List of Observers Who Made Comments

Day 1 (July 25, 2000):

Rick Hind, Greenpeace
Robert Musil, Physicians for Social Responsibility
Marcie Francis, Chlorine Chemistry Council
Thomas Starr, National Paper Association
Arnold Schecter, University of Texas
Jeffrey Hahn, Ogden Energy Group
Charlotte Brody, Center for Health, Environment, and Justice

Day 2 (July 26, 2000):

William Kelly, Federal Focus, Inc.
Barbara Petersen, Novigen Sciences, Inc.
Abhaya Theile, Citizens Concerned with Waste Incineration Now
Herb Estreicher, Covington and Burling

This appendix contains unedited transcripts of the comments made by the observers listed above. Transcripts appear in the order in which comments were presented.

Appendix F—Observer Comments

Transcript of Comments by Rick Hind, Greenpeace (Day 1)

My name is Rick Hind, I'm the Legislative Director of Greenpeace Toxics Campaign. Pat Costner was not able to be here today, so I'm going to attempt to fill in, but I will hand you each a copy of a paper that Pat wrote on dioxin and the implications for policy, especially regarding materials policy which is the direction that Greenpeace comes at this issue.

I think that if, in fact, if the EPA had done a life-cycle analysis of chlorine, we would probably be talking very differently today. But at least key questions about dioxin toxicity can no longer be denied, nothing can be denied regarding the ubiquitous exposure that we all have to dioxin, especially in the industrialized world since the 1930s. And of course little about the sources can be denied, although clearly how to characterize these hazards and risks and how to eliminate the problem is probably the debate that will still haunt us.

Again, we would approach this, not from a risk paradigm, but instead a materials policy as a way to eliminate it. In fact, we have not been, we would argue and the report, this seminal document that we think does a great job in terms of risk assessment, even though we have always been very critical of risk assessment as a tool for regulation, but certainly as a way to establish priorities for problems, it may play a role by looking at the many different congeners of dioxins, furans and PCBs.

We think the Agency has done a great job in terms of understanding the real world exposures we all have are not just by one congener or one chemical at a time. The down side is that you most likely underestimate risk because there are many other combinations of things going on in the body and exposures that we all have that may be affected through synergy or additivity that dioxin has with the lead that's in our bodies or other heavy metals or brominated and dioxins in brominated furans, just to name a few.

So when the Agency says upper bound risk and then says that the risk may also be zero, we think it's really likely that the upper bound risk is higher. And that will be key in terms of regulatory decisions because that's a political situation and we hope that political considerations will not cloud the clear thinking science that's gone into the last nine years of this dioxin reassessment. What I'll also hand you is a report that Greenpeace did in '97, which we think still stands today, although more evidence is in to strengthen that.

And that is a report on the life-cycle of PVC plastic, which is the largest single use of chlorine in the world. As you know, chlorine production is increasing. Chlorine, PVC production is also increasing, and more than half of any PVC material is chlorine. And so adding to that the thing we cannot eliminate, namely fire, you have the ever present opportunity for dioxin formation.

Again, the Agency in talking about a reservoir sources, tends to confuse or we think mischaracterize what maybe happening. When we say reservoir sources, for example, from land fill

fires or run off from land fills, for example, we wouldn't refer to these reservoir sources, for example, as a superfund site, a reservoir source for trichloroethylene. It's clearly that what goes into that site that makes a big difference in terms of why that's a contamination problem.

And so the PVC that ends up in our incinerators, which is probably the major chlorine donor in the incinerator, is also the major chlorine donor in land fill fires, most likely. But also in, a contributor, a major contributor, if not the biggest, to the incinerator ash that is now put into sanitary land fills instead of hazardous waste land fills, representing also a ground water risk to the environment.

We would also urge, in terms of language, that the Agency not use the term reservoir source, but really treat it as what it is, which is the long term contamination as a result of putting the chlorine materials and products into play in the environment. Similarly, when we look and talk about background exposures, we again think this is a euphemism for human contamination, in this case, or also contamination of air, water and soil media.

And so we ought to call it what it is, again, and that's human, it's contamination of whatever the material is that we're talking about, rather than just some benign background material. That's important again because you're communicating not only to the public, but to policy makers and policy makers who you have to keep in mind will do the least possible in terms of environmental protection unless they are forced to by the public.

Let me just check my notes to make sure I—I think others will echo these, I hope, but I think again in your recent summary you point out that the risk levels are as high as one in 100 and that some communities, or I should say within the average there's a variance of two to three times that. Well, that's again given the many variables in that risk calculation. But in addition to that you acknowledge that there are much higher risks and that assumes, for example, the exposure to children before they are even born.

And also to certain communities that are much higher exposure. Well, what about a child who lives in that community? What about a child who is the mother of a person who works in a facility with high contamination levels? So I think you need to consider the environmental justice implications of that. And lastly, I think the Agency needs to consider and hopefully with representation here today, the global implications. Because dioxin knows no borders, it will travel 2,000 miles or more from the initial source and contaminate as we saw in the Arctic regions of the world where the UN and 100 some nations are now negotiating and debating what to do about persistent pollutants like dioxin and whether or not to eliminate them.

And I think, again, emphasizing the life-cycle issue, when you look at that you can see that we can eliminate dioxin at least to before the levels that existed in the 1930s, which is when the chlorine industry really revved up. And my concluding note is to watch for a report coming out tomorrow from

the European Union which will address the issue of PVC burning in incinerators. They've already said that it was not viable to recycle and they'll be looking at, answering the question of, is it economically viable to subsidize an industry putting hazardous materials into the way stream that the public then has to deal with in incinerators and land fills.

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Transcript of Comments by Robert Musil, Physicians for Social Responsibility (Day 1)

I'm Dr. Robert Musil, I'm the Executive Director and CEO of Physicians for Social Responsibility. And I want to thank you for the opportunity to publicly comment on the Draft Re-assessment. I want to focus on the science at issue, and I speak on behalf of over 18,000 physician and health professional members around the country.

We would like to express our support for the U.S. EPA's effort to finalize the Draft Re-assessment of Dioxin. After nine long years of study, the EPA has produced an excellent review, in our view, of the literature on dioxin. The science, as you know, has evolved considerably since this process began and will continue to evolve. However, we believe that the Science Advisory Board's 1995, concerns have been addressed adequately and that the draft toxic equivalency factor chapter and the integrated summary and risk assessment sections, as well as the rest of the re-assessment shall now be made final without any further delay.

The new Draft Integrated Summary confirms earlier scientific indications that dioxin and dioxin-like compounds are highly toxic. PSR supports the health findings reflected in this document, including the characterization of TCDD as a known human carcinogen. The Agency's estimates of cancer risk for humans are persuasive because they rely on a combination of both animal and human studies, as you have been discussing.

The animal data take into account an up-to-date understanding about inter-species differences and reflect equivocally that dioxin causes cancer in animals. The Agency has also reviewed the recent human epidemiological data including a number of studies published in the 1990s. The IARC relied on these same studies in making its 1997, cancer determination. Together, the animal and human data that EPA has reviewed showed that current exposures to dioxin are enough to contribute substantially to cancer risks in the general population.

Moreover, and quite importantly in PSR's view, the weight of scientific evidence also points to the likelihood of a spectrum of non-cancer health consequences including reproductive, developmental and immunological effects which may be triggered at astonishingly low levels of exposure. In addition to the health data, the re-assessment accurately reflects that people are being exposed to dioxin at levels of concern.

In spite of an apparent decline in releases from some sources, dioxin contamination in the United States is still widespread. It is disturbing given the health implications of dioxin that the Agency is compelled to admit that its inventory or dioxin sources likely underestimates total releases and the changes in human tissue levels are likely to lag any decline seen in the environment. In the Draft Risk Characterization, the Agency notes that background exposures may extend to levels at least three times higher than the mean due to variations in diet and other factors. But adults who engage in high fat diets are not the only excessively exposed population.

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Native Alaskans, workers in certain industries, young children and people who live near dioxin sources across the country are also more highly exposed. We believe the risk to these populations deserves greater emphasis. We understand the EPA's apprehension about translating data about dioxin toxicity and exposures into a risk characterization for the American public. Physicians don't like to have to tell their patients that their health is at risk.

Pediatricians don't like to tell children learning to fish that their fish is poisoned. General Practitioners don't want to have to tell anyone they are filled with this dangerous pollutant. Nevertheless, the data makes the case that dioxin is a potent carcinogen and endocrine disrupter. That food and the people in the U.S. are contaminated and that so-called background levels are now at or near the levels associated with adverse affects. Based on these data, we believe it is appropriate for EPA to conclude that dioxin proposes a significant threat to the health of the American people.

In fact, we believe this can even be more clearly and sharply stated. In conclusion, I want to say in general we welcome the re-assessment. On behalf of Physicians for Social Responsibility, I urge this Peer Review Panel and the Science Advisory Board to accept the re-assessment with no major revisions. Thank you.

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Transcript of Comments by Marcie Francis, Chlorine Chemistry Council (Day 1)

Thank you for the opportunity to speak on behalf of the Chlorine Chemistry Council. Five minutes is insufficient time to allow for a detailed discussion of even the key issues we have with the dioxin re-assessment. So I'll hit the highlights and refer you to our written comments that were apparently already passed out to this Peer Review Group.

I apologize for reading this, but I want to get done in my allotted five minutes. EPA has concluded that background levels of dioxin exposure are at or near levels that cause adverse affects in humans. EPA has estimated that background exposure levels are associated with an upper bound cancer risk as high as one in 100, and maybe causing adverse non-cancer affects to the general population.

To reach these conclusions, EPA over-interprets the data making tentative conclusions seem sure, disregards critical human data and makes numerous overly conservative assumptions. As written, Part 3 is unnecessarily alarmist and fails to communicate the uncertainty associated with EPA's estimates of upper bound cancer risk. The upper bound cancer risk relies on a single human study. EPA disregards other valid human data that support a different conclusion. For example, EPA has ignored the quantitative dose response data available from the ranch hand and Seveso cohorts.

In our written comments we discuss methods EPA should use to improve the quantitative analysis of human data. EPA has also disregarded critical human data from the ranch hands and NIOSH cohorts in its quantitative assessment of non-cancer dose response. EPA relies instead on an inappropriate benchmark dose analysis with an uncritical grouping of animal effects endpoints. The resulting range of ED01 values gives equal weight to effects ranging from changes in biochemical endpoints that are in the range of physiologic noise, to frank toxicity.

EPA should have narrowed its benchmark dose analysis to discernible adverse effects in humans and should have evaluated the animal derived values against the NIOSH and ranch hands data that demonstrate no significant non-cancer effects at comparable or even higher body burdens. Furthermore, EPA relies too heavily on a TEF approach in concluding that background exposures to dioxin-like compounds, of which only about ten percent is TCDD, present health risks.

For many of these compounds, adverse effects have not been demonstrated, even in laboratory animals. In addition, EPA acknowledges that many laboratory studies of endpoints of interest indicate that TEFs over-predict the effects of mixtures by a factor of two to five. A significant factor with respect to the assessment of background exposure. These uncertainties have not been captured in Part 3. CCC does not object to the use of TEFs for regulatory purposes, however the uncertainties are too great to use TEFs to predict risks to human health and to draw sweeping conclusions, as EPA does, concerning threats to human health at background levels.

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EPA reports that breast feeding should be encouraged, even though breast feeding leads to dioxin and dioxin-like compound doses to infants of roughly 100 times adult doses. Unfortunately, this well-founded recommendation cannot be reconciled with EPA's quantitative assessment of risks at or near background levels of exposure. EPA's conclusions are too important to be publicly debated at a single two-day meeting with a five minute comment limit.

There are thousands of pages of new information that will not be peer reviewed. Part 3 does not properly reflect the data and conclusions presented in the earlier chapters. It is unclear to me how the panel can evaluate Part 3 without a review of all the reassessment documents. Please review these chapters and look again at Part 3. Everything is couched in language that alludes to the uncertainty underlying the data.

Phrases such as may be associated, data are limited, appear everywhere. These uncertainties and limitations are largely ignored in EPA's conclusions, however, and are not clearly communicated to the public. We hope the recommendations of this Peer Review Panel will include having EPA redo the cancer risk assessment using all the data, properly consider a non-linear approach. They should also address the uncertainty at all levels of analyses and have the new information in the re-assessment chapters peer reviewed. Thank you.

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Transcript of Comments by Thomas Starr, National Paper Association (Day 1)

I am here today on behalf of the American Forests and Paper Association. I've been following dioxin ever since the re-assessment activities started ten years ago, but these views on the assessment documents are my own. In its deliberations I want to focus the Peer Review Panel's attention on an issue that Bill brought up with his last slide. And that is that some of the assessment is based on scientific facts, and other aspects of it are based on policy choices.

I think what you need to do is clearly distinguish between those two kinds of elements in the re-assessment documents. And I want to address just four areas in which science and policy have played important roles. One, the alleged human carcinogenicity of TCDD. Two, the exaggerated risks that have been predicted as a consequence of background exposure. Three, the implausibility of the linear dose response models that have been used for these predictions. And finally, and the use of TEFs in predicting risks of cancer and toxicity.

The focus in each of these areas on how much of this is based on scientific fact and how much of it is based on policy? Bill mentioned that EPA wants to classify dioxin as a known human carcinogen. In my view, despite the decisions by IARC and the tentative decision by the National Toxicology Program to declare it a known human carcinogen, it's not a known human carcinogen. And the criteria that EPA has to reach or satisfy are different from those other agencies.

During a draft guidelines review by the Science Advisory Board for EPA, here is what was said. Most of the members favored restricting the descriptor, "known human carcinogen," to scenarios in which there was conclusive epidemiologic evidence. Some felt it could also apply with strong animal evidence, plus evidence in exposed humans, that the chemical is causing measurable changes that are on the causal pathway to cancer in humans.

EPA's proposed guidelines themselves require that the modes of carcinogenic action and associated key events in animals have been determined. And the same key events that precede carcinogenicity in animals have also been observed in observed humans.

Now what are these keys events? You've got receptor occupancy, but that is described only as possibly necessary for all the forms of dioxin toxicity. What other key events are implicated causally in cancer in humans or animals?

The risks predicted at background body burdens are exaggerated. If you use the upper bound slope factor of five times ten to the minus three per picogram TEQ per kilogram of body weight per day and carry out the calculation for the U.S. population or worldwide, you get 64,000 cancer deaths per year in the U.S. alone, and over one million cancer deaths worldwide. If this is so, how can EPA at the same time say that the food supply that we eat, which is the primary source of our exposure, and breast feeding, which is a primary source of exposure for kids, that those routes of exposure are still safe.

Another point to consider is that 90 percent of that predicted extra risk arises from Ah receptor ligands other than 2,3,7,8 TCDD and these have been implicitly treated as known human carcinogens in that calculation. But IARC, when it looked at the evidence, found all of these to be non-classifiable as to their carcinogenicity because most of them have never even been tested in the laboratory.

Now the human and animal dose response modeling is also inadequate, it's very poorly documented, you cannot determine where the exposure levels came from in some of the analyses. And in fact, some of the dose response relationships fail what I would call a laugh test in terms of consistency with the data and biological plausibility.

This overhead shows total cancer relative risk from the NIOSH study. The dotted line represents the relationship that is actually observed in that study in relationship to SMRs plotted versus body burdens. The straight line or the linear, the solid line is the linear fit to that data. The low end of exposure axis has been exaggerated some so a straight line is not quite straight in this diagram. But what is happening is that the highest relative risk is appearing at the lowest, non-trivial exposure level. And the slope goes down from there.

How can that possibly square with a straight line fit through the origin? The same is true for the Hamburg cohort which is the source of the high end potency factor. Here all of the risk from zero, at very, very low levels, up to the highest level at 101 nanograms per kilogram whole body is attributed to dioxin exposure by the linear extrapolation. And yet there appears to be a steady background of risk which is quite substantial, about 25 percent increased mortality that's unrelated to dioxin exposure that has not been adequately dealt with.

In terms of the mechanistic modeling that EPA has argued supports the human analysis, it lacks biologic plausibility in the following respects. TCDD has been described as a classic promoter. It lacks genotoxicity. Everybody knows that. The mechanisms of action have been associated with increased cell proliferation and critical tissues. But the Portier, et al., two-stage model of the Kociba data describes the relationship with cancer as an initiation increase proportional to liver CYP1A2, an increase in cell birth and death rates that are both linear, and liver EGFR, but with the death rate slope about 3,000 times greater than the birth rate slope in the initiated cell compartment.

Another effect of that is that promotion is not occurring, it's being inhibited by dioxin exposure TCDD assess models as an anti-promoting initiator. This characterization and dose response assessment need to discuss that anomaly.

Think about TEFs. We've included two published documents about TEFs that haven't appeared in the assessment so far. Thank you very much.

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Transcript of Comments by Arnold Schecter, University of Texas (Day 1)

I sent Bill Farland comments from Vietnam a couple of weeks ago, and I'll just summarize briefly. I think the document is outstanding. It's a marked improvement over what was previously done. It's very sophisticated and the transparency, the openness of discussion is amazing. I think EPA is to be commended on setting an example for all government agencies.

However, none of us are perfect and I would strongly suggest an index so that we can follow every page in the document, every page be labeled. I have perhaps a dozen Page 25s and I find it very difficult to reference it. The summary chapter particularly needs the references which with great difficulty we did extract from previous chapters. I would like to see cited, for every statement, for every graph, what the references are in the summary chapter, because that's going to be the chapter everyone is going to read.

And I couldn't even figure out what was my own work on human tissue level or food from that summary chapter, until I went to the previous chapters which I found with great difficulty. Again, every page should be numbered from one to 3,000, consecutively. There should be listed on the top and bottom of each page, one should be able to tell at each page which section you're in.

It's a wonderful document, but if you can't find things, it's a challenge. I would take the opposite point of view. I think the document, as you stated in the document, underestimates risk. Chlorinated and brominated compounds and the chlorobromos are not taken into account, even though we know from European data that they exist in humans. Other compounds working by different mechanisms, but with same toxic endpoints, illnesses are not considered.

For example, lead and PCBs on childhood cognitive abilities. The sources, I feel a little uneasy as a public health physician discounting the dioxins taken to toxic land fills unless there's some clear scientific evidence that they are not going to find their way into humans. The bio-availability issue that Umbert and Gello so beautifully described years ago in their science and chemo-surgic work, I'm not sure that that finds its way from the food into the humans.

I think we probably should think about it a little more. In light of the policy implications, the change in administrations which are about to come on the nine or ten year history, I hope this will be finalized with just a little touch up here and there and putting, addressing some of the important issues raised today on the earlier meeting clarifying a little more elaborate discussion, but finalizing because ten years is enough. And it's time to start the next update of this.

So it's a great document. It can be improved, it can be made easier to read, and let's finish this one and go to the next version five years from today.

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Transcript of Comments by Jeffrey Hahn, Ogden Energy Group (Day 1)

I'm Jeffrey Hahn with Ogden Energy Group. I'm representing IWSA, the Integrated Waste Services Association, this morning. Number one, I thought that it would be fitting that EPA, if you are going to issue this in December, that you issue it on December 20th, that's the date our MACT Standard takes affect for all of our waste energy plants.

That MACT Standard will cover 90 percent of the waste combusted and waste energy plants in this country. And I think we've transmitted under separate cover that in order to meet that MACT Standard and get these levels low, it's cost the cities and counties and the operators of these plants almost 900 million dollars. That will be finished on or before the 19th of December for the retrofits. So when you discuss Question 20 for the sources, realize that many of our plants have had MACT implementation and have been tested over the last several years and are well below the MACT Standard.

All of our plants will be meeting the MACT Standard. And while the standard is 30 nanograms for TCDD, TCDF, most of our plants are coming in at less than one, up to about ten nanograms. So we want you to take that into account. EPA has the data, they can get it from their Regional offices and all the plants will be tested in conformance with MACT. They will also have these data every year, that's part of the MACT Standard. So it's a question of a well-known source that has proven technology to reduce dioxins and I think at this point it should be part of the EPA's success story and be certainly integrated into your risk management document that would come out at the same time. Thank you very much.

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Transcript of Comments by Charlotte Brody, Center for Health, Environment, and Justice (Day 1)

On behalf of the Center for Health Environment and Justice, I want to say how glad we are that this day has come. That we are all here at what should be one of the last steps of the completion of this nine year process of reassessing the health risks of dioxin. During this period, scientific studies have provided much new information which is well summarized in the document. Its contents provide the strongest reason for finalizing the reassessment before the end of the year.

There are too many health effects of dioxin, too many sources, and too much exposure for us to wait any longer. We need the final dioxin reports so we can move on to the difficult but critical job of eliminating dioxin exposure. The draft report states the decrease in estimated releases between 1987 and '95, was due primarily to reductions in air emissions from municipal and medical waste incinerators. For both categories, these initial reductions have occurred from a combination of improved combustion and emission controls and from the closing of a number of facilities.

The phrase, a number of facilities, seems a poor choice given that the 1995, estimate is based on 63 percent fewer municipal and medical waste incinerators than the 1987 inventory. We would suggest the sentence be changed to, for both categories, these emission reductions have occurred as the result of the closure of 63 percent of the facilities in the 1987 inventory, and from improved combustion and emission controls on the remaining incinerators.

The grass roots groups CHEJ works with take pride in the fact that their activism played a large role in the closure of many of these incinerators. It is also important to note that for the source categories in which a significant number of facilities have not shut down, hazardous waste incinerators, sewage sludge incinerators, estimated emissions have gone up. The report says body burden is the best dose metric for health effects from dioxin. While this seems well justified for assessing scaling, the document should also present conclusions based on daily dose.

Daily dose, unlike body burden, can provide the public with the information they need to estimate their currently daily intake and take protective actions. The sections on margin of exposure, background population exposures and risks of breast feeding, all contain well-crafted scientific findings. But they all end up with underwhelming conclusions, no matter how potent the evidence.

For example, the report includes findings like, a reference dose that the Agency would recommend under the traditional approach is likely to be two to three orders of magnitude below current background intakes and body burdens. And impacts on neurobehavioral outcomes in children or changes in circulating reproductive hormones in men, illustrate the type of responses that support the finding of arguably adverse effects at or near background.

But missing is a risk characterization like, the current average body burden or background is

100 to 1,000 times higher than would generally be considered adequate to rule out the likelihood of significant human health effects. Without sentences like this, CHEJ is concerned that the use of the word background will come to mean normal or acceptable.

On special populations, we would add, normal variability of diet can triple the level of dioxin exposure. Beyond this variability special populations may be exposed to even higher levels of dioxin. These special populations include individuals living near discreet local sources, subsistence or recreational fishers, consuming more highly contaminated species and nursing infants. For these special populations the reassessment should include as much specific information as possible about what unusually high amounts or large quantities actually means in grams per day.

The report must consider the environmental justice implications of dioxin, given that many communities of color are likely to have exposures greater than average from discreet sources in their communities and/or subsistence fishing. The risk characterization should include an explicit discussion of dioxin's effects on environmental justice communities, just as it does for children. The report tries to soften the impact of the finding that the average annual dose of dioxin in breast milk is 77 times higher than adult daily intake by stating that the effects on infant body burden is expected to be less dramatic and that for many non-cancer effects, particularly in children, are more strongly associated with prenatal exposure in the mother's body burden.

Let me tell you as a mother who breast fed her sons, that this statement does not soothe me. The conclusion must include clear statements that more efforts should and will be made to minimize our exposures to dioxin so that the many beneficial effects of breast feeding are not being comprised. The National Research Council's recent report on milk provides a good template. To protect infants and the advantages of breast milk, the long-term goal needs to be a marked reduction in the dioxin levels in women of child-bearing age.

This reduction will be accomplished through an aggressive program to continually minimize dioxin emissions to the environment that will result in lower levels of dioxin in breast milk and dairy products, fish, meat, eggs and poultry. In the interim, replacement of foods high in animal fat with other foods will help minimize dioxin levels in pregnant women and in breast milk.

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Transcript of Comments by William Kelly, Federal Focus, Inc. (Day 2)

My name is Bill Kelly. I'm here for Federal Focus, which is a nonprofit private foundation. I have three points. The first has to do with quantitation of cancer risks.

The quantitation can only be as good as the underlying data and we have to realize that the quantitation at this point is being based on a TEQ. And as you can see from Table 5.1 which has been referred to, that TEQ may be comprised of anywhere from 50 to 90 percent non-TCDD dioxin congeners. In many cases, it's likely that you won't even have any detectable TCDD in a mixture that people are exposed to. So what we're doing is running a quantitative cancer risk largely off of non-TCDD docs and like congeners.

Now the point I want to make is a point that Dr. Rappe has already made to some extent and that's that a very large IARC expert working group in 1997, 25 members, five of them from U.S. government agencies, three others from the U.S. including several people in this room, comprehensively reviewed the dioxin and congener data in 1997. It upgraded TCDD to its group one. It put all the other dioxin congeners in its lowest category of not classifiable as to carcinogenicity.

Now it's important to understand under IARC's classification scheme what that means. Not classifiable means the data is so inadequate that it's even below possible. The reviewers cannot even say that these agents are possible carcinogens for humans. And this is considering not only epi data, but both epi and human data.

Now EPA has proposed to take these same substances and classify them as likely. And this is largely an artifact of what's been done with the definition of likely in the latest version of the proposed cancer guidelines, and I'll talk about that as my second point. But you might be saying, well, isn't there an international consensus on using TEQ and TEF? And I've heard people say, almost as a matter of course, well of course, you know, everybody agrees we could use TEQ and TEFs for risk assessment. And that is certainly implied throughout this document. But I think the answer to that question is a resounding no. And a little reference to source documents and history needs to be done here.

First of all, in 1989, as we've pointed out before, in the last go around on this, what was called the international TEF was actually an EPA paper that was generated by EPA and was not signed off on by the NATO CCMS group.

Perhaps realizing this WHO took up the issue in 1998, again with a large expert working group and it came up with what are now called the WHO TEFs. But you have to read the actual WHO report. What I want to do is just quote one portion of that report which was published in Environmental Health Perspectives in December of 1998. And I'm going to quote from page 776 of that issue of EHP. And what it says is, in talking about the TEFs that are arrived at in the paper, it says, "the biological meaning of these values is obscure. Nevertheless TEQ values can be used as relative

measures between different abiotic samples, e.g., sediment and soil, to prioritize remedial actions." In other words, these were envisioned as a screening methodology for prioritizing remediation activities. They were not envisioned with a way to come up with a health risk assessment number, which is what's being done here.

Okay, so at a minimum, we need some better explanation that an alternative risk estimates taking that into account.

The second point is the risk assessment guidelines that this whole thing is hinging on are proposed. And they say right on the front of them, do not quote, do not cite, and they do not represent agency policy. Now regardless of their being called guidelines, they are rules under the definition in the Administrative Procedure Act. As such, they become under the Congressional Review Act, which says no rule can take effect until it has been finalized and it has gone to Congress and the Comptroller General with a certain report. So EPA is really setting itself up for some litigation on this and using post-guidelines rather than the final guidelines that are still in effect from 1986.

Finally, last point, the third point is on exposure, it seems to only go up to 1995, and yet the document says that there are major reductions coming from regulations imposed on incineration by municipalities and medical waste. But those regulations have not really taken effect except in the last five years. So those exposure and time trends need to be brought up to date from 1995 to the present and that needs to be taken into account in the risk estimates. Thank you.

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Transcript of Comments by Barbara Petersen, Novigen Sciences, Inc. (Day 2)

I'm speaking on behalf of the Food Industry Dioxin Working Group, a coalition of food and agricultural trade associations to represent a broad spectrum of the food production of the United States. And we do appreciate the opportunity to comment on the Environmental Protection Agency's dioxin reassessment.

But before I get into the substance of my remarks, we want to note the EPA has no jurisdiction over human food or animal feed products. The dioxin reassessment's current focus on food, therefore, seems inappropriate and beyond the scope of EPA's charge. If any reassessment is required it should be the primary responsibility of the Food and Drug Administration, the agency with statutory responsibility.

In addition, although there have been some isolated industrial accidents in which food has been contaminated with dioxin, dioxin is not inherently a part of any food. It's not added to food, nor is it created during food processing. To the extent that dioxin becomes a constituent of food, it is the result of environmental contamination from sources outside the food industry. And so we feel this should be the focus of EPA's study, not the current focus on individual foods.

Given the agency's clear intention to proceed, however, we do have some comments on the document. Today's consumers are interested in health considerations when making dietary choices and communicating to consumers about theoretical risk must be done with the greatest of caution. Because health risks, even when in the discussion stages today, can rapidly be perceived as warnings and recommendations. Therefore, we should exercise as much thought and care as possible about the reassessment's possible impact on consumers attitudes and consumption patterns.

In general, we feel there are serious problems with the statistical approaches used in the reassessment, problems so serious that they render the reassessment's conclusions invalid. Today, we're going to address the exposure component as, I think, the toxicity's been discussed pretty much in depth by others.

The U.S. is a nation of varied landscape and climate and major analyses of the food supply require approaches that consider seasonal, climatic and landscape variations. For example, a comprehensive study is now underway by one of our coalition members about the source of nitrate and nitrite in the food supply and it's a very complex study involving the variety of foods that are found in supermarkets, the consideration of the types of supermarkets, their volume, seasonal differences and so forth. While such comprehensive approaches are commonly used by food researchers, the dioxin reassessment we believe inadequately considers the complexity of the food supply and relies on grossly inadequate numbers of samples for the conclusions.

For example, only eight composite samples were collected for milk and only three for eggs.

Appendix F—Observer Comments

And yet there's no discussion of how the average dioxin level is computed or whether these values have been adjusted to reflect differences in production.

For some commodities like beef and poultry, there are a larger number of samples and it's clear from even a cursory review of those samples that the data are not normally distributed, but rather are extremely skewed and a few large observations significantly affecting the estimates of the mean. Therefore, we think the statistical evaluation of that data needs to be conducted to determine whether the estimates can be appropriately derived and used in any subsequent analysis. It may be that it would be more appropriate to use median values than means, or it may be that no meaningful analysis can be drawn, or no meaningful conclusions can be drawn from these data.

These are standard statistical procedures and it's not apparent to us that they've been applied to the data and they should be before the assessment's complete.

The data on residues in fish are extremely outdated and are derived from fish that are not representative of the seafood that Americans eat today. To make matters worse, while the agency notes that residues are declining in the environment in general, they assume no decline in fish. Such a notion is completely flawed and we believe these data should be disregarded.

Measuring the presence of a component in food in the picogram per kilogram level, parts per quadrillion is heroic, impractical, and misleading. At these levels we expect very large analytical variation and that it would be difficult to determine whether an apparent reading is truly a residue or is system noise, let alone the amount of variation you would see in different cultivas. Certainly the variation if expressed in terms of statistical standards of deviation would be larger than the range of values reported in these documents.

Beyond the general statistical weakness inherent in report, we believe the agency is deviating from its own standard practice, which requires adequate data collection before regulatory conclusions are drawn. EPA routinely rejects petitions for regulatory decision-making when they're insufficient numbers of samples to ensure that the data are representative.

For example, the Office of Pesticide Programs requires many more samples than are included in this document in order to evaluate the presence of pesticides in foods. And likewise, the Office of Water bases its regulations on reliable estimates derived from large sample sizes. Why should the dioxin assessment be any different?

Consumer consumption practices are also not adequately characterized by EPA and we will submit the written comments for why we think that is true. Thank you.

Appendix F—Observer Comments

Transcript of Comments by Abhaya Theile, Citizens Concerned with Waste Incineration Now (Day 2)

My name is Abhaya Theile. I am here today representing two local citizens' organizations from near Charlottesville, Virginia. Citizens Concerned About Waste Incineration Now, and Citizens to Preserve Buckingham County.

I would like to take this opportunity to acknowledge the extensive work done by EPA on its latest draft of the dioxin reassessment. The agency has taken a major step in classifying dioxin as a human carcinogen. While the draft assessment is indeed an important milestone in educating Americans on the health effects from dioxin, there are, I believe, at the same time serious omissions in the report which should be corrected before the report is released in its final form.

Because of the limited amount of time today, I will restrict my comments to what I consider to be one of the most serious and significant omissions. It is that the document did not quantify the output of dioxin from chlorine and related chemical manufacturing facilities. Because of this, what is referred to as the inventory of source releases should more accurately be referred to as the inventory of source releases as presently quantified.

Because the EPA has not as yet required these facilities to report the output of dioxin, the reassessment as it now stands categorizes this data as insufficient. However, as a small step toward correcting this omission, it could be useful for the document to at least restate that chlorine is a major component in the formation of dioxin and to refer to the industries own estimate of its annual production of chlorine. For instance, as reported in the Chemical Market Reporter, 1998 production of chlorine was over 13,000 short tons from over 24 major plants.

It would also be useful for the reassessment to make reference to the figures provided by the toxic release inventory for annual chlorine releases into the environment. For 1998 alone, they were as follows: 59 million pounds released into the air, 230,000 pounds released into the surface water, 61,000 pounds released underground, and 56,000 pounds released into the land. This comes to a total of 60 million pounds of on-site releases and 27,000 pounds of off-site releases.

While certainly not all these releases of chlorine translate into releases of dioxin, the figures nonetheless are indicative of the vast production of one of the principal components of dioxin. Inclusion of these figures would be especially pertinent because it will not be until 2001 that the chlorine-related industries are mandated to publicly report their dioxin emissions as directed by Section 313 of the Emergency Planning and Community Right To Know Act, which was recently finalized.

The reassessment could go still further and make a specific reference to the new inclusion of dioxin and related compounds under Section 313 so that the public will be aware that these figures will be available annually. I believe that these suggestions will provide some small compensation for the

significant emission of chlorine-related industries as sources of dioxin. And I would like to thank the members of the peer review for the opportunity to share my concerns today. Thank you very much.

Appendix F—Observer Comments

Transcript of Comments by Herb Estreicher, Covington and Burling (Day 2)

Hi, my name is Herb Estreicher. I'm with Covington and Burling here in Washington and my comments are my own views. It's been a very, very interesting peer review and I want to commend the panel. I think that particularly today, the discussion today on cancer characterization and cancer potency has been very, very interesting. And I hope that EPA is willing to grapple with some of the hard issues that the panel has brought forward today and isn't simply looking for suggestions on how to beef up the arguments it already has in the draft chapters. I hope it's really willing to grapple with some of these hard issues.

I think there was a very, very good debate on cancer potency, a very good debate on cancer classification. I would have liked to have seen more discussion on some of the other issues, such as non-cancer effects and TEQs.

I believe the real issue here is not whether what the EPA is saying in the reassessment is plausible, but whether what it is saying is correct. It's not really a case where the question is whether we have to apply the precautionary principle. I think everybody agrees that dioxins are bad. There have been extraordinary resources expended by industry and government in reducing exposures. What we don't need, and I think what we're concerned about, is an extremist risk assessment which provides an outcome which argues for bans of chlorine, bans of combustion and things like that.

Now, I think risk communication is very important. On cancer potency Tom Starr said that there's about 1.3 million cancers that are predicted from EPA's risk estimates. If you look at 1970 levels, it's about 5 million cancers. I think the question is, is that a real number? We've had some discussions here that it may not be a real number. Now EPA says that background levels are high enough to cause many non-cancer effects. And the press reports that we're in danger. Where's the evidence of that in population? We heard from Linda yesterday about a four point lowering in the IQ levels in certain populations. And I asked the question as to whether that's really what we're talking about. Is that really the danger that the press is reporting?

Anyway, levels are going down. And the question is are we healthier? Do we really believe that improved health is due to dioxin reduction? Now EPA says that TCDD's are human carcinogen. I think there was a great deal of surprise around the table on that point. And I am not clear that EPA's cancer guidelines permit that kind of classification and are actually much more laxer than other guidelines.

EPA says that dioxin-like compounds are likely carcinogens. And the question is are we really going to brand chemicals as carcinogens in the absence of positive rat tumor data? EPA says the TEF's are valid. Well, let's take a look at OCDD, for example. If you take the WHO TEF for OCDD and apply it to the Q1 star for TCDD, you get a cancer potency that's ten times that of arsenic, a known human carcinogen. The real question is do you really believe that? Is there really any real

data showing that OCDD causes dioxin-like effects? As you know, the NTP tried to have a cancer bioassay with OCDD and had to discontinue it because they couldn't feed the rats enough OCDD to get a result.

The OCDD question really raises a risk management paradox. And the question is, is a one gram TEQ reduction in OCDD better from a risk perspective than a .1 gram TEQ reduction in TCDD. If you believe in TEQ's, you have to say that an OCDD reduction is better, even though because the TEQ's are the same and you're getting a much higher TEQ reduction of the OCDD. But the question is, is that really true and is that really what the data shows you?

I think what the problem here is that we're seeing in many ways the limitations of the risk assessment process itself. We're having a cascade of various assumptions all highly conservative, perhaps all justifiable individually and in their own right, but when you put them together with the various leaps of faith that EPA has developed, with respect to mechanism, half-lives, TEFs, cancer causation, the real question is, do you get an answer where the outcome is correct? Thank you so much.