me a copy of an EPA report on the Texas Motor Vehicle Emission Control Pilot Testing Program I went by there earlier this afternoon and had my personal car checked on the EPA monitoring devices.

Now, it's an 1980 model, and according to 1980 standards, 1980 standards call for at least -- well, 200 parts per million of hydrocarbons or less.

My particular vehicle on the second idle registered well under the 200 hydrocarbons -- as a matter of fact it was registe only 23 hydrocarbons -- 23 parts per million in hydrocarbons.

EPA's standards also called for two percent carbon monoxide for the 1980 model year or less. And my vehicle was emitting two one-hundreths of a percent of carbon monoxide.

And on the propane gain, wher they give it a propane test, the value should be ten or more; and my vehicle read "100," which is roughly ten times cleaner than the standard calls for.

So it seems that at least Detroit has made a very legitimate effort to reduc vehicular emissions.

And I'm sure that there are those in other industries who are making similar legitimate efforts in order to try to reduce emissions from their stationary standards.

One of the things that we must not overlook that Nature causes a large number of pollutants to be emitted into the atmosphere.

For instance, the three greatest volcanic eruptions that have taken place world-wide, in this century, have done more to pollute the atmosphere than all -- this is according to Stanford -- than all of the manmade pollutants.

So what we have here is Nature by Her own acts has contributed more to pollution -- even the Indians who were living in the state of California back in the 1600's referred to California as the "land of the smoke," simply because of the hydrocarbons which were emitted by the natural sources: trees and vegetation -- were great enough back then for the Indians to notice visible smoke.

Now, obviously they didn't have Dow Chemical or any of the other chemical plants or rubber plants or petrochemical plants

operating in California in the 1600's.

But we have to realize that there are certain sources which we have no controls whatsoever, no matter how well-intentioned the EPA, or the Texas Air Control Board may be, or private citizens or environmental groups may be.

There are certain sources, mainly Nature, that we cannot control under any circumstances.

So we must remember that when we do formulate and when we do promulgate rules for emission controls that we do not take a meat-axe approach and try to acheive limits that are somehow unattainable, limits which were set forth a few years ago when EPA was in Houston around, I believe, '73 or '74, with their proposals to try to reduce vehicular miles travelled in the Houston area by some magical 75-percent figure without an adequate mastering of the system or anything else.

Some of the standards that were being discussed at that time were -- had required cleaner than is available in the middle of the Gulf of Mexico, where no stationary pollutic sources exist, where no vehicular pollution sources

exist.

So we have to use a more reasonable approach, a more balanced approach and we have to realize that industry, with its money limitations can emit only a certain amount of funds,can expend only a certain amount of funds for pollution control efforts simply because if you just tell industry haphazardly, "You will reduce your pollution levels to a certain standard no matter what the cost," then what can we expect to pay for this added benefit?

Now, true, everyone wants cleaner air, whether it's industry -- I'm a private citizen. I'm not here representing any of the industrial sources in the Houston area or anywhere else. I'm not representing any sort of a lobby group whether it's environmentalist of industrial.

I'm a private citizen concerned that if we take a meat-axe approach that in order to achieve a non-existent level of pollution, that we're going to end up paying ten and twenty times more for a product simply because industry obviously is not going to foot the bill for pollution.

They have to pass this bill on to the consuming public.

If you fine an industry for instance for pollution violation, do we seriously think the industry is going to absorb that fine?

No. They will have to pass it on to the consuming public. No one is going to allow their plant to absorb the cost. This wil merely mean higher prices to the consuming public, just like it really -- it really angers me whenever Government officials say, "We're going to tax this industry or that industry. We're going to levy a tax," like the so-called wind-fall profits tax, when in fact industry merely passes the tax along to the consuming public and it is the consumer not the industry who has to pay for it in the end.

So I think a balanced approach cooperation with industry and the EPA is necessary not a meat-axe approach trying to achieve an infinitesimal amount of pollution, a quote, "no-pollution aspect," because we can't do it. And I think industry is doing a fine job. And in cooperation with the EPA and a balanced program, I

think we can lick the pollution problem. But the things that we have to realize, again, in summation, is that there are sources of pollution of which we have no control over, particularly pollutants, as Stanford University pointed out in a study around 1973, that some 93 percent of all hydrocarbons are emitted by Nature, not by man.

So we have to realize this and we have to realize that industry has to be given cost-effective guidelines because they can't just expend all of their funds fighting pollution.

It has to be done in a balanced approach.

Any questions?

CHAIRMAN PADGETT:

No, I think we agree with you on that.

Do you have any comment?

MR. FAFOUTAKIS:

Mr. Padgett, if I may make one suggestion, since you gentlemen and ladies are here with EPA, has anyone as far as reducing vehicular emissions to a greater level, doing whatever part you can to reduce emissions, has

anyone thought of asking the refineries to concentrate more on gasohol, because having lived up in the Colorado, Wyoming area, I do know that gasohol does work, I have used it in vehicles befor that gasohol as a matter of fact can reduce emissions far greater than any catylitic converter or anything like that simple rather than trying to clean up the emissions after it's gone through the engine this is a cleaner burning fuel which allows lower emissions levels, greater fuel economy and more power for the vehicular engine (sic).

And gasohol, I think, would also be beneficial in helping the farmers to get over their plight of not being able to sell all that grain that were going to sell to the Soviet Union and other countries which is of course being boycotted by the President.

So I think this would be a very good point here to expand the use of gasohol to further reduce vehicular emissions even for non-controlled vehicles such as pre-catylitic-converter vehicles and heavy-duty trucks which of course do not have emission controls on them.

Thank you very much.

CHAIRMAN PADGETT:

Thank you.

Do we have anyone else who wants to speak tonight?

TESTIMONY OF LOU ANN ANTHONY

MS. ANTHONY:

My name is Lou Ann Anthony and I'm talking as a private citizen.

I did read this EPA proposed legislation and I would like to compliment the authors for their very even-handed and intelligent review of what I preceive to be the current state of the art.

I would like to make three brief statements in support of what I perceive to the EPA's position on three things.

First of all, in the article it was viewed as what would be the optimal kinds of data we would like to base our decisions on?

And I think rightfully it's pointed out that good epidemiological evidence in humans would be our first choice.

But I would like to suggest that we do not ignore or denegrate animal testing. To the best of my knowledge, there are only two substances -- benzene and arsenic -- which are factors which are known to produce cancer in human and don't produce it in animals.

So I think the correlation

between animal data and human data is quite strong and I hope you don't neglect it and simply go to saying, "We have to have epidemiological evidence in humans for our criteria for defining whether something is a human carcinogen." So I would urge retention of animal testing.

I would also like to suggest that one of the criticisms of using animal testing is that it is 1) expensive and 2) it takes a long time. Typically, carcinogen tests take something like three years and maybe cost something like $500,000.

Many scientists are suggesting the use at least in a preliminary sense of the in-vitro Aimes Test, which is basically a mutagen test, and there is a strong correlation of a number of substances. I think the correlation is something like 70 percent that substances which are mutagenic are later found to be carcinogenic.

So this is a relatively inexpensive screening test which may be used as preliminary data to at least suggest the substance is a carcinogen.

Secondly, I would urge that

the EPA change the philosophy which seems to be expressed in the proposed standards. Again, the philosophy -- and that in the absence of identifiable expressed thresholds -- that carcinog do pose some risk of cancer at any exposure level.

And I think a number of speakers have spoken to this and have urged retenti of this process. And I would like to express my support of this philosophy as well.

And finally I would like to urge the continued interpretation of the language of Section 112 that states that the EPA, or as it is expressed in the language of the proposal, the "administration," provide an ample margin of safety to protect the public health.

And what I'm trying to get at here that I urge you not go to a risk-benefit ratio kind of philosophy which oftentimes industry has proposed as an alternative to this type of language.

I think using risk-benefit ratio or risk-benefit analysis is a cop-out, because we have to at some point appoint someone to be that all-knowing, all-seeing person who can put a dollar value on cancer. And I don't think

that can be done.

So I would hope that this type of analysis would not be used for determining whether something is a carcinogen or what level of carcinogen it is supposed to be.

Thank you very much.

CHAIRMAN PADGETT:

Any questions?

MR. KELLAM:

Just one question. Ms. Anthony, you mentioned that you feel the bacterial immunogenicity tests that Bruce Aimes pioneered would be useful in -- and low-cost -- in determining whether substances have a high -- or whether substances might be genuine carcinogens.

But do you feel that it should be given or that EPA should consider regulating a substance if the only evidence that's available is a positive mutagenicity assay?

MS. ANTHONY:

No. But I'm saying that this could be used -- You know, one of the speakers earlier on said, you know, there's many potential carcinogens and one of the things that EPA's trying to determine, "Well, which ones are we going

to focus on?" Or "Which are the ones that we should be concerned about as co-carcinogens or promoters?" or so forth

And I'm just suggesting that this is a technique where we might get at some of these additional substances.

MR. KELLAM:

So you feel that might be a useful screening test to --

MS. ANTHONY:

Right. I'm not saying that this should be the only piece of data which says, "Aha! We're going to ban this."

But I'm saying that this could be used as a useful screen.

MR. KELLAM:

All right.

Thank you.

CHAIRMAN PADGETT:

Is there anyone else who'd like to speak tonight?

(There was no response.)

CHAIRMAN PADGETT:

If not, then, we will adjourn the meeting. Thank you for coming.

(Whereupon, at the hour of 8:02 p.m., the hearing in the above-entitled matter was closed.)

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C E R T I F I C A T E

This is to certify that the attached proceedings before the Environmental Protection Agency, in the matter of the

U.S. Environmental Protection Agency

Public Hearing

Houston, Texas

Thursday, March 13, 1980

on

Proposed National Emission Standards

were held as herein appears and that this is the official transcript thereof for the files of the Environmental Protection Agency.

Misha C. Preval

Misha Christophe Preval,
Certified Shorthand Reporte