NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
(NIOSH)

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UPDATE OF NIOSH CARCINOGEN CLASSIFICATION AND TARGET RISK LEVEL POLICY FOR CHEMICAL HAZARDS IN THE WORKPLACE

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MONDAY
DECEMBER 16, 2013

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The meeting commenced in the Surface Transportation Board Hearing Room, Patriots Plaza One, 395 E Street, SW, Washington, D.C., at 9:00 a.m., Lauralynn McKernan, Deputy Director, Education and Information Division, NIOSH, presiding.

PRESENT FROM NIOSH

LAURALYNN McKERNAN, Deputy Director of the Education and Information Division, Chair
JOHN HOWARD, Director of NIOSH
T.J. LENTZ, Document Development Branch Chief
KATHLEEN MacMAHON, Associate Director for Science of the Education and Information Division
FAYE RICE, Policy Response Coordinator
PAUL SCHULTE, Director of the Education and Information Division
CHRISTINE SOFGE, Risk Evaluation Branch Chief

T-A-B-L-E O-F C-O-N-T-E-N-T-S

Howard Marks, National
Asphalt Pavement
Association, declined.

T-A-B-L-E O-F C-O-N-T-E-N-T-S
(continued)

P-R-O-C-E-E-D-I-N-G-S

(9:07 a.m.)

DR. McKERNAN: Good morning. Well, you know, it wouldn't be a public meeting without a few technical glitches first thing. So we've gotten all those out of our system and we should be good to go now.

So, good morning, and welcome to this public meeting to present and discuss the draft document entitled, "Update of the NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace."

My name is Lauralynn Taylor McKernan, I'm the Deputy Director of the Education and Information Division at the National Institute for Occupational Safety and Health. I will be chairing today's meeting.

You'll be hearing opening remarks

from Dr. John Howard, followed by a presentation by Dr. Paul Schulte, comments from a number of my NIOSH colleagues who were on the team that developed this document.

First, I have a number of matters of housekeeping. I've been informed this morning that this is a coffee-free room. So if you have coffee, please be extremely careful with it. This is a water room. You can have as much water as you want.

I'd also ask you to note where the exits are in this building. You can tell that you can either exit from the door from which we entered, or you can go out this exit door over here. We need to go through three double doors and then make a left to go onto Fourth Street.

From Fourth Street, we're going to go under an underpass and we're going to go to the baseball diamond, and we are all to meet on third base. And in case you

wanted to see that, I have a map up on top of the screen.

Restrooms are out the door and to the left from which you entered. If you have a cell phone, we ask that you mute it now. If you want to use your cell phone, I've been told that the only place that it works is on the corridor on the fourth floor. So if you go out this door and make a left, you'll see nice benches and chairs for your cell phone use.

Okay, we have individuals participating remotely via teleconference. We have muted their phone lines to prevent distractions from the presentations. We will unmute the telephone lines periodically to allow those participants to ask questions. And during the first break we will take roll call of those that are on the phone.

When NIOSH announced the availability of the document, it also

announced that stakeholder comments regarding the draft policy will be accepted until 5:00 p.m. Eastern Standard Time on February 13th, 2014. Written comments are requested to be submitted to the NIOSH docket as instructed in the Federal Register notice.

Today's public forum will be recorded and transcribed. Transcriptions will be made available within 30 days, in the NIOSH Docket Office and on the NIOSH Docket Website. Consequently, all discussions, presentations, and comments as a part of this meeting are considered to be in the public domain and will be documented as such.

Therefore, if you have a question, you are asked to step to a microphone. We have a walking microphone up here. And please identify yourself and your affiliation. If you are on the phone and are calling in and make any comments, you

will also be asked to identify yourself and your affiliation.

This public meeting satisfies our Office of Management and Budget peer review requirements for a highly influential scientific assessment document. But we also see this as an opportunity to allow the authors of the document to present the salient technical points, but also to hear from our stakeholders and their perspectives.

Our overall goal is to provide a document that is scientifically sound, has relevance and utility, and is developed according to a rigorous, consistent, and transparent process.

Towards that end, I'd like to introduce the panel of my NIOSH colleagues who are also coauthors on this document: Dr. Paul Schulte, Director of the Education and Information Division; Dr. Kathleen MacMahon, Associate Director of Science for EID; Dr.

T.J. Lentz, the Document Development Branch Chief; Ms. Faye Rice, the Policy Response Coordinator; and, shortly, Dr. Christine Whittaker Sofge, the Risk Evaluation Branch Chief, will be joining us.

According to the agenda, the first part of the morning will be dedicated to a technical presentation of the document followed by a question and answer session. Following the questions from our attendees in the room, we'll be asking those on the phone if they have any questions.

The second half of the morning will be an opportunity for stakeholders and members of the public, first who have signed up in advance, to give brief presentations and comments. You should know that stakeholder order was randomly assigned. Those presentations will, again, become part of the public record and be archived in the NIOSH docket.

If time allows, there will be

other opportunities following those presentations for other members of the public and for those present to provide comment. The meeting will adjourn no later than 4:00 p.m.

So, without further ado, I'd like to begin with our first speaker, Dr. John Howard, Director of the National Institute for Occupational Safety and Health.

DR. HOWARD: Thank you, Lauralynn. And thanks to everybody who came today. We really appreciate it. And to everybody on the phone. I hope that I can be heard on the phone, and if not, let us know and we'll try to amp up the volume.

This is a scientifically complex issue that we're facing. As you'll hear, NIOSH has been in the process of doing this sort of thing since 1975, actually, so it's nothing new.

We welcome, in fact we need, all comments. We need everyone participating,

because science policies aren't done every day and they last a long time and they affect a lot of people: workers, employers, and scientists also.

So please enjoy the meeting. Thank you again for those who are listening on the phone and those of you who are here for coming, taking time from your busy schedules to help us out. Thank you very much.

DR. McKERNAN: Thank you, Dr. Howard. I'd now like to invite Dr. Paul Schulte to the podium.

DR. SCHULTE: Thank you. Welcome, we're glad you're here. This is a process where NIOSH listens to the public and tries to get the best input it can to help finish out this document.

It's the NIOSH Carcinogen Policy, or more specifically, the "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the

Workplace." And I will give you an overview of what is in the document.

So, why are we doing an evaluation and an update of the cancer policy? Well, there have been new advances in risk modeling, biologic mode of action, and analytic methods over the last couple decades that have driven us to think through what should be in our cancer policy.

Moreover, we've had some input from the public about some of the aspects of the current cancer policy, and I'll talk to you about them, that cause us to want to rethink the policy. And we want to use this opportunity to receive peer and public input.

And so there was an initial public meeting to get input, and then there is this comment process and period. So we look forward to that. And we hope by all these actions that we've increased the transparency of the process and that the

occupational safety and health community will be more familiar with how NIOSH makes decisions about occupational carcinogens.

We will present this policy in a document we call "The Current Intelligence Bulletin." There are three elements in the policy. There's the carcinogen classification; there's a target risk level for carcinogen recommended exposure limits, or RELs; and there's a section addressing analytic feasibility and engineering achievability.

Let me give you a little bit of the history of the carcinogen classification as it's been practiced at NIOSH. Since 1978, we used the term "potential occupational carcinogen" as the highest designation for a substance.

And there was some dissatisfaction with that term because it included well-known carcinogens, such as asbestos, benzene, and cadmium. And, hence,

they were labeled as if we didn't know for sure that they were carcinogens. And so that was one of the main drivers for why we wanted to reconsider the policy.

And so we requested public input in 2011. We had a kick-off meeting. And then today we have this public meeting on the draft document. And it's currently on the Web for peer and public comment. We look forward to any comments that you would like to submit.

So, first, the classification aspect of the policy. Historically, NIOSH classified the candidate substance going through an evaluation of all the scientific literature. To avoid duplication, and for more efficient use of government resources, the new policy utilizes classifications from well-respected, authoritative organizations.

So, we'll be using the National Toxicology Program, the Environmental Protection Agency, and the International

Agency for Research on Cancer's classification of chemicals.

The role that NIOSH will play, then, is to assess the occupational relevance of those classifications and the evidence on which they were built.

And then, to assist employers to follow the OSHA Hazard Communication Standard, NIOSH will assign a Globally Harmonized category for hazard communication. And I'll get in to that a little later.

Let me just elaborate a little bit on the part of determining the occupational relevance of a carcinogen classification. For the most part, occupational relevance will be somewhat obvious because NIOSH would not be assessing the material if it didn't pertain to workers.

But we wanted to further assess the extent to which there was worker

exposure and the applicability of the evidence for occupational carcinogenicity. So is the mode of action appropriate for humans, if it was based on animal data? Are the routes of exposure appropriate for workers? And so those will be a major part in the process.

And you can see that in this slide. It's a little small here; you may be able to see it better on the monitors.

And so let me walk through the slides a bit. The first box says, is occupational exposure to a chemical likely? If no, then we would go to a stop and have no further action regarding carcinogen classification.

If yes, then we would ask the question, is the chemical classified by one of these agencies? And if the answer is no, then there are two options. We would end it in terms of carcinogen classification, but we might further assess it in terms of other

health effects.

If yes, if there was other evidence of carcinogenicity but there was no classification, we would nominate it to NTP for classification. Or, in some cases, such as under specific time pressures or otherwise, NIOSH would evaluate it itself using the Globally Harmonized System, GHS, criteria.

Then going back to the left side, if indeed the chemical was classified by one of those agencies, NIOSH would evaluate the occupational relevance. And, if yes, assign a GHS category, and report it as an occupational carcinogen.

If no, NIOSH would report it as not anticipated to be an occupational carcinogen. We still would provide the underlying classification of the various agencies.

And so we wanted to show you how the various classifications line up. And

this is the extent to which the classifications by the various agencies correspond with the Globally Harmonized System categories.

Now, if you are familiar with the Hazard Communication Standard, it requires that employers, or manufacturers, actually classify a material. So NIOSH is just providing this as information to assist employers.

So you can see for the most part, those materials known to be human carcinogens, or the highest category in each of the various classifications, crosswalk over to the GHS Category 1A.

But then when you get to the NTP Reasonably Anticipated to be A Human Carcinogen, that straddles a couple categories: the GHS 1B and the Category 2. And the main driver there is in -- I don't have a pointer that shows, but if you look under IARC Group 2B, the main driver there

is differentiation on the basis of the animal evidence.

So under IARC 2B, the first box, if there is adequate animal evidence, that will then translate to GHS Category 1. And if there is limited animal evidence, that will translate to GHS Category 2.

While the GHS approach has different risk labeling, and that will need to be pursued by employers, NIOSH, for all intents and purposes, will treat all suspected carcinogens, or known carcinogens, the same in terms of risk management procedures. So, if we're concerned about carcinogenicity, we will provide the same guidance across the board.

So, this is how the system will report out. This is not the flow chart; this is the end product. And NIOSH will publish this in the Pocket Guide or other documents.

So, this is an example for the

substance benzene. NIOSH would report it as a known, as a NIOSH occupational carcinogen, GHS Category 1A, known human carcinogen, based on NTP's Known to be Carcinogenic to Humans, EPA's Group A Human Carcinogen, and IARC's Group 1 Carcinogenic to Humans.

So we believe that by doing this we will then provide NIOSH's summary recommendation based on all this information, the corresponding GHS category, and then all the nuanced information coming from the various authoritative organizations as shown there.

Now here's another example. This is for heptachlor. Now, NTP doesn't have a classification for heptachlor. But there are EPA and IARC classifications. So this would be reported out as a NIOSH occupational carcinogen, GHS carcinogen Category 1B Presumed Human Carcinogen, based on EPA's B2 Probable Human Carcinogen, Sufficient Data in Animals, and IARC's Group

2B Possibly Carcinogenic, Sufficient Data in Animals.

So those are how we're going to report out the results of the process of classifying carcinogenic substances.

Let's move on to the second element of the policy. And that involves risk levels and the concept of a target risk level. But this is by no means the center part of this policy. It's one tool to enable us to establish a REL. We need to have some cut point for establishing a REL.

Prior to 1995, NIOSH did not have quantitative RELs and with carcinogens just said, "control it to the lowest feasible concentration." This may seem like it's a highly protective bit of guidance, but indeed it was really left to be determined by employers. And employers had to evaluate the technical and economic options. And, consequently, the exposures that could have occurred could be much higher than, say, 1

in 1,000. And so, indeed, the risk could be much higher than, say, 1 in 1,000. So, indeed, lowest feasible concentration had some limitations.

So, in 1995, NIOSH adopted a quantitative basis for RELs. And this is based on quantitative evaluation of risk using mathematical models to evaluate exposure response relationships. For the most part it involved animal data, though we prefer epidemiologic data, human data. But for the most part we have animal data. And that involves using mathematical models to extrapolate from animals to humans, and from high doses to low doses.

And in this policy, in 1995, it was acknowledged that there would be risks, residual risks, at a REL. So that the REL did leave a certain residual risk and the intent was that hopefully it would be relatively small.

Inherent in establishing the REL

is the need to have some sort of target risk level, because that becomes the driver, or the cut point for which we start to consider where to have the REL.

But the target risk level is only part of a broader context in which risk levels are considered. And that context is described in this slide. And so the key feature is that NIOSH affirms the prevailing scientific knowledge that the only way to eliminate excess risk from carcinogens is to prevent exposure.

And so NIOSH advocates using safer alternatives and to substitute non-carcinogenic chemicals whenever feasible. Unfortunately, however, removing all carcinogens in commerce is impractical. It won't be feasible to replace them all with alternatives, and so there is need for guidance on reducing carcinogen exposures. And NIOSH will develop this guidance, as I said, using quantitative risk assessment.

And when that risk assessment is conducted, NIOSH will communicate an array of lifetime cancer risks for exposures from 1 in 100, to 1 in a million. We believe that this information will be useful to employers and workers to take preventative action.

And so, in addition to the risk assessment, there is a heavy emphasis on risk communication. We will also identify within that array of risks a minimum level of protection. And this will be the 1 in 1,000 risk level as a nominal cut point to help establish a REL.

But throughout the policy and a strong position by NIOSH is the advocation to try to achieve exposures resulting in risks lower than 1 in 1,000.

Now, what is the basis for this 1 in 1,000 designation? Well, reflect upon the U.S. Supreme Court's benzene decision, which characterized the range of risks

between 1 in 1,000 and 1 in a billion, and indicated that regulatory action should occur when there was significant risk. And they implied that 1 in 1,000 was a significant risk. So NIOSH will use that level because it better relates to OSHA's work in developing occupational exposure limits. And we will conduct the assessment of that using mathematical models.

This is not the first time NIOSH has used the 1 in 1,000 risk level in interactions with OSHA or in putting out guidance. And so you can see going back to 1990 with the benzene PEL related to leukemia, in testimony to OSHA, NIOSH gave analysis of risks with recommendations focusing on the 1 in 1,000 risk level.

Similarly, in 1990, in testimony on the cadmium PEL, and in 1991 on the 1,3-butadiene PEL. In 1995, this isn't cancer, but NIOSH used the 1 in 1,000 risk assessment in our criteria document to set

the coal dust REL.

Similarly, in 1998, in collaboration with OSHA, we developed a journal article for cancer risk from diesel exhaust. In 2001 and 2002, we had two different journal articles related to using the 1 in 1,000 cut point for risk guidance, one for silicosis, and one for cancer.

Then in 2007 NIOSH published a journal article with a risk assessment that identified the 1 in 1,000 level for manganese-related neurobehavioral effects.

In 2011, NIOSH as the first government agency in the world to develop a protective REL for workers exposed to nanoscale titanium dioxide, used the 1 in 1,000 level as a cut point. That resulted in the lowest REL anywhere in the world.

In 2013, to protect workers against lung cancer from exposure to hexavalent chromium, NIOSH used the 1 in 1,000 cut point as the basis for our REL.

And currently we're working on a REL for the flavorings, diacetyl -- flavoring compounds -- diacetyl and its substitute 2,3-pentanedione to protect against respiratory dysfunction and bronchiolitis obliterans. And again the basis is the 1 in 1,000 risk assessment.

So, historically, in RELs that have been widely acknowledged around the world as being useful and protective, NIOSH has focused on the 1 in 1,000 cut point. There are additional protections afforded by the risk assessment and the related communication in the policy.

For example, in our mathematical modeling we use a 45-year working lifetime. Workers, then, who work less than 45 years will have less than the 1 in 1,000 risk. And not all workers work 45 years with the exposure to that same material.

We also in our modeling treat exposure at the low dose as a linear

function. This is more or less a default assumption. Sometimes we have data to actually model it, but often we don't.

And so in this slide, which shows risk by exposure -- and this is at the low end of the dose response curve -- we would assume, for modeling purposes, that the relationship is linear, that one unit of exposure relates to one unit of risk.

But in fact, in many cases, and for some carcinogens, the risk will be sublinear. And so, again, the actual risk that we identify will overestimate the true risk. So, the true risk will be less than 1 in 1,000, potentially, to workers.

And then when we model, we make the result of the modeling as maximum likelihood estimates of risk. And then they have confidence intervals to reflect the variability and uncertainty on either side of them. NIOSH will use the dotted line by the designation "95 percent lower confidence

limit" as the estimate that we actually use.

So we won't use the maximum likelihood estimate of risk, per se, but rather the 95 percent lower confidence limit. That means that 95 percent of the estimates are between that dotted line and the solid line in the middle.

And indeed, in some cases, that can be almost an order of magnitude lower than 1 in 1,000. And so, indeed, workers could be protected to close to 1 in 10,000 in that regard, in some cases.

Additionally, we continue to counsel that risk should be kept well below the REL because lower exposures lower the risk. We recommend alternatives whenever possible, and for these reasons the actual risk on which a REL is based, we believe, will be less than 1 in 1,000.

Now, moving on to the third element of the policy. This is the element that deals with two issues: analytical

feasibility and engineering achievability. Now, in our history, going back at least to 1988, NIOSH stated that engineering controls should be used to control occupational exposures to the fullest extent feasible.

Again, that issue of control to the level feasible, and this will be based on what levels can be feasibly achieved by engineering controls and managed by analytic techniques. So there are two issues here. There's the controllability and the measurability, if you will.

And just by way of background, not all NIOSH RELs are health-based. Historically, in many cases, the basis for the REL was not the health data but limitations of the analytical method. That we could not -- the analytical capabilities were not in existence to allow us to measure down to the level that would be below the lowest observed effect. And so, in which case we had to default and set the limit at

the level of analytical feasibility.

With regard to engineering achievability, while that was talked about in the 1995 policy, NIOSH hasn't routinely conducted analyses of the technical feasibility of achieving RELs. Nor was that ever defined in the policy.

And so, from henceforth in this policy, NIOSH will no longer establish carcinogen RELs relying on the evaluation of engineering control achievability. That will not be a determinant in the evaluation process.

But NIOSH will make an effort and provide in every REL document an overview of the effectiveness of engineering controls. Moreover, as we develop the RELs with the quantitative risk assessment, we also have to assess whether or not we can actually measure the chemical at the level that we would recommend.

And so to help the public

appreciate the difference and to see more transparently what the basis of a REL is, we will use these two designations. We will use health-based RELs. And with a chemical, we will use the designation REL in the Pocket Guide or other documents if it's health based. But if it's based on analytic feasibility, we will use REL with the subscript AF. That will allow people to know which ones are based on an analytic limitation and which ones are health-based.

This is another slide that, without a pointer, it's hard to see. Let me walk you through it, but, essentially, if there is a 1 in 1,000 risk, we ask the question, is there a validated analytic method to measure the substance?

If no, then we recommend research to develop a validated method. This can take many years, but at least it will fill a gap.

In the interim, or if yes, if

there is a validated method, we ask the question, can the validated method detect the concentration that equates to a 1 in 1,000 risk? And indeed, if that does, we will provide recommendations to utilize a hierarchy of controls and issue a recommended exposure limit.

If not, we will adjust the REL to the analytical limit. And that would be the limit of quantitation, or the reliable quantitation limit. And for those RELs we will add the AF designation.

So, those were the three elements of the NIOSH cancer policy. We're here today having this public meeting. We hope to receive all public comments by February 13th, 2014, and then receive all peer review comments by March 2014. That one month difference is because we want to avail the peer reviewers of all the comments of the public.

So in addition to reviewing the

document, they will have, as input, the comments of the public. And we anticipate the completion of the final cancer policy sometime in 2014.

I want to acknowledge the NIOSH intramural team that has worked on this document over the last two years. And we appreciate all their input. And draw your attention to the NIOSH carcinogen policy web page where you can get updates on this process.

And so I thank you for your attention, and we look forward to your questions and comments. And I think right now we'll take clarifying questions. Then we'll get into the comments by individual members of the public.

DR. McKERNAN: Thank you, Paul. We are going to take questions. We're first going to take questions in the room. After they have been completed, we'll then take questions from the phone line. I'd like to

remind everyone to please state your name and your affiliation. And we have a portable mic that will be rotating throughout the room.

(Pause.)

MS. CASANO: Hi, I'm Pat Casano, GE. And I apologize, I was a few minutes late. So, if you answered this question in your presentation, I'm sorry for the duplication.

The classifications upon which you're proposing to rely -- IARC, NTP, EPA -- are of varying quality. In your process are you going to take that into account and provide an opportunity for people to comment on the quality of the assessments? Or are you going to take those classifications at face value?

DR. SCHULTE: Whenever NIOSH develops a recommended exposure limit, the limit and the documentation will be open for public comment. And so there will be an

opportunity to comment on that. I would say, though, that we have viewed these three agency reviews as of all sufficient quality to be part of our determination, and we don't intend to rethink their determination.

So we will accept them at face value. We welcome comment about that, but unless there is some issue related to occupational relevance, they are de facto the source of our classification.

MR. SIVIN: Darius Sivin, UAW. Could NIOSH give an example, if not for a specific agent, for a hypothetical agent, of how it might find an agent found to be carcinogenic by these various agencies not occupationally relevant?

DR. SCHULTE: Chris, you want to do that?

DR. SOFGE: We expect that to be a very rare occurrence. And I'd love to just pull out a chemical and tell you, but it is a very rare thing that we would find

something not occupationally relevant if it's been considered to be a carcinogen by one of these three agencies. Because just the fact that they're looking at it means there's probably exposure and it's probably relevant.

What we put this in there for is those situations where you could imagine if there was a chemical that caused tumors if it was injected, and that's not a route of exposure you would ever have in an occupational setting. Or something like that. It gives us a way to deal with those kinds of chemicals.

(Pause.)

MS. WISE: Can everybody hear me?

DR. SCHULTE: Once you turn it on it takes a couple seconds before it activates, it seems.

MS. WISE: Okay, so hopefully -- there we go. Kimberly Wise, with the American Chemistry Council. You mentioned

that there will be a peer review of the document. Is that going to be an open forum meeting? Or is it going to be like a letter peer review? I just want to know about how that peer review process will go and how the comments will be taken into consideration in that peer review.

DR. SCHULTE: The peer review is done by about six or eight peer reviewers who will review the document independently and provide a written report. There will be no attempt to achieve a consensus from the peer reviewers. Kathleen, did I say that correctly?

DR. MacMAHON: That is correct. What I would add to that is that the peer reviews will be made publically available on the NIOSH website, and we also will document our responses to the peer review comments.

DR. SCHULTE: And that will all be in the public docket.

MR. ELLIS: Thank you, hello.

Okay, Mark Ellis with the Industrial Minerals Association-North America. I noticed that your model looks at a linear relationship in terms of carcinogenesis. Can you tell me why you discounted the operation of any threshold that may operate?

DR. SOFGE: Well, in practice, when you're doing risk modeling, thresholds are particularly difficult to locate using statistical models. So, part of it is a pragmatic point of view.

That being said, we have had situations where if we know enough about the mechanism of action, or mode of action, to be confident that there is a nonlinear response, we have taken that into consideration when we have sufficient data to support that.

So, even though, in general, we look at it from a linear point of view, that's in the situation where we don't have sufficient data to rule out a linear

response.

MR. ELLIS: And that is spelled out in the policy?

DR. SOFGE: The policy's the general sort of thing. For individual chemicals, we always use the best data we have. I mean, and that is NIOSH's policy.

MR. ELLIS: To be specific about it, does the policy --

DR. SCHULTE: Use the microphone please.

MR. ELLIS: Does the policy recognize a specific exemption for potential operation of a threshold based on mechanism of action?

DR. SOFGE: Well, this policy isn't designed to really get into the specifics of how we do quantitative risk assessment and what data we're going into. But, in practice, like for titanium dioxide, for example, that's one chemical where we did have sufficient data that we thought

supported a sublinear dose response.

So, in practice, that's what we do. This policy doesn't go that far in to prescribe the specific risk assessment practices, like which model to use.

DR. SCHULTE: It does, however, specify that we will use the best data available. So if there are data that would allow modeling for a sublinear relationship, that would be included in that. And indeed, as Chris said, we did that in the risk assessment for titanium dioxide.

DR. McKERNAN: We're now going to switch over to any questions that are on the telephone line.

AUTOMATED PHONE MESSAGE: The conference is now in talk mode.

DR. McKERNAN: I remind those that are on teleconference to please state your name and also your affiliation.

MR. MIRER: Hi, this is Frank Mirer and I'm a peer reviewer. The sound is

really bad, you can't hear any of the audience comments, and it's kind of shaky half the time from the NIOSH participants. That's just a point of personal privilege. I don't have a technical question at this time.

DR. McKERNAN: Okay, thank you.

DR. SCHULTE: We'll try to speak up for the folks on the phone.

MS. JACOBS: This is Molly Jacobs from the University of Massachusetts-Lowell. And I have a question regarding the chemical classification piece of things, and wondering if NIOSH will include more agents, in quotation there, rather than just chemicals.

I'm thinking of ionizing radiation and/or radio frequencies, and potentially in the future issues around mixtures rather than single chemicals. Can you speak to whether those type of agents will be inclusive of NIOSH's review of

occupational carcinogens?

DR. SCHULTE: Yes. They will not. This is the NIOSH chemical carcinogen classification policy. Subsequently, once we get this done, then we are going to move to physical agents. So any physical agents, such as ionizing radiation, won't be addressed in this, but we expect to address them subsequently.

With regard to chemical mixtures, we don't specifically single out an approach for them in this policy, but we have a review of the literature on chemical mixtures which we hope to publish in the near future, where we don't think at this time we're ready to have a particular policy on it. We don't think the science is evolved enough.

But we are interested in following the science on mixtures and particularly on cumulative risk assessments. And we hope to at least review that

literature in the future.

DR. McKERNAN: Do we have any further questions on the phone line?

MR. HERRICK: Yes, this is Bob Herrick, Harvard School of Public Health. I just have one question. It's kind of a hypothetical, but let me just pose it to you anyway. How would NIOSH approach a compound that is turning up evidence in the scientific literature as being a carcinogen, but none of those three entities that you mentioned have acted on it yet? How would NIOSH proceed?

DR. SCHULTE: Thank you, yes. There is a point in the flow chart of Figure 1, the third box down which says, is there other evidence of carcinogenicity? And if the three agencies have not classified the substance but there is other evidence of carcinogenicity, NIOSH has two options in that case.

We can nominate it to NTP to

classify it, or if there's a need to move with more dispatch, we can evaluate it ourselves using the Globally Harmonized System of labeling and classification criteria.

So, that's how we would deal with those. So, there would be a way to take something that has not been addressed by one of the three authoritative agencies.

MR. HERRICK: Thank you.

DR. McKERNAN: Is there another question from the phone line? Do we have any further questions in the room?

MR. MIRER: Yeah, actually, I do have another question. This is Frank Mirer.

DR. McKERNAN: Go ahead.

MR. MIRER: Is it NIOSH's intention to present an array of risk rate estimates for the chemical, and exposure levels associated with various risk rates?

DR. SCHULTE: Yes, in part. When we do the risk assessment we will

communicate an array of risks, from 1 in 100 to 1 in a million. And so that will be part of the report-out of the risk assessment in the REL developing document. So, in that sense, we will identify what the risks are.

For the 1 in 1,000 risk, certainly we will show the concentration REL that relates to that. I don't know if we had planned on doing it for the other risks from 1 in 100 to 1 in a million.

We weren't going to report an exposure that corresponded, or were we? Okay, we are. Yes, I stand corrected. We are going to do that, Frank. We will array the risks from 1 in 100 to 1 in a million. And we will also report the corresponding exposure level that relates to those.

MR. MIRER: One other question. Is it NIOSH's intention to go back through the RELs and through existing chemicals and classify them according to this new system?

DR. SCHULTE: Yes, we have

already started on thinking about a retrospective application of this policy to the previously classified NIOSH substances. It's a little more complicated than one might think. And we can't really move ahead on it until we get the policy finalized. So, once this policy is finalized, yes, we do intend to try to apply it retrospectively.

DR. SOFGE: And I want to clarify that that's the chemical carcinogen piece, not developing new RELs for everything.

DR. SCHULTE: That's correct, just the classification.

DR. McKERNAN: We have another question in the room. We're going to do that now.

DR. SCHULTE: Yeah, that's a good idea.

MS. CASANO: Pat Casano, GE. Just to clarify, when you talk about you know , risk of 1 in 100, or 1 in 1,000,

you're really talking about excess cancer risk, correct? So, it's not as though -- you're not saying that you have a 1 in 100 chance of developing cancer from this particular exposure? Is that correct?

DR. SCHULTE: Yeah, let me repeat the question. The question was, when we talk about risk levels, like 1 in 100, or 1 in 1,000, we're really talking about excess risk levels. And indeed you're exactly correct. And that's the way it's specified in the policy.

DR. McKERNAN: Do we have any further questions on the -- oh, we have some more in the room. Okay.

MR. ERKKILA: Hello. Brian Erkkila from the FDA. I was wondering if you could comment on the AF designation and how you would approach it if there's a large difference between the health-based and the analytical, how big a difference is acceptable.

DR. SCHULTE: Well, I think if the limitation on the analytic method was so great that the risks were much greater than 1 in 1,000, that that level -- or just greater than within the range of 1 in 1,000 and 1 in 10,000 we would have to treat that on a case-by-case basis.

Clearly, we would say to have exposures at the level you can measure wouldn't be appropriate. And we'd probably put more emphasis on calling for substitutes or alternatives in that case, or engineering controls that were essentially leading to zero, or very low exposures. But that would have to be more on a case-by-case basis.

DR. McKERNAN: We would also put additional energy into trying to create an analytical method that would be able to measure to a lower level. And we have a very talented group of scientists at DART that have that analytical expertise.

MR. HELMES: This is Tucker

Helmes from SOCMA, Society of Chemical Manufacturers and Affiliates. What's the dynamics between NIOSH and NTP, for example? Specifically what I mean, you know, NTP accepts nominations for its annual report on carcinogens. Does NIOSH make nominations to NTP for that because of a concern about an occupational exposure? Or does NIOSH wait and see what the NTP publishes in its report on carcinogens, and then evaluate whether there is an occupational relevance?

DR. SCHULTE: For those on the phone, the question dealt with the relationship between NIOSH and NTP.

NIOSH is a founding member of the National Toxicology Program and continues to have a seat on the board that governs it. NIOSH also has the capability of making nominations to NTP and in some cases we do that. And NIOSH also utilizes the information in the report on carcinogens after that's put out. So all of those are

possibilities. But we are a member of the NTP and participate in deliberations of it.

MR. ELLIS: Mark Ellis with the Industrial Minerals Association again. When you talked about analytic feasibility, are we talking about the limits of detection, or are talking about limits of quantification? And are there confidence intervals on either side of that?

DR. McKERNAN: I'll take that one. So, when we develop a REL, we'll typically use a validated NIOSH method or a validated OSHA method. If it's a NIOSH method, we're going to be using LOQ, limit of quantification. But our colleagues at OSHA don't use LOQ, they actually use an RQL, a reliable quantification level. So, depending on the analytical method that we use, we use those two terms.

(Pause.)

MR. SIVIN: Darius Sivin of UAW again. Could you tell us what criteria

NIOSH will use to determine whether a data set is adequate to justify a deviation from a linear model, and whether, at least in the case of each individual agent, those decisions will be subject to public comment?

DR. SCHULTE: Chris, would you handle this? Let me just repeat for the phone people. The question was: what criteria will NIOSH use to deviate from the assumption of a linear model at low doses to make its analysis?

DR. SOFGE: Yeah, that will be done on a case-by-case basis. And all of our documents always involve opportunity for public comment and peer review. So there would definitely be opportunities for input on those decisions.

Now, as far as we don't have a set of criteria, it really depends on what the mode of action is, how much confidence we have in that mode of action.

DR. SCHULTE: But, clearly, as we

did in the titanium dioxide report, upon using the data to model a sublinear relationship, we subjected that whole analysis to a sensitivity analysis. And that was put in the report and made available for public comment.

DR. McKERNAN: Do we have any further questions in the room? If not, I'm going to switch back to our colleagues that are on the telephone and ask them if they have any further questions?

(No response.)

Okay. Then we'll go ahead and shift gears. For our colleagues on the telephone I wanted to apologize that your audio experience is not everything that we hoped it would be. I am comforted by the fact that we are taking a whole transcript of what's going on in the room. And that transcript will be posted on the NIOSH Docket within 30 days.

Additionally, I wanted to remind

you that the presentations made today will also be posted on the NIOSH Docket Website. So I apologize that your experience is not 100 percent. But I hope that those two additional items will make today, at least post-today, more meaningful.

Okay, so we're going to shift gears now and we're going to have some of our stakeholders make some comments. Again, these were people that signed up in advance. If there is anyone else that would like to make formal comments today, please let us know. We did put all the stakeholder names into a hat and randomly selected them.

And our first speaker today is going to be Darius Sivin from the International Union UAW. I'd like to invite him up to the podium, please.

(Pause.)

MR. SIVIN: Good morning. Thank you for the opportunity to comment on NIOSH's draft carcinogen policy. The

International Union UAW did submit comments at the 2011 public meeting. And I recently had an occasion to revisit them in the Docket online. And I noticed that a crucial page was missing.

And that was the page where we specifically stated our opposition to the use of the 1 in 1,000 risk level. Now, I assume that this was an accident. It appears, looking at what's online, that our document was printed off email and then re-scanned and uploaded, and in the process of re-scanning, a page was missing.

But since we did submit those comments on time, I will be a happy to resubmit them so that NIOSH can correct the Docket.

DR. McKERNAN: We'd be happy to correct the Docket, and we apologize if an error was made. Those have been on the Docket from 30 days since the last public meeting, but we would be happy to correct

that for you.

MR. SIVIN: Thank you. I would like to commend NIOSH, first, for bringing its carcinogen policy in line with IARC, EPA, and NTP, and GHS. And, secondly, for having adopted a policy of strongly advocating safer alternatives.

On that second point, I would like to recommend that each criteria document for a carcinogen indicate that the REL is only properly used after safer alternatives have been sought. And that it would be an improper use of the REL to not start at the top of the hierarchy of controls and go directly to engineering controls or administrative controls rather than looking for safer alternatives first.

I do have grave concerns about the use of the 1 in 1,000 risk level. First of all, I would like to disagree slightly with Dr. Schulte about his interpretation of the benzene case.

In the first place, that number appeared in a non-binding footnote to what was in fact a plurality and not a majority decision. And the 1 in 1,000 number comes from the Solicitor of Labor's interpretation of that non-binding footnote.

And so I think it should hardly form the basis of a policy of recommended exposure limits from a scientific organization in the U.S. Public Health Service. In fact, I think it would be outrageous for any entity in the U.S. Public Health Service to issue a recommendation which, if followed, would result in a thousand fatal cancer cases per million workers exposed.

If there are legal or administrative reasons for which NIOSH needs to provide the information, for example for OSHA's use, since OSHA is subject to the Solicitor of Labor, NIOSH should provide that information in that array of risks that

you talked about, but not describe that as the recommended exposure limit.

Scientifically, I think it's not necessary to have a particular target risk level at all. In part because of the great uncertainty in determining what level of exposure is associated with a particular risk, as described in the Silver Book, called Science and Decisions: Advancing Risk Assessment.

I would commend the use of sensitivity analysis as in the titanium dioxide documents. And I would suggest that, in all RELs, when saying that such and such dose is associated with such and such a risk, that NIOSH publish not only the array of recommendations, and not only indicate that it's a lower confidence interval, but also always publish an analysis of the sensitivity of the models to assumptions and indicate under different assumptions what those risk levels would be.

In particular, for example, if NIOSH were to go to a sublinear model for any particular REL, I would strongly recommend that you indicate in the criteria documents what the exposure level would be if you used the linear model. And clearly describe the assumptions of the data set that justified not doing so.

So, I also think that it is very important that NIOSH indicate in its policy and its criteria documents that people have the same right to protection at work that they do in other activities. That there is no principal justification for setting exposure limits for workers that provide less protection than the 1 in a million lifetime risk in the general population. So, that I can imagine justifying a particular REL on the grounds that the robustness of the data set doesn't permit going down that low.

I certainly think, as I said,

that for all carcinogens, NIOSH should indicate very strongly that the REL is not properly followed, and, as I say, in each criteria document and I think in the NIOSH Pocket Guide, that you're not properly following the REL if you haven't looked for safer alternatives first.

Yeah, those are -- oh, I would also like to add a comment on analytical feasibility, which is my concern is that obviously criteria documents can become outdated either due to advances in the science telling us what the risk is, or the analytical feasibility.

But I think they'll become outdated faster if we have analytic feasibility RELs and not just health-based RELs, because if we set it at a health basis and then analytical feasibility improves, then we can have -- that same REL will still be applicable and now we can measure to it.

Whereas if we set it at

analytical feasibility and there's an advance in analytical feasibility, the REL will become outdated much faster and also it will be less protective.

And so thank you very much for the opportunity to comment on the policy. I appreciate it.

DR. McKERNAN: I'm actually going to allow the panel to see if they've any clarification questions that you'd like to ask? We don't. Thank you.

Going to move on to our next speaker, who is Anna Mazzucco from the National Cancer Center for Women and Families.

DR. MAZZUCCO: Hi, thank you very much for allowing me the opportunity to speak today. My name is Dr. Anna Mazzucco and I represent the National Research Center for Women and Families and our Cancer Prevention and Treatment Funds.

After completing my Ph.D. in cell

and developmental biology, I also conducted research at the National Cancer Institute and I bring those perspectives today. I speak as a cancer biologist who's concerned that these regulations still lag behind the state of the science and fall short of their goal of protecting Americans from cancer as they work.

In 2013 alone, more than half a million Americans will die from cancer. And a 2003 joint report from the NCI and the National Institute for Environmental Health Sciences stated that exposure to a wide variety of natural and man-made substances in the environment accounts for at least two-thirds of all the cases of cancer in the United States.

Yet after reviewing the current state of regulatory policy and research, the President's Cancer Panel reported in 2010 that environmental health, including cancer risk, has been largely excluded from overall

national policy on protecting and improving the health of Americans.

When decades-known carcinogens such as asbestos and radon are still present at either unsafe or unknown levels in American workplaces, how can the public have confidence that our regulations can handle new and complex occupational hazards arising every day?

The National Institutes of Health also estimated the total cost of cancer in 2008 at $201.5 billion in both direct health care costs and the indirect cost of lost productivity due to premature deaths.

Another recent study estimated that cancer is responsible for 20 percent of all healthcare spending in the U.S., and that disability days cost $7.5 billion in lost productivity each year. And these numbers cannot attempt to capture the human value of lives lost.

Although we appreciate the

adoption of a classification system by NIOSH, we are concerned that this report still represents a more reactive rather than proactive approach to regulation. It maintains a historical risk threshold which may no longer be appropriate. And it still places burdens on workers rather than on the industry.

We have five areas of concern that we want to emphasize. And I'll just briefly state them and just give a few details.

Number one. Safe exposure limits must be based on actual, not theoretical, workplace exposures. Real-life workplace chemical use involves multiple agents and complex exposures. This report does not give any concrete statements on how to address the true chemical milieu to which workers are exposed, and there is no scientific reason to limit our safety analyses to single agents.

If the goal is to prevent chemical hazard exposure in the workplace, then we must start with the workplace, not a theoretical framework which likely applies to very few real life situations.

And I know that this issue already came up on questions on the phone, and so we look forward to the work from NIOSH on addressing more complex chemical situations.

Acceptable occupational risk assessments should be based on up-to-date, circumspect and truly representative information. As we discussed also already, NIOSH uses a lifetime excess cancer risk of 1 in 1,000 as the minimal acceptable regulatory threshold, while stating that controlling exposure to lower concentrations is always warranted. We appreciate that, especially the statement that an excess risk of 1 in 1,000 is one or more orders of magnitude higher than what the United States

permits for the general public.

And this is justified in this report by two arguments which we already heard a little bit of this morning. The first being the historic benzene decision, which we also think was used more in a rhetorical example. But the second also being that this justification has been used historically because workers represent a very small subset of the population, and higher exposures for small numbers of people may be considered acceptable if they are comparable to the overall risks of that employment itself.

But we think, in this particular case, actually even at that time and certainly now, many occupations have lower than 1 in 1,000 risk. And so we think that that should also be recognized.

There is also increasing evidence that occupational carcinogens spread into the greater environment. For example, TCE,

an industrial solvent, is now present in as much as one-third of the U.S. water supply. And so we think that distinguishing between occupational versus overall environmental exposures is very difficult. Especially given that the EPA 1 in a million target threshold is what they prefer for the largest number of people possible, and that's a 1,000 times lower than the NIOSH threshold.

And the bottom line is that there is no scientific basis for these differential safety standards, and we now know that occupational and environmental exposures can become difficult to distinguish. And for that reason, it would be better for the workplace, and the general public, more comparable protections.

And I'm just going to stop here because I'm worried I'm going to go over time. But we also just wanted to mention that a safe exposure level based on

technical feasibility rather than safety does place workers at risk. NIOSH plans to use the recommended exposure limit to the highest detectable dose, the reliable quantitation limit, as we heard this morning.

But this would directly place workers in potentially unsafe conditions, and they would also be powerless either to detect or remove the agent to guarantee safe levels.

If we really want to guarantee absolute safety to workers in that situation, the better thing to do would actually be ban these chemicals until a more safe and sensitive detection method is developed. And such a policy really would protect workers while also creating an incentive for industry to develop more sensitive diagnostic capabilities or find safer alternatives.

And, lastly, I just wanted to say

that sensitive subpopulations need to be addressed in more detail. For example, we know that birth defects, childhood cancer, and adult cancers can all caused by in utero exposures. And this report doesn't provide any really specific details on how sensitive subpopulations would actually be protected.

And just as the NIOSH risk threshold, you know, is intended to protect all workers, we really need to make sure that everybody is included in that.

So just to end, we urge you to consider these changes and use every resource at your disposal to ensure that our national policies regarding occupational carcinogens meet their goal of protecting Americans at work. This will ensure a healthy society, a thriving economy, and also safeguard our environment for the future. Thank you.

DR. McKERNAN: Does our panel have any questions? I have a question for

you. I just want to clarify. So are you recommending that NIOSH not consider analytical feasibility when establishing a REL for a carcinogen?

DR. MAZZUCCO: I mean, I understand, you know, the practical limitations, and I think, you know, I think it gets to the question that was asked earlier about kind of if the difference between the analytically feasible limit and the REL, you know, how much of a difference would be acceptable between those two numbers, would be kind of the really salient point just to make sure that in those situations the risk isn't, you know, in greater excess of the 1 in 1,000 threshold.

DR. McKERNAN: Thank you. Okay, we're going to rotate to our next speaker, who is James Melius from the New York State Laborers' Health and Safety Trust Fund.

(Pause.)

DR. MELIUS: Okay. Good morning

everybody. And, again, first of all, thank NIOSH for holding this meeting and giving us the chance to come back and talk to you again. I actually did read the transcript from the last time, which was two years ago. I do admit, I read it on Friday, so, I haven't checked my comments but that -- a couple things.

One, first of all, I think, first of all I'd like to thank you for some significant improvements in what was discussed, at least, two years ago in this document. I think the new, more detailed, more layered classification system is good. And I think the approach to sort of compatibility or conversion with NTP, EPA, and IARC are good.

I mean, the science is advanced enough now that certainly these kinds of, you know, multi-level classification policies make much better use of the scientific data and certainly are much more

-- better in terms of communicating what is known about a carcinogen or a potential carcinogen without going into, you know, a complete 500 page criteria document or whatever.

So I think that is useful and I think also the approach to conversion to the GHS is also very reasonable.

One area I'd like to point out, and again I don't think it's a change to this document, but I think it is an area that may require at least some more mention in the document is it's very clear that we're relying, or are going to have to rely more and more, on mechanistic data in terms of classifying chemicals as carcinogens or potential carcinogens, whatever.

Our understanding of the development of cancer, its progression, is greatly increased. I think we're recognizing more mechanisms, and I think we're also doing fewer epidemiological studies, having

more difficulty getting those done for many materials that are used in the work place.

And similarly animal bioassay and the other kinds of information we used to rely on heavily in these classification systems are much less available than they used to be. Therefore, we're looking for substitutes for that. It's a complicated evolving area and I think that needs to at least be acknowledged in this. And I know you are well aware of it and well-versed in it, but I think in terms of developing some consistency and development of proper classification systems, this needs to be brought into the system. Much as you're doing in terms of background documents on risk assessment and so forth.

It's obviously, I think, much too detailed to be part of this document. I'm not sure that anybody really has come up with a good global approach to this, but since it tends to be very substance

specific, or at least within classes of materials, but I think it is important. I think it's worth mentioning in more detail in this document.

I'd also have a number of other sort of recommendations I'll put in writing at this time. I think, Paul, I'd like to thank you and your staff. Your presentation today actually clarified a number of areas that I think warrant a little bit more emphasis in the document itself. They sort of get lost in the detail, and I think it would be very helpful to do that.

The one area I remain very disturbed about is the target risk assessment level. I think that is not, and should not, be NIOSH policy, the 1 in 1,000 excess risk. It is not what, I don't think, Congress intended when it set up the agency.

And as I can quote from Page 31 in your own document, was requesting NIOSH develop exposure levels at which no employee

will suffer impaired health, or functional capacities, or diminished life expectancy as a result of his work experience.

And I think 1 in 1,000 clearly violates that. And I think something -- I don't think that NIOSH should be bound by a feasibility determination that's been made by OSHA as part of a regulatory process involving economic and other feasibility determinations as part of setting a level. So I think that has to go.

I guess we're all -- I think your overall policy of sort of no safe level, or very reduced as much as is feasible, or as possible, is much better. I do think that it needs to be implemented in some way for the greater occupational health community in terms of a recommended, an REL, recommended exposure level, and do that.

I don't think that 1 in 1,000 is adequate. I think a lower level is much more appropriate for that and it would drive

exposures down and provide a much more healthful workplace for workers. And better guidance for people that are overseeing these workplaces.

I also would agree with Darius's comment. I don't think analytic feasibility should be directly tied to the REL. I think if you're going to -- it's fine to make the determination, as Darius mentioned, those analytic feasibility tends to change over time. And even change from workplace to workplace depending on background contamination, the nature of the work process.

So I think having a dual notation, one being a recommended health based exposure limit, is intended by the Occupational Safety and Health Act for NIOSH to recommend.

And, secondly, to list with that a feasibility limit based on the analytic feasibility, based on the current methods

that would change. That would provide guidance for people, not only as to what would be feasible in terms of measuring in the workplace for industrial hygiene purposes, but also would tell people sort of how much residual risk there may be based on what is feasible to analyze at this point in time.

But I think that whole section needs to be really rethought and revamped before this policy goes forward. I understand your concerns, however I don't think that the precedent that's been made in terms of recommendations to OSHA and so forth, I think, are in a different context.

And I think that the 1 in 1,000 is not an appropriate targeted risk level for NIOSH to be making. So, I thank you for your time.

DR. McKERNAN: Can we please have any questions from the panel?

DR. SCHULTE: Yes, thank you,

Jim, that was very helpful. I wanted to probe a little bit on the idea of the analytic feasibility. If you can't measure it, you really don't know what you have. So, it doesn't matter if we say some other level; if you can't measure that level you don't really know what's going on in the workplace. So, it's not really clear what's happening there.

DR. MELIUS: Yes, but often analytic feasibility is based on what can be routinely measured. And there may very well be techniques that are non-routine and maybe not practical for everyday use, but allow measurements within the work place and do that.

And a great example is asbestos, where phase contrast microscopy allowed one level of measurement, and electron microscopy could go to a much lower level. Now, all this may be substance specific.

But I think that having sort of

the dual designations, first of all, one for an REL, second for what currently can be measured based on an analytic feasibility, routine analytic feasibility, I think would convey the same information, but recognizing there may be some level of residual risk that will not be able to be routinely measured in the work place.

I don't think it's an easy answer to it, but I think that's the best compromise.

DR. SCHULTE: Well, thank you, we appreciate your comments.

DR. SOFGE: I have a question about --

DR. McKERNAN: Is your mic on?

DR. SOFGE: Is that better? I have a question about you don't like 1 in 1,000 risk. So, do you have a recommendation for where you think we should go with what would be an acceptable risk level in your mind?

DR. MELIUS: Well, I think for a number, either 1 in a million, or 1 in 100,000. One in a million is preferable, but ties in more with other government policy and so forth.

DR. SOFGE: Thank you.

DR. McKERNAN: Thank you. We're now going to shift to our next presenter, who is Lee Anderson from the BlueGreen Alliance.

MR. ANDERSON: Thank you very much. I think I might be too tall for your microphone but I'll give it a try. Thank you, good morning. I'm vertically challenged in a different way, but thank you and good morning. I appreciate the opportunity to give comments here today.

Dr. Schulte, first of all, I wanted to say a couple things about a couple comments that you made that I thought were very positive this morning. You said that, whatever standard you're going to use, that

it will be NIOSH's aim to keep the risk lower than the stated standard, which is to the good.

And that you would promote alternatives, safer alternatives, also to the good. It's actually something that our organization, the BlueGreen Alliance, has spoken on at great length. And we have an entire report on this on our website.

The whole point being that the research and development needed to create safer alternatives is also a job creator. And I wouldn't be doing my job as a member of the BlueGreen Alliance if I didn't bring up jobs. So those are very positive comments and I appreciate them.

And I also was struck by your comment that the information that you'll be providing will set out the entire spectrum of risk, from 1 in 100 to 1 in a million. So you won't just be providing a single data point, 1 in 1,000.

That's great, that makes a lot of sense and gives a lot of data on which to base implementation decisions. So, also to the positive.

But I wanted to talk about that risk level, the 1 in 1,000 risk level that we've heard other folks talk about this morning, because it is a primary point of concern for my organization as well.

It is a little intimidating to be in the room with so many people who have doctor in front of their names. I'm just a simple country lawyer. But for that reason, you know, I wanted to talk about the old benzene case that all this is based off of.

It struck me on the Metro as I was riding in today that more than two decades have passed since I first read that case as a first year tort student, which I find humbling.

And I think I had memorized the phrase, significant risk, at the time.

Wrote it in a blue book and promptly forgot it. But then this came up in my career professionally, representing trade unions and workers, and working on toxic tort cases to see the real world affect that the lack of appropriate chemical regulations can have on people. In my particular case, the context was asbestos and silica.

And now here I am again 20 years later trying to find out what do we mean when we say, "significant risk?" Significant how? Who decides what's significant to whom?

Well, since we are basing all this on this on the old decision, I thought, well, what did Justice Stevens, who wrote the opinion, actually say about it? I don't want to put words in the man's mouth, so I just brought it here. And I thought I would just read it.

In the famous language that we all know, he says, "It is the Agency's

responsibility to determine, in the first instance, what it considers to be a significant risk."

It is NIOSH's job. You decide what is significant risk. It has, "an obligation to find that a significant risk is present before it can characterize a place of employment as unsafe." And, by the way, risking error should be done on the side of overprotection rather than underprotection.

Why is that important? Because who's deciding what is or is not significant? That's your job. Even went so far as to say expressly, we, the Supreme Court, are not making that decision today. Again, I'll just read the language because Justice Stevens is a way smarter guy than I am.

He says, "Nor do we express any opinion on the more difficult question of what factual determinations would warrant a

conclusion that significant risks are present." He expressly says they are not deciding that. They are not saying, the Supreme Court, they are not saying that 1 in 1,000 is the tip-over point. That is not the cut point, which is a term I heard earlier this morning.

It's somewhere in that interval between 1 and a 1,000 and 1 in a billion. Where is that tip-over point, however? That's for you to decide. If you say it's 1 in 10,000, 1 in 100,000, 1 in a million, then it's the court's job just to evaluate whether the method by which you came up with that number was appropriate.

Now, you can imagine the argument in the Supreme Court when one of the justices says, now, where did you get this 1 in 1,000 standard? And the lawyer replies, well, we got it from you. What? That is not what the benzene case said. They did not say we are giving you a standard to

follow.

It even came up, I noticed it, it was even in the concurring opinion written by Justice Burger. He says the Secretary's factual finding of risk must be quantified sufficiently to enable the Secretary to characterize it as significant in an understandable way. Precisely what this means is difficult to say.

I should say it is. Twenty years later we're still not entirely clear what significant risk means. So I understand the balancing that has to be done here because you have an obligation to OSHA, and I understand that OSHA has adopted that. But that presumes on the front end that OSHA's decision was correct.

The discussion and battle over whether OSHA should be using that standard is for another day and another forum. Our question here is, should NIOSH be legitimizing and enshrining that decision?

That, what I would call, a bad decision, 1 in 1,000.

Now that's why I appreciate your comments, Dr. Schulte, when you say, we will push for greater protection. We will push for alternatives. That's great.

But in the real world we all know there will be people who say, I've met the 1 in 1,000 standard, now leave me alone. Maybe you have some way for doing 1 in 10,000, but I'm not going to do it. I don't have to, because that's not what it says.

They're interested in what does it say in the regulation. Doing otherwise I think it's simply advocating the Agency's responsibility over to the Supreme Court, which is not what is supposed to happen.

Two, and I'll finish this point with an absweer to relate to the question that was asked, what should the number be? And it ties into some of these basic issues of fairness that we've heard other

commenters talk about

If we're going to say, in this context it's 1 in a million, over here it's 1 in 100,000, over here it's 1 in 10,000, at a bare minimum it needs to be lined up with these other policy decisions.

One in a million, what's wrong with 1 in a million? I don't know if 1 in a million is perfect. But that is at least the sort of policy considerations upon which this decision is to be made. That's the phrase that Justice Stevens used.

He said deciding that number is supposed to be a policy consideration. And the agencies are where the policy comes from. So if you say, look, EPA has set it at a 1 in million standard in these contexts for all these number of years, why is that not perfectly valid? Why is that not, in fact, more valid than relying on the Supreme Court Justices, who do not set policy? So there's that.

It was also -- I -- one final comment on that, I noticed that in your actual document you say, "Keeping risk within 1 and 1,000 is the minimum level of protection. Controlling exposure to lower concentrations is warranted because of excess risk of 1 in 1,000 is one or more orders of magnitude higher than what the U.S. permits for the general public."

But what is not stated, there's not another sentence that says why this different level of risk should be acceptable in the workplace, when it is not acceptable for soccer moms shopping at Target. I take the point, but I don't know the why. Why is it different?

It cannot be that we're saying a condition of your employment is that you accept a 1,000 times greater risk of cancer because you took this job. That cannot be.

It's just, you know, representing trade unions, as I did for a long time, and

working with folks on the shop floor, what invariably got them wound up and wanting to file a grievance or do an organizing campaign, was a basic sense of unfairness. I am being treated differently than that person over there. It's just human nature.

And when you say 1 in a million over here, and 1 in 1,000 over here, it's glaringly unfair. I know why it's happening, I know why it's being proposed. I'm not characterizing, but there is an appearance there, a perception that can be, that can grow up in workers' minds to say, look, you're valuing my life less than you are valuing those lives over there by forcing me to accept this greater risk.

And then the last thing I wanted to touch on was this question of analytic feasibility. Again, I'm not an engineer, I'm not a scientist, I don't want to talk about it from that aspect. But I do want to point out some unfortunate legal history

that played out in regard to asbestos and the old TSCA regime.

An over reliance on this cost benefit analysis way of thinking is what broke National Chemical regulation. It's why TSCA does not regulate asbestos. Asbestos is unregulated because of an over-reliance on cost benefit.

Am I saying there should be zero cost benefit analysis? No. I recognize it's a balancing act. But you have to be very careful about that. And you can see it even now in the proposed fix to TSCA that's circulating up on the Hill right now.

It contains what I think is the same type of cost benefit language that is going to be a trap door down the road, if that actually should become law.

You know, there's other folks here who can talk about the science and the engineering controls much more articulately than I. I'm just pointing out as a matter

of the unfortunate legal history, what can happen when you place too much reliance on cost benefit analysis to say, look, be very careful with that or you'll end up not being able to regulate it at all.

With that, I think I will close. I'll be happy to answer any questions you may have.

DR. McKERNAN: Do we have any questions from the panel? No. Thank you. Okay, our last scheduled presenter is Howard Marks from the National Asphalt Pavement Association.

MR. MARKS: I'm going to decline at this time.

DR. McKERNAN: You're going to decline at this time? Okay. Okay, great. Is there anyone else in the room that would like to make public comments at this time?

(No response.)

Okay, Paul, do you want to make any additional comments at this time?

DR. SCHULTE: We're very grateful for all the comments. Certainly they were thoughtful comments and we will take them under consideration, sincere consideration. And hopefully they will be able to improve the policy and we look forward to any written submissions that you might want to make. And also those of the peer reviewers.

DR. McKERNAN: We wanted to give one more opportunity for the folks on the phone to make any comments if they wanted to.

AUTOMATED PHONE MESSAGE: The conference is now in talk mode.

DR. McKERNAN: Okay, go ahead, sir.

MR. LOOMIS: So, I am Dana Loomis from the International Agency for Research on Cancer in Lyon, France. And --

DR. SCHULTE: Dana, try speaking up.

MR. LOOMIS: -- information as

part of the process that they've described. I would just briefly like to comment on the proposed policy. I appreciate a chance to do this. In general, I think the proposed policy is very reasonable and consistent with current scientific understanding.

And given the large number of substances that are used in industry and commerce, it's very important, I think, to have a scientifically robust and efficient way of identifying carcinogens. And the proposed policy accomplishes this, in part by drawing on existing evaluations from this agency and U.S. EPA and NTP.

NIOSH has asked some specific technical questions that I wanted to comment on, and I'll submit written comments that go into more detail here, but one particular issue is that NIOSH has asked about the classification of IARC group 2B agents.

And what I want to point out is that the proposed process actually neglects

one group of IARC 2B agents, and those are ones that have inadequate evidence in animals, but limited evidence in humans. We assign those to group 2B.

It looks like NIOSH would not classify those to any GHS category. And I would suggest that these be approached the same as the other IARC 2B agents with less than sufficient evidence in humans, and assign these also to GHS Category 2.

The rationale for that is that even though the animal evidence is weaker than some other IARC 2B agents that would be assigned to Category 2, human evidence is stronger. And stronger human evidence should in essence compensate for the relatively weak animal evidence.

Again, I'll describe this in more detail in written comments which I'll submit later. But that would be one recommendation.

Just two other comments very

briefly. In the description of the evaluation process that we do for the IARC monographs, I think it would be useful to note that, like the EPA evaluations, these are also based on the weight of the evidence.

Now, we have some documents that talk about strength of evidence, but it's noted in those documents that that wording is employed for historical continuity.

We acknowledge that the preferences in terminology have evolved quite a bit over in the last few decades since we've been making these evaluations and that now people see -- or at least some people see a dichotomy between strength and weight.

So, I'd suggest adding those words, “strength of evidence,” to the description of the IARC monograph process.

And finally, although IARC does not conduct quantitative risk assessments or

make recommendations about exposure levels, we do support the notion that any such recommendations should be based on the science and not on other considerations.

Well, that's all. Thank you very much for the opportunity to speak.

DR. McKERNAN: Thank you. Do we have any further questions from the panel for our speaker? No questions here. Thank you. Do we have any other speakers on the phone line that would like to make comments?

(No response.)

Anyone left in the room that would like an opportunity?

(No response.)

Okay. Did you want to make any additional comments? I have some ending ones.

DR. SCHULTE: No, just again to say thank you to everyone for attending.

There was a comment?

MR. SIVIN: Yes, please.

DR. McKERNAN: Please hold on and wait for the microphone, sir.

DR. SCHULTE: Okay.

MR. SIVIN: Does NIOSH intend to make use of IRIS risk assessments in any part of its recommended exposure limit process? Either for carcinogens or for non-carcinogens?

DR. SCHULTE: The question was: does NIOSH intend to make use of EPA's IRIS risk assessments in any part of its process? We have been looking at them. Chris, do you want to talk about that?

DR. SOFGE: Yeah, we've been looking into trying to do that sort of thing. It's not as easy as it seems like it should be, and that's one of the things we'd really like to get to that point where, you know, we shouldn't have three, four agencies looking at the same chemicals. And so, yes. That is -- we're working on that.

DR. SCHULTE: Okay, so, seeing no

other hands, once again thank you all for your input. Please send us your comments. We look forward to receiving them and we will be responding to them in the NIOSH Docket.

DR. McKERNAN: Okay, so just a few concluding comments. I want to express my gratitude for all of you attending, both on the telephone and in person.

I did get some emails that our sound quality did improve on the telephone in the latter part of the meeting, so I'm happy to hear that.

I want to encourage everyone to consider submitting comments. And remind everyone that there are two methods to submit written comments.

They can be submitted through the federal e-rulemaking portal, which is regulations.gov. And you need to follow the instructions on that Website. Be sure to reference the agency name and docket number,

which is CDC-2013-0023.

You can also mail your formal comments to the NIOSH Docket Office. And that address is the Robert A. Taft Laboratories, 4676 Columbia Parkway, Mail Stop C-35, Cincinnati, Ohio, 45226. All of these details are in the Federal Register notice and also at the NIOSH topic site which shows the cancer policy.

Unfortunately, we have an error on of the slides that was shown today with the correct Website. I wanted to give that address to everyone. And that is: www.cdc.gov/NIOSH/topics/cancer/policy.html. And we will be putting that up momentarily, so if you wanted to write that down, you could.

Given the input that we've received today, after you submit your comments, I would like to recommend that you actually go back and double check. There are humans involved in this process, so just double check that all the pages were

submitted and posted.

Thank you so much for your attendance today and have a wonderful day.

(Whereupon, the meeting in the above-entitled matter was concluded at 10:51 a.m.)