Public Hearing

before

ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

"The scientific basis for the selection of the risk level of an additional cancer risk of one-in-one million for human carcinogens for the remediation of contaminated sites; alternative scientific standards and criteria; and methodologies of risk assessment and their efficacy and applicability for the purposes of establishing remediation standards"

LOCATION: Cook College Campus
Student Center
New Brunswick, New Jersey

DATE: March 10, 1994
7:00 p.m.

MEMBERS OF COMMISSION PRESENT:

Michael A. Gallo, Ph.D., Chairman
Christopher P. D'Alleinne, Ph.D.
David S. Kosson, Ph.D.
Rita M. Turkall, Ph.D.

ALSO PRESENT:

Raymond E. Cantor
Judith L. Horowitz
Office of Legislative Services
Aides, Environmental Risk Assessment
and Risk Management Study Commission

Hearing Recorded and Transcribed by
The Office of Legislative Services, Public Information Office,
Hearing Unit, 162 W. State St., CN 068, Trenton, New Jersey 08625-0068

ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

LEGISLATIVE OFFICE BUILDING, CN-068
TRENTON, NEW JERSEY 08625-0068
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REVISED

NOTICE OF PUBLIC HEARING

The Environmental Risk Assessement and Risk Management Study Commission will hold a hearing on the following topics:

The scientific basis for the selection of the risk level of an additional cancer risk of one in one million for human carcinogens for the remediation of contaminated sites; alternative scientific standards and criteria; and methodologies of risk assessment and their efficacy and applicability for the purposes of establishing remediation standards.

The hearing will be held on Thursday, March 10, 1994 at 7:00 PM at Cook College Campus, Student Center, New Brunswick, New Jersey.

*The public may address comments and questions to Judith L. Horowitz or Raymond E. Cantor, Aides to the Commission, at (609) 292-7676. Anyone wishing to testify should contact Carol Hendryx, secretary, at (609) 292-7676. *Any person wishing to testify must send written confirmation to Judith L. Horowitz or Raymond E. Cantor by mail or fax (609) 292-6510 by close of business, March 7, 1994. Oral testimony may be limited to five minutes.*

*Those persons presenting written testimony should provide 15 copies to the commission. *Written testimony may be submitted until April 11, 1994.*

(OVER)

Issued 2/17/94
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at the New Jersey State Library)

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MICHAEL A. GALLO, Ph.D. (Chairman): Folks, I think we ought to get started. I don't know where my colleagues are. Maybe it was such a bad night last night-- Maybe they decided this was going to be another bad weather night and didn't show.

What we are going to do tonight is hear testimony from four or five people who have requested to speak. This is a public meeting -- public hearing on the ISRA bill. The topic of the hearing is the scientific basis for the selection of a risk level of an additional cancer risk of one-in-a-million for human carcinogens for the remediation of contaminated sites. The Committee is to consider alternative scientific standards and criteria, and methodology risk assessment and efficacy in applicability for the purposes of establishing remediation standards.

This is the second of two meetings. We had another meeting last night down in southern New Jersey, and tomorrow the Committee will meet at NJIT in the afternoon for the third hearing. According to the bill, we were to hold one hearing. As a Commission we felt that was unfair to the citizenry of the State, so we requested to have three hearing in the general regions of the State where we could reach the most people.

As I said, the purpose of this hearing is to hear your comments. According to the public notice, folks had to sign up ahead of time, so we have five speakers tonight.

Before we get started, I'm Mike Gallo. I'm the Chairman of the Commission. What I'd like to do to keep it fair -- because this is what we did last night -- is to limit the comments to five minutes. What I'll do is set a timer at five minutes, the alarm will go off, and I'll give you one minute to finish your comments. So you get a total of six minutes.

Also the Commission is accepting written comments; any and all until April 11. So I think that's -- that gives you a chance to get paperwork in to us. After April 11, we will

evaluate it, draft our findings and our recommendations. That will become public. We'll hold another public meeting, and then we will finalize our report.

Is there anything else I should add? No? (no response) Okay.

You guys want to introduce yourselves, go ahead. Just so you-- They're shy.

MS. HOROWITZ (Commission Aide): I'm Judy Horowitz, Aide to the Commission.

MR. CANTOR (Commission Aide): Raymond Cantor, Aide to the Commission.

DR. GALLO: Okay. All right. Just so you know what this sounds like-- This is what happens when you're a lab-based scientist. So you know what your listening to -- two seconds (timer beeps) that's it. So you know, it's not the roof caving in, and I hope no one is wearing a beeper. But that's our five-minute warning and our one-minute warning, so I would hope that you would stick with that.

Okay. Our first individual testifying tonight is James Jernigan. Is he here? (no response) Sorry for the lighting.

J A M E S D. J E R N I G A N: Good evening, my name is Jim Jernigan. I'm the Supervisor of Toxicology for Amoco Corporation. Over the past several years, I've been actively involved with various aspects of toxicology and health risk assessment. I greatly appreciate the opportunity to participate in this important public hearing. Amoco has a bulk petroleum terminal and a number of service stations in New Jersey that could potentially be affected by changes in the risk assessment program.

I'd like to discuss two subjects concerning risk assessment this evening. The first subject concerns the differences between actuarial and theoretical risk. The difference between these two types of risk are important when addressing the scientific basis for the selection of risk levels associated with the hazardous waste site.

As we all know, each of us every day faces a number of risks to our lives and health. For example, the annual risk associated with riding a motorcycle is about 2 percent, or 2000 deaths per 100,000 persons who ride motorcycles regularly. Lightning kills 5 people per 10 million each year, for an annual risk of about 5 times 10 to the minus 7 (5×10^{-7}). The annual risk from being hit by a meteorite is about 6 times 10 to the minus 9 (6×10^{-9}) and the list goes on.

Whether it involves personal activities or natural disasters, we all face risks. What's important to realize, however, is that each of these types of risks are real -- obtained by counting victims. They are actuarial risks. They depend only on how accurately the deaths are recorded and on how accurately the populations at risk are identified.

Actuarial risks are not based on inferences from animal data, nor do they rely on worst-case assumptions. For example, the theoretical cancer risk from chlorinated drinking water has been estimated to be about 8 times 10 to the minus 6 (8×10^{-6}) per year. Although this theoretical cancer risk is expressed in the same units as actuarial risks, the distinction between the two is important.

First, chemical risk usually is based on the finding of an adverse affect in an animal study. In the case of chlorinated drinking water, it's based on several rodent studies using various chlorinated compounds. The inherent assumption in stating the theoretical cancer risk for chlorinated drinking water is that humans and rodents respond the same way to these compounds. However, it's not at all clear that this assumption is valid.

The second major difference between actuarial and theoretical risk is that theoretical risk is a result of a worst-case or upper-bound estimate. It's based on a mathematical extrapolation of adverse effects on animals exposed to very high dose levels, to the much lower levels humans might be exposed to.

Why this regulatory policy is followed is beyond the scope of my comments this evening. Suffice it to say, however, that the reliance on the worst-case estimates of theoretical cancer risk can overstate the degree of threat posed by chemical exposure, resulting in unnecessary panic and in incorrect prioritization of remediation needs.

The bottom line is this: It's important to make certain that a theoretical risk level of, say, one-in-a-hundred thousand is not misunderstood. It's not an actual risk; that is, we don't expect one out of every hundred thousand people to actually get cancer because of exposure to a particular chemical. Rather, it's a mathematical risk based on a number of assumptions and conservative estimates.

The second subject I'd like to discuss concerns the methods by which theoretical risk is determined. Whether you believe risk assessment is a science or an art, one thing for certain is that it's being continually refined and improved. A considerable amount of human and financial resources are being devoted to research to help us better define chemical risks, and to reduce the uncertainty of our risk estimates.

Unfortunately, some Federal and State regulators have turned a blind eye to advances in our knowledge of toxicology, human behavior, and statistical science. Soil ingestion rates, bioavailability considerations, and Monte Carlo analysis are just three examples of new scientific information and methodological approaches that enable us to better characterize risk. I urge the Commission to incorporate a mechanism that allows new data and scientific information to become a part of the standard procedures used to assess chemical risks in New Jersey.

In closing, let me just say that the Commission has an important opportunity to enhance the process of waste site remediation in New Jersey. We commend the Commission for taking the time and effort to critically evaluate risk

assessment methods used in the State. An intelligent use of risk assessment can provide the scientific underpinnings to ensure that remediation is both cost-effective and fully protective of human health and the environment.

Thank you.

DR. GALLO: You're welcome. Thank you very much. Right on time. Five seconds to spare, not bad.

MR. JERNIGAN: (speaking from audience) I practiced that for a long time.

DR. GALLO: Did you? (no response) Let me just introduce these two hirsute individuals to my left here. On the far end is Chris D'Alleinne. Dr. Chris D'Alleinne, who is a member of the Commission, and Dr. David Kosson, who is also a member of the Commission. They understand risk. They don't know how to tell time, but other than that we're okay.

DR. D'ALLEINNE: If you could do something about the traffic around here, we'd appreciate it. That's your next--

DR. GALLO: Route 18, for any of you who know, there was an accident out here on Route 18. It was just blocked coming in, so you had to know where all the back streets were.

Okay, our next witness is Donald Esch. Again, before you start, if you have written testimony, please hand it in so we have it for the record. Thank you.

D O N A L D D. E S C H: Okay. I would also like to thank you for the opportunity to testify before this Commission.

I'm Donald Esch. I'm the New Jersey Area Manager for Exxon Company, USA, with primary responsibility for remediation activities at our former refining sites in Linden and Bayonne. I've been a New Jersey resident for the past 23 years. My comments are both on behalf of my employer and as a concerned citizen of this State.

Senate Bill No. 1070 offers a promise of becoming a model for others to follow. As a commonsense approach to industrial site revitalization, however, the most significant

challenge remains largely in the hands of this Commission; that is, the challenge of bringing common sense and reality to environmental risk assessment. To assist in meeting this challenge, there are three recommendations that I'd like to offer to the Commission:

First, that we encourage the Commission to adopt sensible alternative risk levels of one-in-ten thousand, and one-in-a-hundred thousand for individual contaminates, based on their carcinogenic nature.

Secondly, we encourage the Commission and the NJDEPE to strictly adhere to the spirit of this legislation, and require and insist upon reasonable and nonredundent exposure assumptions in deriving generic cleanup standards.

Third and finally, we ask the Commission to advise the Legislature and the Department to accept valid new data and state-of-the-art methods, both from periodic updates of the generic standard and precise, specific risk assessments.

I would like to expand somewhat on these recommendations. In reference to the first challenge, that of providing for sensible risk levels:

The Commission should insist that risk-based remediation standards, by definition, pass a blush test of reasonably comparing to the voluntary and involuntary risks that we as citizens of this State face every day in our private and working lives. These everyday risks far exceed a standard of one-in-a-million.

By the same token, risk-based remediation standards should reflect the weight of scientific evidence for causing cancer. Contaminates not known to be human carcinogens should not be subject to the same low level of risk as contaminates know to be human carcinogens. Risk-based standards should be based on known chemical-specific toxicity, rather than unfounded generalizations. For example, the toxicity of benzoapyrene should not be used as a surrogate for all multiring hydrocarbons.

With regard to our second recommendation, which asks for your diligence in ensuring that risk assessment methodology under ISRA is reasonable and nonredundant, we have many concerns:

We know that the natural rule-maker's quest for conservativism ultimately leads to incrementally insignificant levels of risk reduction, which add little to our health and safety, while detracting from the economic health of our families, communities, and the State.

We know that well-intentioned and seemingly reasonable adjustments of one order of magnitude of risk, just to be sure, more often than not result in at least one order of magnitude in cost escalation. As an example, while bioremediation is at $20 to $50 a ton to achieve a target of ten parts per million for oil-contaminated soil, it is likely to be totally inappropriate at the one ppm level for heavier oils, which could require soil incineration at $300 to $1000 a ton. For large industrial areas, such as exist along the Arthur Kill and other areas in our State, we are especially concerned that reasonableness prevail.

Some of our specific concerns are:

* That the potential risks associated with low-level contamination at sites within these areas be kept in context with the surrounding environment.

* That groundwater standards be likewise put into perspective, considering nonpotability due to naturally occurring salinity, as well as anthropogenic contributions unrelated to the industrial activities of the site.

* That risk assessment factors reflect the true availability of contamination to industrial workers and the public. For example, the bioavailability of contamination absorbed in soil versus that of the pure materials.

* That risk assessment assumptions truly reflect industrial activity and daily worker exposure, rather than the

extreme assumptions that are often used. Known variability in job function, assignments, responsibility, and changes in employment simply do not support the common assumption of 40 hours a week for 30 years.

Regarding our final recommendation to require the ongoing acceptance of valid data and state-of-the-art methodologies for assessing risk, we ask:

* That the NJDEPE be encouraged to continuously use and allow the use of the most current data and methodologies to more appropriately represent calculated risk.

* That responsible parties be allowed to present valid, newly available toxicity data for specific compounds to appropriately modify established generic standards.

* That state-of-the-art distribution analysis tools (timer beeps) be employed and allowed in both developing generic standards and for site-specific risk assessments.

Thank you for the opportunity to provide this input.

DR. GALLO: Somebody else had practiced five minutes.

MR. ESCH: Yes, a little bit off.

DR. GALLO: Thank you very much.

MR. ESCH: Thank you.

DR. GALLO: Could we have a copy of that, please?

MR. ESCH: Yes, you can. (distributing testimony)

DR. GALLO: Okay. Our next witness is Mark Zdepski.

J. M A R K Z D E P S K I: I'd like to thank you for the opportunity to speak this evening.

I've endured a 1 in 125 lifetime risk of fatality in driving my vehicle by coming to this meeting. I'm right in the middle of that risk as a matter of fact. Nationwide there are 268 fatalities for every 1 million miles driven. Nationally that translates to a 2 point 6 times 10 to the minus 4 (2.6×10^{-4}) risk in death from driving. The risk of being a victim of a violent crime in the suburbs is one-in-one thousand, or 1 times 10 to the minus 2 (1×10^{-2}).

My name is Mark Zdepski. I am a certified professional geologist, and I own and manage a geological consulting company in Flemington, New Jersey. I have followed the ECRA reform legislation, and I have participated in the process from the beginning. My presence here tonight is part of my continuing desire to see real reform in environmental regulation and legislation.

To investigate the scientific basis over the selection of the risk level of one-in-a-million, the Commission need only go to the ISRA public hearing transcripts, or tapes from the Assembly Policy and Rules Committee on June 3, 1993, and listen to the testimony of then Commissioner Scott Weiner. Commissioner Weiner said, "There is no scientific basis." Risk level is something that should be legislated. In other words, the one-in-a-million standard is political.

Recent scientific writing corroborates Commissioner Weiner's view. People as diverse as Dr. Ames, developer of the Ames Toxicity Test; Jay Lehr, formerly of the National Groundwater Association; and Dixie Lee Ray have spoken out about the absurdity of some of our environmental laws and regulations. The one-in-a-million risk level is one of the more absurd standards to come along.

A toxicity expert had also spoken at the ISRA hearings; this time at the Senate Environment Committee hearing on March 15, 1993. This gentleman spoke of the absurdity of the one-in-a-million risk. He equated the one-in-a-million risk for industrial sites as having one million people living on your industrial site, each eating several grams of soil everyday until they are 18, and then when they are 70, one of those million would develop cancer from the experience. The Commissioner should find those transcripts, identify the person, and interview the expert. In lieu of that, I'm sure the Chemical Manufacturers Association could provide the information. They're the ones who brought him to the table.

The one-in-a-million cancer risk is so absurd that the NJDEPE has bitter internal disputes among the staff-level technical professionals. This dispute is not a joking matter inside the Department of Environmental Protection. The Commissioner should interview a gentleman named Mr. Thomas McNevin, of the Office of Science and Research, and have Mr. McNevin present a talk called, "What is Background," which was presented to the Association of Engineering Geologists. I had the privilege of hearing this.

As a practical matter, the Department has already had to retract the one-in-a-million risk level for arsenic. In January of 1993, the Department set a level of arsenic of two milligrams per kilogram-- It was the one-in-a-million number. In January of 1994, the Department raised the level to 20 milligrams per kilogram. It seems that the one-in-a-million risk of two violates the natural existing soil in New Jersey. Assistant Commissioner Lance Miller has authored an article stating that natural soils in New Jersey vary from 0.02 to 48.9 milligrams per kilogram of arsenic.

Clearly a strict one-in-a-million risk level makes no sense whatsoever. The U.S.EPA has developed a range from 10 to the minus 4 (10^{-4}), to 10 to the minus 6 (10^{-6}). A range would provide the appropriate level of protection -- our Federal government scientists think so. After all, if 10 to the minus 4 (10^{-4}) were used, the arsenic content of natural soils in New Jersey would be acceptable to the NJDEPE.

Finally, I'd like to leave you with a few other risk levels. Children have a 1 in 89 risk of death from a bicycle accident, and a 1 in 140,000 chance of death from handguns. One to really think about is the chance that the airplane pilot who is flying your airplane is drunk; that one is 1 in 117. Your chance of an IRS audit is 1 in 100.

What are one-in-a-million risks? The chance you will see a UFO today is one-in-three million. The chance you will win the lottery is one-in-four million.

I would like to thank you for the opportunity to speak. Please consider your task carefully as scientists. Please leave emotion out of it. Rational thought should prevail in setting of risk level. Thank you very much.

DR. GALLO: Thank you.

And another member has arrived.

DR. D'ALLEINNE: Another survivor of the traffic.

DR. GALLO: Another survivor of the traffic, Dr. Rita Turkall, at the far end of the table.

Okay, our next witness is Madelyn Hoffman.

M A D E L Y N R. H O F F M A N: My name is Madelyn Hoffman. I'm the Director of the Grass Roots Environmental Organization in New Jersey. I've been working with citizens' groups fighting toxic chemical pollution problems since 1980.

I'm the only one who has spoken so far who is not dressed in a suit. I think that's because I represent real people living in these communities where these decisions that will be made today-- This is where-- These are the people who will be affected by the decisions that are made not today, but in the course of your deliberations over this one-in-a-million standard.

I would like to say up front that I'll be submitting a long paper on -- that supports my point of view, within a few -- within a week or so once I receive it. But I'll just tonight give you a sense of what my concerns are, and the concerns of grassroots groups that I work with.

First of all, I think it's important to realize that in New Jersey, we already lead the country in terms of the amount of pollutants covered under the TRI data. We have the most per square mile of any state in the country. We have the highest number of Superfund sites. We just issued -- or will soon be issuing mercury advisories for fish in 32 out of 55 New Jersey waterways. We have an environmental problem that is already there; that's real and identified. Any attempt to roll back on those kinds of protections that people and communities have already would, I think, be a real mistake.

We're in an atmosphere, in a climate where this is going to probably be the rule rather that the exception, with the passage of NAFTA, with regulations that have been passed recently -- or at least considered recently -- which would "streamline" the permitting process; which would take away the rights of people to sue in cases where there is a problem. We have to consider what the environment is, what the current environmental problems are, and what the tendency is. It has been recently to strip away the rights and protections that people have.

So it is in that context, as well as in the context of what makes sense, that I would say that the one-in-a-million risk assessment standard, flawed although it is-- And I will speak about how it's flawed from the other side, to the side that's been presented so far by industry. Flawed as it is, the one-in-a-million risk assessment that stands now must stay in place until something better is developed.

First of all, I would say that the risk assessment is an art rather than a science, and that the assumptions you begin with will determine the results you get. That difference-- Those differences in range of risk could vary anywhere from 1 to 10,000 times based on how you start it. So it's really an art, not a science.

Number two, people so far have spoken about one-in-a-million and it's relationship to cancer. Cancer is not the only problem that people experience from exposure to toxic chemicals. There are reproductive problems; there are nervous system problems; there are immune system deficiencies. The one-in-a-million risk as it stands now looks only at cancer. It only looks at one chemical at a time, and the toxic soup we have out there -- the high levels of air pollutants, water pollutants, and soil pollutants-- To only look at one chemical at a time and deal with it in that way is flawed. To only deal with one pathway of exposure--

Usually, when determining a risk assessment, they are not talking about the possibility of eating it, breathing it, and drinking it, and how that would all combine within a person. The person that is used as the baseline for judging is a healthy male. Okay, we have lots of people in our society who are not healthy males that are between -- white males -- between the ages of 25 and 40. We have populations that are more environmentally sensitive. We have senior citizens; we have children; we have people who already have respiratory ailments; we have people who have other kinds of problems. To only focus on a healthy male gives you -- is making this the one-in-a-million -- is even not making the one-in-a-million stringent enough.

Because of these variables, the current risk levels that we have right now -- the one-in-a-million -- is as minimally protective as we can be. It has to serve as a surrogate for everything else, because the things that I mentioned are not even included in the equation when dealing with whether or not a remediation project has reduced the risk to that level of one-in-a-million. They're not looking at the extremely sensitive populations. They're not looking at more than one chemical at a time. They're not looking at multiple--

DR. GALLO: One minute.

MS. HOFFMAN: --pathways of exposure. They're not looking at other illnesses besides cancer. So when we start to believe that what we're doing at one-in-a-million is actually identifying a real risk, I mean, we're getting into some trouble here. It's my concern that we need to stay minimally protected by holding onto the standard.

I'll wrap up with telling you what I would suggest, and, again, this will be coming to you in greater detail later on. A multiexposure risk assessment examining all routes of exposure -- that looks at more than the toxic chemicals impact on cancer, but looks at other diseases. In the meantime,

rather than explode the standard and leave it up to the chemical industry to determine on a case-by-case basis what is in their best interests economically, and not what is in our best interests as far as public health, I think is doing a real disservice to the citizens of New Jersey and the citizens of the country. (timer beeps)

DR. GALLO: Thank you. Great timing.

MS. HOFFMAN: Right on the dime. Thank you.

DR. GALLO: Thank you. Let me get the last note down here.

The next witness is Warren-- Is it Favre? Faure, that's a U? (no response) Oh, okay. I thought that was a V. I'm sorry.

W A R R E N F A U R E, ESQ.: That's all right.

DR. GALLO: In Trenton they write wrong.

MR. FAURE: I want to thank the Commission for giving me the opportunity to present my comments. I've provided copies of my written comments to everyone on the Commission.

My name is Warren Faure, and I am offering my comments tonight as a resident of Middlesex County, New Jersey. I am also a practicing attorney and geologist who has spent many hours reviewing risk and exposure assessment guidance documents published by our government, as well as Senate Bill No. 1070 -- the reason we are here tonight.

When the Legislature passed Senate Bill No. 1070 last June, it set the State on a new remedial track for dealing with the environmental mistakes of previous generations; a path which would at once protect public health and the environment, while recognizing the limitations of our economy to pay for a return to an absolutely pristine environment. The Legislature, however, recognized that many of the final decisions should be made only after a thorough assessment of technical information had been completed. Thus, Senate Bill No. 1070 created

commissions such as this one, and mandated that the DEPE direct resources to study these issues before final decisions are made.

The APRC Committee -- the legislative Committee on the Assembly's side -- provided in the legislative history of S-1070 that the decision on the one-in-a-million cancer risk management level was "principally a policy decision," charged this Commission to review scientific evidence and make recommendations on what the standard should be, and more importantly in my view, recommendations on the methodology that should be used to reach the risk level established.

The methodologies used by the DEPE and EPA for calculating risk from exposure to contaminated media are full of what I consider to be redundant conservative assumptions. In the EPA's "Guidelines for Exposure Assessment," published in the Federal Register last May 29, the word conservative appears 14 times. While not every reference in the document is to a conservative assumption, the fact remains that conservatism plays an important role in the current protocols. In it's wisdom, the Legislature provided in the history of Senate Bill No. 1070 that DEPE has the authority to depart from EPA guidance if it or a party can show it is technically defensible to do so.

While I want a clean environment for my children, I do not want to spend the money for a Cadillac cleanup when a Volkswagen will accomplish the same goal: to reduce the risk from waste sites to a relatively safe level -- a level in line with the other risks in our life. The public needs to be made aware of the risks of these sites in comparison to other risks, which we all face from such everyday things as food and water. The public has been insulated from risk decisions in the past, and that needs to change.

I suggest that the Commission make every attempt to communicate its deliberations to the public, and seek a technically supportable middle ground.

Thank you.

DR. GALLO: Thank you very much.

Is there anyone else? (no response) We thought we might have a couple of other witnesses. Is there anyone else who has written testimony to follow that wants to take the five minute? (no response) I would prefer to have it that way.

If you have written to follow, it just, I think, makes it better for everybody. If you want to do that tomorrow, there is going to be a short witness list also. If you have some written testimony that you want to enter tomorrow, you can make the presentation tomorrow.

Okay. That was short and sweet. Thank you very much. I appreciate everyone for coming.

(HEARING CONCLUDED)

APPENDIX

Submitted by Donald E.

ISRA RISK MANAGEMENT STUDY COMMISSION TESTIMONY

March 10, 1994

OPENING COMMENTS

- I am the New Jersey Area Manager for Exxon Company, USA with primary responsibility for remediation activities at our former refining sites in Linden and Bayonne. I have also been a New Jersey resident for the past 23 years.

- I would like thank the Environmental Risk Assessment and Risk Management Study Commission for providing the opportunity for input to this important process. My comments are given both on behalf of my employer and as a concerned citizen of this state.

- We commend the New Jersey Legislature for the enactment of S1070 which offers the promise of becoming a model for other states and the federal government to follow as a common sense approach to industrial site revitalization.

- We strongly support the approaches provided for in this legislation which, while mindful of protecting the public health, call for efficient and timely cleanups and the elimination of unnecessary financial burden in remediating contaminated sites.

- Exxon is committed to responsibly addressing the environmental concerns which may exist from our historical operations and are hopeful that this legislation, the recommendations of this commission and enlightened regulations will provide a sensible framework for discharging these responsibilities.

KEY MESSAGES

- While S1070 provides an excellent foundation for achieving this goal, a significant challenge remains largely in the hands of this commission, the challenge of bringing COMMON SENSE AND REALITY TO ENVIRONMENTAL RISK ASSESSMENT.

  To assist in meeting this challenge, there are three key recommendations that I would like to offer to the commission:

  - FIRST, we encourage the commission to adopt SENSIBLE, alternative incremental risk levels of one in ten-thousand and one in a hundred-thousand for individual contaminants based on their known carcinogenic nature.

- SECONDLY, we encourage the commission and the NJDEPE to strictly adhere to the spirit of this legislation and require REASONABLE AND NON-REDUNDANT exposure assumptions in deriving generic cleanup standards.

- THIRD and finally, we ask the commission to advise the legislature and the NJDEPE to ACCEPT valid, NEW DATA and STATE-OF-THE-ART methods both for periodic updates of generic standards and for site specific risk assessments.

SUPPORTING COMMENTS

- I would like to expand on these recommendations. In reference to the first challenge, that of providing for SENSIBLE risk levels:

  - The commission should insist that risk based remediation standards, by definition, pass a "blush test" of reasonably comparing to the voluntary and involuntary risks that we as citizens of this state face every day in our private and working lives. These everyday risks far exceed a standard of one in a million.

  - By the same token, risk based remediation standards should reflect the weight of scientific evidence for causing cancer.

  - Contaminants not known to be human carcinogens should not be subject to the same low level of risk as contaminants known to be human carcinogens.

  - Risk-based standards should be based on known chemical-specific toxicity rather than unfounded generalizations. (For example, the toxicity of benzo(a)pyrene, should not be used as surrogate for all multi-ring hydrocarbons).

- With regard to our second recommendation, which asks for your diligence in ensuring that risk assessment methodology under ISRA is REASONABLE AND NON-REDUNDANT, we have many concerns:

  - We know that the natural rule-makers quest for conservativism ultimately leads to incrementally insignificant levels of risk reduction which add little to our health and safety while detracting from the economic health of our families, communities and state.

  - We know that well-intended and seemingly reasonable adjustments of one order of magnitude in risk "just to be sure" more often than not result in at least one order of magnitude in cost escalation:

  - As an example, while bioremediation at $20-50/ton may work to achieve a target of 10 ppm for oil contaminated soil, it is likely to be totally inappropriate at a 1 ppm level for heavier oils which could require soil incineration at $300-1000/ton.

- For large industrial areas such as exist along the Arthur Kill and other areas in our state, we are especially concerned that reasonableness prevail. Some of our specific concerns are:

  - That the potential risks associated with low level contamination at sites within these areas be kept in context with the surrounding environment.

  - That groundwater standards be likewise put into perspective, considering non-potability due to naturally occurring salinity as well as anthropogenic contributions unrelated to the industrial activities of the site.

  - That risk assessment factors reflect the true availability of contamination to industrial workers and the public. (For example, the bioavailability of contamination adsorbed in soil versus pure materials).

  - That risk assessment assumptions truly reflect industrial activity and daily worker exposure rather than the extreme assumptions often used. (Known variability in job function, assignments, responsibility and changes in employment do not support the common assumption of 40 hours a week for 30 years).

- Regarding our final recommendation to require the ongoing ACCEPTANCE OF VALID DATA AND STATE OF THE ART methodologies for assessing risk, we ask:

  - That the NJDEPE be encouraged to continuously use and allow the use of the most current data and methodologies to more appropriately represent calculated risk.

  - That responsible parties be allowed to present valid, newly available toxicity data for specific compounds to appropriately modify established generic standards.

  - That state-of-the-art distribution analysis tools be employed and allowed both in developing generic standards and for site specific risk assessments.

WRAP UP COMMENTS

- To summarize our three recommendations,

  - We encourage the risk assessment commission to give full consideration to reasonable incremental risk levels of one in ten-thousand and one in a hundred-thousand. We ask that arguments for more restrictive levels be subjected to a "blush test" of common sense, rather than blindly pursuing a course of zero risk at any price.

  - We also ask that the commission include specific comments in its report to the NJDEPE and the legislature that this same test be applied to the redundant exposure assumptions that tend to pervade existing methodologies for deriving generic cleanup standards.

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- Finally, we ask that the risk assessment commission support and recommend that the NJDEPE continue to accept new and valid data and state-of-the-art techniques for use in maintaining up-to-date generic standards and for site-specific risk assessments under ISRA.

- Thank you for the opportunity to provide input for this important effort.

April 1, 1987

To Whom It May Concern:

Enclosed please find an article entitled "Risk Assessments. A Community Perspective." I am sending it to you for inclusion in the hearing document produced after a series of hearings on the "1 in a million risk level" for contaminants at hazardous waste sites.

I would like the following statement to be included as an introduction to this article:

The following article was written by former Love Canal activist, Lois Gibbs, in response to frequent questions about the role of risk assessment in the siting of new facilities and the clean up of existing contaminated sites. The reason I have submitted it as testimony is that it summarizes the grass roots' communities' concerns about the inadequacies of the current system of risk assessment. Because of these inadequacies, it is <u>imperative</u> that the current "1 in a million standard" remain in effect to afford the most minimal protection, instead of being eliminated to allow the chemical industry to set the standards as <u>they see fit</u>.

Thank you for adding this article to your hearing document.

Sincerely,

Madelyn Hoffman
Director, Grass Roots Environmental Organization
P. O. Box 146
Flanders, NJ 07836

201-252-0797

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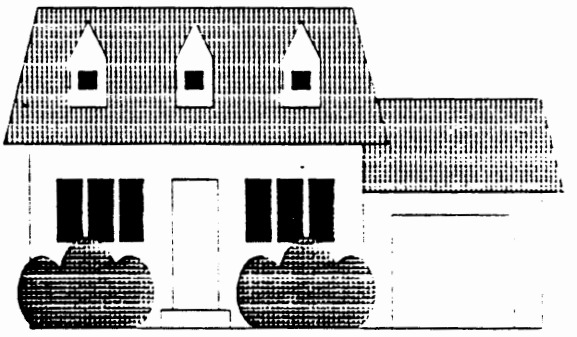
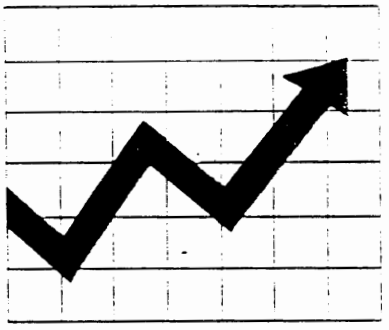
RISK ASSESSMENTS
A COMMUNITY PERSPECTIVE





CITIZENS CLEARINGHOUSE FOR HAZARDOUS WASTES
P.O. BOX 6806, FALLS CHURCH, VA 22040
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need for answers to the many questions now running through your mind. Has my child been harmed? Is his asthma (or constant earaches or skin rashes) caused by the chemicals? Will he suffer later as a result of exposure to this contamination? You want to hug your child but resist because you do not want to communicate your fears to him. You look at your home, which always gave such a sense of security. Now it feels like a trap, a threat, a place that could be poisoning you and your family has become a liability instead of an asset. You look to your spouse for comfort and help. But your spouse feels helpless. He does not understand the problem. He feels inadequate because he does not have enough money to move the family. He feels as if he has failed to protect his family.

This scenario is not that far from reality in communities faced with an existing toxic chemical problem or with a proposed facility such as an incinerator or a dump site. To such a community come the experts with their risk assessments. These risk assessments are presented as hard science, believable numbers, to the community. They are used as a tool to achieve an end point, a decision, which is a reflection of a certain set of values.

These values differ depending on where you sit and what you stand to lose. Since corporations and government hold the "power," it is their values and judgements that determine the outcome of a situation. The values of government or industry have to do with economics: how much money will it take to clean up a site or how much profit can be made if this proposed disposal facility is built. The values of the local community have to do with health, environment and the quality of life. Both sets of values are legitimate, but health and environmental effects are much harder to quantify than profits or cleanup costs. As a result, the community's values are not perceived as tangible or worthy, and that translates into a lack of respect for the values of the local families. This lack of respect is validated through the use of risk assessments that fail to consider health and environmental effects beyond cancer.

Recently, I asked to give a lecture on risk assessment to an evening class in a Maryland University. Most of the students were adults working in consulting firms in the Washington, DC area. I carried a large bottle of water to class. After speaking about Love Canal and other communities faced with environmental threats, I discussed the issue of trust briefly. Then I demonstrated how communities feel when asked to trust people whom they perceive to have different interests and values than they do. I described the bottled water as coming from a source that our government had tested and validated to be safe for human consumption. I also explained the water did contain some chemicals that at high doses could cause cancer, liver damage, and central nervous system problems. I reminded them that the government said the water was perfectly safe as I poured a small paper cup of water for each student and asked them to drink it. After a few awkward minutes, no one had touched their cup of water. When I asked why, no one would volunteer a reason. The reason was trust; they did not trust me.

Even though I am an environmental advocate, opposing the poisoning of people, these students could not trust me when I said the water was safe. In fact, the water had come from my kitchen tap and the toxic chemicals it contained were chlorine and fluoride. Even though I was perceived to be on the "right side" of the issue of protecting public health, that was not enough to gain the trust of these professional adults. How then can government or corporations gain the trust of local communities, especially when making decisions that will expose the community to involuntary risks?

Communities perceive many flaws in risk assessment. The first is who is being asked to take the risk and who is getting the benefit. From a community's perspective, risk assessments are "the risks that someone else has chosen for you to take." What is a life worth is the burning question, but equally important is whose life. Is, for example, the life of a professor who teaches at a university worth more than a farmer? These debates over risks usually are not occurring in communities where highly educated and affluent people live. People who are more affluent can chose to move out of a contaminated community or to buy organic fruits and vegetables while working class and lower income families have no realistic choices. Consequently, the people who are most often asked (or told) to bear the risks of a polluting industry or facility often have little ability to escape the

much does our chance of disease increase when our water is also contaminated "a little?" All of these exposures must be added, not treated as individual isolated exposures.

The most disgraceful use of risk assessments I have experienced was at Love Canal in Niagara Falls, New York. After the original neighborhood had been evacuated, and some limited cleanup had been carried out, the State wanted to determine if the Love Canal neighborhood was habitable, so they could resell the homes and resettle a new community in the area. The state used a risk assessment strategy that compared the air, surface water, ground water, and soils at Love Canal with two other census tracts within the City of Niagara Falls (3). If the levels of "indicator chemicals," which were 5-6 of the 250 chemicals found at Love Canal, were similar to those found in the control areas, then Love Canal would be declared habitable for resettlement.

This approach seems reasonable at first glance. However, the two census tracts chosen by the State were both contaminated with the same chemicals by the same corporation that dumped their waste at Love Canal. One control area was downwind of the corporation's incinerator, and the second tract was found to have barrels of waste from this company illegally buried beneath the surface. Despite vigorous protests, the State refused to use a control area in a nearby community that had no chemical industry. Not surprisingly, no significant difference was found between contaminant levels at Love Canal and the control areas. Therefore, Love Canal was declared to be habitable. But is it really? Comparing a rotten apple with a rotten apple and concluding they are the same does not indicate whether it would be safe to eat the apple.

Communities wonder why one of our important civil rights- to be treated as innocent until proven guilty- is extended to a chemical. Risk assessment reinforces the assumption that chemicals are innocent until proven guilty and exposed communities are simply hysterical until proven right. Communities feel that when there is doubt, public policy should be conservative and err on the side of protecting public health. When communities report an increase in childhood leukemia or birth defects, this is the health damage.

the face of these uncertainties. In fact, it was the lack of scientific certainty about the effects of low dose exposure that led to the development of the risk assessment process in the first place.

The scientists who carry out the risk assessments are often well aware of all the uncertainties (the problems of extrapolating from animals to humans or from adult male workers to the general population, the unknown shape of the curve in extrapolating from high dose to low dose, the uncertainty of the exposure numbers, the degree of variability among humans in response to chemicals). However, when the risk assessments are provided to others, the limitations of the process are ignored and the numbers are treated as truth or hard science rather than guesses. The experts using the risk assessments seem to have forgotten that the risk assessment process is an attempt to bridge uncertainties by making assumptions about real world conditions that may not be accurate. The greatest failure of risk assessment is that the experts have begun to believe that their numbers are more valid than the facts and conditions of a real life situation. Make no mistake, the risk assessment process is more art than science.

At the same time that governmental agencies are using risk assessment to assure us that chemicals are being managed and controlled, our ecosystem and public health are being damaged in many ways. The press warns us daily of declining productivity of the ocean and farmlands, of holes in the ozone, the global warming, of increases in many health problems such as asthma, infertility, attention-deficit disorder, ectopic pregnancies, and birth defects. We should not forget that the end result of a risk assessment is an opinion, not a fact, and those opinions may be wrong. Often risk assessments are used by polluters and government agencies to justify bad decisions that protect special interests. Risk assessments are used to justify dumping huge quantities of toxic chemicals into rivers and lakes and to justify leaving families in communities that are heavily polluted despite having statistically significant adverse health outcomes.

manufacturing processes and use small on-site advanced technologies for your wastes. Once you have done that, then come talk to us about what to do with the residue and what risks people are willing to take." Until that point is reached, community groups will work to stop every proposed hazardous waste site and every new incinerator.

What is acceptable for existing facilities?

What community groups want when faced with leaking landfills, polluted air, or contaminated water is full participation in the decisions that will affect their lives. They want a seat at the table, a voice in the decision-making process. What they want is old-fashioned democracy. Once the community has a seat at the table, then risk assessment may be one of the tools that they will use in coming to an informed judgement on the appropriate actions. But they will apply their common sense and intelligence to the risk assessment. Any acceptable one must contain the following elements:

1. The risk assessment must be concerned with the health problems that are experienced by the community. A risk assessment for cancer because that is what the experts know how to do is not acceptable when miscarriages are the problem.

2. The risk assessment must take into account exposure to multiple chemicals, which is the real life situation.

3. The risk assessment must take into account the chemicals that the community is exposed to in food, air, water, soil, and on the job. The risk assessments must be additive at the very least.

4. The risk assessment must take into account the most susceptible parts of the community: the pregnant woman, the babies and children, the elderly, the already sick.

Risk assessments as currently done fail to address these critical issues. As a result, they do not provide a realistic picture of the true health risks people living in contaminated communities face. At known contaminated waste sites people are exposed to hundreds of chemicals in low doses. Site

manufacturing industries, and to grow and process foods without heavy chemical usage. What is missing is the political will by our leaders, who hide behind risk assessments to justify decisions.

Groups that are part of the Grassroots Movement for Environmental Justice and other environmental groups are joining together to abolish the use of risk assessments and to change the way society deals with its wastes. We have blocked every proposed new hazardous waste dumpsite in America for the last 10 years, and we plan to stop every proposed incinerator during the next 10 years.

Once these inappropriate and dangerous methods of dealing with hazardous waste are stopped, then society will be forced to deal with waste in a more environmentally sound manner. This grassroots movement is also coalescing to protect the Delaney Clause, a 1958 addition to the Food and Drug Act that prohibits adding cancer-causing chemicals to our food. The Environmental Protection Agency wants to eliminate the Delaney Clause and replace it with risk assessment. During the next few years as this issue is being debated, a much larger segment of our population will become educated about the inherent problems of risk assessments. As a result of this new level of understanding, people will be motivated to act and their actions could significantly change and perhaps abolish the use of risk assessments.

References

1. Cerrel Associates, Inc. Waste to Energy. Report prepared for State of California Waste Management Board, 1984.

2. Eppley Associates. Report prepared for State of North Carolina on the issue of a site for a low level nuclear waste disposal facility, 1992.

3. New York State Department of Health. Love Canal Habitability, 1988.

Amoco Corporation
200 East Randolph Drive
Chicago, Illinois 60601-7125
Environment, Health and Safety Department
312-856-7865

Donald M. Barker
Director, Product Stewardship and Toxicology

April 8, 1994

FEDERAL EXPRESS

Michael A. Gallo, Ph.D.
Chairman
Environmental Risk Assessment and
Risk Management Study Commission
Legislative Office Building, CN-068
Trenton, New Jersey 08625-0068

Risk Assessment Methodologies

Dear Dr. Gallo:

Amoco Corporation, on behalf of its operating companies, appreciates the opportunity to comment on the use of risk assessment methodologies in the State of New Jersey as they pertain to the remediation of contaminated property. Dr. James D. Jernigan, Supervisor - Toxicology, Amoco Corporation, testified at the public hearing you held in New Brunswick on March 10, 1994. The comments provided below are intended to supplement Dr. Jernigan's oral testimony.

Although we were not directly involved in the preparation of comments submitted by the American Industrial Health Council, we have reviewed them and support them fully. Our comments provide additional support and address issues of particular concern to Amoco.

As you are aware, the science of risk assessment is being continually refined and improved. The fields of toxicology, pharmacokinetics, epidemiology, molecular biology, and others have made significant progress in improving our understanding of chemical substances. However, not all of these advances have been routinely incorporated into the risk assessment process. The knowledge gained from our experiences in conducting risk assessments, coupled with the scientific advances in the past several years, provide the opportunity to systematically improve the risk assessment process from a scientific and regulatory perspective, if given the chance.

It is essential, therefore, that a mechanism be developed to allow new data and scientific information to become part of the standard procedures used to assess chemical risks in New Jersey. In other words, risk assessment methodologies should be "evergreen". For example, risk assessors no longer have to rely on default assumptions for many exposure factors, such as soil ingestion rates, meteorological considerations, or

residency time, because a considerable amount of human and financial resources have been devoted to more precisely identifying realistic values for these factors. In this regard, it is important to note that a reliance on default assumptions is an admission of ignorance, not wisdom. In addition, the regulatory specification of simplistic default assumptions has a debilitating side effect--it arrests further inquiry.

It is very likely that, in the future, many of these exposure values will be revised, based on new information. The State of New Jersey would be best served if a mechanism was in-place to allow this new information to be incorporated into existing risk assessment methodologies, thereby permitting a more accurate assessment of chemical risk. Although the use of default assumptions has its place, such as, in screening-level assessments, regulations and guidance documents should embrace the use of site-specific information whenever it is available.

Refinements in risk assessment methodologies are not limited to exposure values. Concepts such as bioavailability, Monte Carlo simulations, multi-pathway analyses, and natural biodegradation of chemicals in various environmental media are being investigated throughout the world. With the appropriate mechanisms in place, the State of New Jersey would have the opportunity to enjoy the fruits of this research.

We appreciate the opportunity to provide these comments to the Commission. For additional information, please contact Dr. James Jernigan of my staff at (312) 856-3509.

EXXON COMPANY, U.S.A.
POST OFFICE BOX 728 • LINDEN, NEW JERSEY 07036

REFINING DEPARTMENT
SITE REMEDIATION

April 11, 1994

Environmental Risk Assessment and Risk
Management Study Commission
Legislative Office Building, CN-068
Trenton, New Jersey 08625-0068

Attention: Ms. Judith L. Horowitz and Mr. Raymond E. Cantor

Dear Ms. Horowitz and Mr. Cantor:

Enclosed please find 15 copies of written testimony by Exxon Company, U.S.A. for the Environmental Risk Assessment and Risk Management Study Commission in response to its current public hearing process. This written testimony builds upon the verbal testimony provided by Mr. Donald Esch, New Jersey Area Manager of Exxon Company, U.S.A. at the March 10, 1994 public hearing, and includes additional detail, examples and references.

We appreciate the opportunity to provide input to the Commission's efforts. If there are any questions, please contact me at (908) 474-6637.

Sincerely,

John E. Hannig
Site Remediation
Project Administrator

Via Courier
Enclosures

JEH:pa

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Draft #2, April 7, 1994

EXXON COMMENTS TO THE ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

April 7, 1994

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INTRODUCTION

The Governor s Environmental Risk Assessment and Risk Management Study Commission (the Commission) was established following adoption of the Industrial Site Recovery Act (ISRA). The Commission was charged with two tasks: 1) examine the scientific basis and applicability of a one-in-a-million (10^{-6}) incremental risk level for establishing remediation standards for carcinogens, and 2) examine methodologies of risk assessment and their efficiency and applicability for the purpose of establishing remediation standards under ISRA.

Exxon commends the New Jersey Legislature (the Legislature) for the enactment of ISRA which offers the promise of becoming a model for other states and the federal government to follow as a common sense approach to industrial site revitalization. We strongly support the approach provided for in this legislation which is protective of public health and which calls for efficient and timely cleanups and the elimination of unnecessary financial burden of remediating contaminated sites.

Exxon is committed to responsibly addressing the environmental concerns which may exist from our historical operations. We are hopeful that this legislation, the recommendations of this Commission and enlightened regulations will provide a sensible framework for discharging these responsibilities.

SUMMARY OF COMMENTS

- We encourage the Commission to adopt sensible, alternative incremental risk levels for deriving remediation standards for carcinogenic contaminants. Historical and current use of risk levels in regulatory decision making indicates that 10^{-6} is an insignificant risk level and is considered essentially zero or de minimus. Accordingly, a risk level of one-in-a-hundred thousand (10^{-5}) is the lowest level that should be used to determine any soil remediation standard. We support the use of a 10^{-5} risk level for setting remediation standards for known human carcinogens, as classified by the United States Environmental Protection Agency (EPA). A higher risk level, such as 10^{-4}, should determine the standards for probable or possible human carcinogens, as classified by the EPA. Alternatively, remediation levels for certain possible human carcinogens can be developed using threshold-based risk assessment procedures.

- We encourage the Commission and the New Jersey Department of Environmental Protection and Energy (NJDEPE) to strictly adhere to the spirit of ISRA and accept use of reasonable exposure assumptions in deriving generic remediation standards. For population-based exposure and risk estimates based on large numbers of people, such as the proposed remediation standards, we recommend use of median or mean exposure values selected from the best, most scientifically valid data.

- We recommend the Commission advise the Legislature and the NJDEPE to accept valid, new data and state-of-the-art methods for deriving alternate remediation standards under the site specific risk assessment provisions of ISRA.

GENERAL COMMENTS

A. Historical review of 10^{-6} as a regulatory standard

A review of the historical development of the 10^{-6} risk level was conducted by Kelly and Cardon (1991). The concept of using a specified level to regulate carcinogens dates back to a 1961 paper by two scientists with the National Cancer Institute, N. Mantel and W. Bryan (1961). For purposes of discussion, Mantel and Bryan assumed that a one-in-a-hundred million (10^{-8}) chance of developing cancer from exposure to a trace level of a contaminant in food, for example a herbicide in cranberries,

was equal to a "safe" level. No discussion of the public health significance of the 10^{-3} risk level was presented in the paper.

In 1973, in a proposed rule concerning residual levels of contaminants in food producing animals, the Food and Drug Administration (FDA) suggested that a risk level of 10^{-6} required no further action (FDA, 1973). The no further action level was raised to 10^{-5} in the final rule published by FDA in 1977. The 10^{-6} criteria adopted by the FDA in this rule-making applies to foodstuffs which are consumed by the general U.S. population.

In 1980, the Food Safety Council (FSC) also described the 10^{-6} value as "essentially zero" or de minimus for population-based food safety decision making (FSC, 1980).

In summary, a historical review of the origin and use of a 10^{-6} risk level in U.S. regulatory standards reveals several important conclusions.

- The 10^{-6} risk level has no scientific basis.
- 10^{-6} is an arbitrary number adopted as a policy decision.
- The 10^{-6} risk level was originally intended as a screening level of essentially zero or insignificant risk for food safety consideration.
- The 10^{-6} level was never intended as a compliance level.
- The 10^{-6} level was adopted for use in assessing population rather than individual risks.

Currently, the 10^{-6} risk level appears in numerous federal and state regulations and standards. However, as described below, higher or less conservative risk levels also appear in state regulations. Also, as described below, there is a trend toward moving away from the use of 10^{-6} as a single, or bright line, risk criteria for public health acceptability and towards less conservative and, in some cases, multiple criteria.

B. Evolution away from use of 10^{-6} as a bright-line criteria

Two authors have reviewed numerous risk decisions made by federal regulatory agencies, including the FDA, EPA, and the Occupational Safety and Health Administration (OSHA) (Rodericks et al, 1991; Travis et al, 1991). Several trends emerge from these analysis.

- Federal regulatory agencies recognize a population risk level of 10^{-6} as insignificant or essentially zero.
- Federal regulatory agencies have found lifetime risks to the general population greater than 10^{-6}, sometimes up to 10^{-4} as acceptable.
- Decisions made by federal regulatory agencies to regulate chemical carcinogens at risk levels between 4×10^{-6} and 1×10^{-6} were based on the size of the population exposed, technical feasibility and associated costs.
- The level of risk deemed insignificant for individuals is even higher, or approximately 4 in a thousand (4×10^{-3}).

A number of recent federal regulatory decisions highlight the shift away from use of 10^{-6} as a regulatory bright-line risk level. In the benzene National Emission Standards for Hazardous Air Pollutants

(NESHAPS) regulation, EPA used an incremental risk level of 10^{-4}. Under Superfund and the National Contingency Plan, EPA employs a risk range of 10^{-4}-10^{-6} (EPA 1990, EPA 1991).

C. Conservatism in the dose response procedures for carcinogens

To derive cleanup standards for carcinogens, as a policy decision, the NJDEPE uses EPA carcinogenicity slope factors (CSF). To derive CSF, as a policy decision, the EPA uses a model to extrapolate from very high doses in animals or high doses in humans to extremely low doses in humans. The model employed by the EPA is called the linear-at-low-dose multistage (LMS) model.

Use of the LMS model adds several orders of magnitude of conservatism to the risk assessment for carcinogens. Other low-dose extrapolation models (e.g., probit, logit, Weibell, multistage) produce less conservative risk assessments (Park and Snee, 1983; Klaassen, 1986). There is no scientific basis for selection between models. They differ only at low dose where no testing has been, or is likely to, be done.

As a policy decision, to calculate CSF, the EPA uses the 95% upper confidence limit (UCL) from the LMS rather than the maximum likelihood estimate (MLE). Use of the 95% UCL rather than the MLE, alone, adds a significant amount of conservatism. The amount of additional conservatism added by use of the UCL differs for different carcinogens/data sets. For example, for methylene chloride, the difference between the 95% UCL and the MLE is less than an order of magnitude. However, for formaldehyde, this difference is several orders of magnitude (AIHC, 1985).

UCLs from various low-dose extrapolation models can differ more than 6 orders of magnitude even when the most likely estimates generated by the models are within a single order of magnitude (AIHC, 1985).

As a result, the decision by NJDEPE to use EPA CSF to derive remediation standards for carcinogens introduces several orders of magnitude of additional conservatism to the standards.

D. Weight of evidence and risk levels

Various regulatory groups, including the EPA and the International Agency for Research on Cancer, use a weight-of-evidence approach for classifying the carcinogenicity potential of chemicals. To classify chemicals using this approach, the strength of the available data in humans, animals, and other test systems are evaluated. The current EPA weight-of-evidence groups are as follows:

Group A: Known Human Carcinogen
Group B: Probable Human Carcinogen
Group C: Possible Human Carcinogen
Group D: Not Classifiable as To Human Carcinogenicity
Group E: Evidence of Non-Carcinogenicity for Humans

There is a strong trend within federal regulatory agencies to link the weight-of-evidence classifications, or groups, to the risk level used for setting environmental standards. For example, in deriving Corrective Action Levels and Reference Air Concentrations under the Resource Conservation and Recovery Act (RCRA), the EPA uses different risk levels for different groups of carcinogens (EPA 1989, EPA 1991b). Similarly, in ranking the potential hazard of superfund sites, the EPA uses different incremental risks for different groups of carcinogens. This approach has also been used in numerous state environmental regulations.

We encourage the Committee to recommend that the Legislature assign different risk levels for different groups or classes of carcinogens, according to the EPA weight-of-evidence classification scheme as follows.

- To derive cleanup standards for chemicals classified as human (Group A) carcinogens by EPA, we recommend use of an incremental risk level of 10^{-5}.

- For chemicals classified as probable (Group B) or possible (Group C) human carcinogens, we recommend use of an incremental risk level of 10^{-4}.

- For certain group C carcinogens, a threshold-based risk assessment procedure is recommended. For example, Reference Doses derived by the EPA may be appropriate for certain group C carcinogens.

These recommendations are discussed in more detail in the paper entitled "One in One Million Risk; A Reasonable Basis for Policy" (Whysner, 1994).

E. <u>Use of reasonable exposure assumptions in deriving generic soil remediation standards</u>

Development of minimum remediation standards under ISRA requires the NJDEPE to use "reasonable assumptions of exposure scenarios as to amounts of contaminants to which humans will be exposed" and to "avoid the use of redundant conservative assumptions." A few exposure factors used by NJDEPE to derive draft remediation standards represent median or mean values. However, most of the exposure factors used by NJDEPE are at the extreme conservative end of the known range of values (Gephart et al., 1994) (Table 1).

An alternative approach to the use of conservative default exposure factors is to use probability distributions of these factors to establish a distribution of remediation standards. The use of a distribution allows the risk manager is allowed to make a more informed decision concerning the range and public health significance of the possible risks.

Use of a probability distribution approach reveals several critical issues when multiple conservative default factors are linked. First, standards derived using multiple conservative default factors are at the extreme end of the distribution of possible standards (generally at the 99 percentile or greater). Second, the standards are hundreds to thousands of times more conservative than those derived using median or mean exposure factors (Gephart et al., 1994). Thus, use and linking of multiple conservative exposure factors adds several orders of magnitude of conservatism to the standards.

We encourage the Commission to recommend that all current data on exposure factors be considered. Many of the factors employed by the NJDEPE are from the EPA Exposure Factor Guidebook. Recently, in response to a tremendous amount of new data on exposure factors, the EPA has announced their intention to update this guidebook (Wood, 1993). The new data on exposure factors should be considered by the NJDEPE. Following a critical review of all available data, only the best, most scientifically valid data on exposure factors should be used for establishing remediation standards.

The draft remediation standards promulgated by NJDEPE are based on potential exposures to millions of individuals. Therefore, for these population-based standards, we recommend use of values derived from a measure of central tendency of exposure factor distributions (the mean or median), rather than extreme values. Medians are preferred since they minimize the impact of extreme values which may be present in the distribution. However, mean value are also considered as "reasonable" values. Such values appear in the attached Exposure Factor Manual (Gephart et al).

In summary, we encourage the Commission to recommend to the Legislature that NJDEPE strictly adhere to the mandate outlined in ISRA for using reasonable exposure assumptions for deriving generic remediation standards. For population-based exposure and risk estimates such as the proposed remediation standards, we recommend use of median or mean values selected from the best, most scientifically valid data.

F. Use of new and up-to-date data and methods to derive alternative soil remediation standards

Section 35 (f) (1) of ISRA allows for consideration of alternative soil remediation standards. "The use of an alternative soil remediation standard is based on: 1) physical site characteristics which may vary from those used by the department in the development of the soil remediation standards adopted pursuant to this section; or, 2) a site specific risk assessment."

Under section 35 (f) (1), "a site specific risk assessment may consider exposure scenarios and assumptions that take into account the form of the contaminant present, natural biodegradation, fate and transport of the contaminant, and available toxicological data that are based upon generally accepted and peer reviewed scientific evidence or methodologies."

In performing a risk assessment for large sites in industrial areas, we are especially concerned that reasonableness prevail. Some of our specific concerns are listed below.

1) The potential risks associated with low level contamination at sites within industrial areas must be kept in context with the surrounding environment.

2) Groundwater standards must be put into perspective, considering non-potability due to naturally occurring salinity as well as anthropogenic contributions unrelated to the industrial activities at the site.

3) Risk assessment outcomes must reflect the actual availability of contamination to industrial workers and the public. The bioavailability of contamination adsorbed in soil may be quite different than the bioavailability of the pure materials.

   For example, recent data show that the potential risk to humans from dermal exposure to benzo(a)pyrene contaminated soils is significantly less than would be predicted using the conservative assumption of total absorption (100%) (Roy et al., 1992). Similarly, the type of soil affected the oral absorption of soil-adsorbed benzene (Turkall et al, 1988) and the dermal absorption of xylene (Skoranski et al, 1989).

4) Risk assessment assumptions must reflect industrial activity and daily worker exposure patterns rather than the extreme assumptions often used. For example, the known variability in job function, assignments, responsibilities and changes in employment do not support the common assumption of 40 hours a week for 30 years (Bureau of Labor Statistics, 1987).

5) Risk assessments must reflect recent toxicology data. Standards based on unfounded generalizations should not be used. For example, the toxicity of benzo(a)pyrene should not be used as a surrogate for all multi-ring hydrocarbons (Rugen et al, 1989).

6) High quality risk assessments provide information on the distributions of population risk. These assessments acknowledge that all members of a community differ in their daily activity patterns, their age, size, and amount of time they live in the community. Variability also exists in receptor intake rates and physiology. Accordingly, we encourage the Commission to recommend to the Legislature that state-of-the-art distribution analysis tools be allowed in site specific risk assessments.

In summary, we encourage the Commission to advise the Legislature and the NJDEPE to accept valid, new data and state-of-the-art methods for deriving alternate remediation standards.

TABLE 1

RECOMMENDED VERSUS DEFAULT POINT EXPOSURE FACTORS

EXPOSURE FACTOR	RECOMMENDED POINT VALUE[a]	VALUE USED BY NJDEPE	DATA QUALITY
Adult body weight	72 kg	70 kg	High
Child body weight	13 kg	11 kg	High
Weekly hr at work	23 hr	40 hr	Moderate
Working tenure	4 yr	25 or 30 yr	High
Weekly hr at home/away - adult	108 hr home 60 hr away	168 hr	Moderate
Weekly hr at home/away - child	138 hr home 30 hr away	168 hr	Moderate
Yr at one residence	8.1 yr	25 or 30 yr	High
Adult soil ingestion	0.01 mg/d	100 mg/d	Low
Child soil ingestion	16 mg/d	200 mg/d	Moderate
Adult water intake	1.4 L/d	2 L/d	High

[a] Recommended point values represent measures of central tendency (median, mode, mean) from the best available source(s) of data. Data sources are cited in the text of Gephart et al., Exposure Factor Manual.

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April 7, 1994

VIA FEDERAL EXPRESS

Environmental Risk Assessment
and Risk Management Study Commission,
Legislative Office Building
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Trenton, NJ 08625-00068

Attn: Judith L. Horowitz

Re: Comments on One-in-a-million Standards under ISRA

Honored Members of the Commission:

I. Introduction:

Thank you for the opportunity to provide comments.

I am a member of this firm practicing in our environmental and business departments. I am not a scientist; therefore I am not competent to provide expert advice on purely scientific issues. As a lawyer, I am competent to provide insight on laws, their underlying policies, their application and their effects. Much of my practice is in the environmental field. As a result, I have worked with many environmental scientists and experts, I have worked with and observed environmental regulators, and have worked for and with the regulated community. I was fortunate to have testified in the State Senate and Assembly on ISRA on behalf of NAIOP. I have also acted as special environmental counsel for an independent government authority. I have worked with NJDEPE as a member of NJDEPE's advisory Committees on ECRA and Site Remediation. These experiences enable me to make some observations on the interplay of the law (as written in ISRA and as applied by NJDEPE) with

science. I also have a family and live in New Jersey and thus have a personal stake in living in reasonable safety.

I attended your March 11 hearing at NJIT in Newark. I was pleased to see the breadth of comments and suggestions, but I am concerned that some issues may be less obvious and may therefore receive less attention. I provide my thoughts in the hope that they may prove useful.

II. Definition of Commission's task:

In ISRA the Legislature tentatively ratified NJDEPE's approach of calculating objective numeric cleanup standards through formula using allegedly reasonable assumptions and objective representative "data" to reach a maximum acceptable risk of one-in-a-million. The one-in-a-million standard can be viewed as an icon, representative of the standard itself together with the underlying calculations, assumptions and data, and the practices and approaches required by NJDEPE in New Jersey to assess whether a site meets the standard. All of these elements are equally relevant to the scientific significance and validity of the one-in-a-million standard. The New Jersey Legislature seeks the guidance of the Commission on the validity of this icon.

In determining the scientific validity of the standard, the Commission must seek to understand the practices surrounding the use of the one-in-a-million standard. If the practices are in error, the standard may be the wrong one for use by the Legislature. For example, a thermometer may be a valid instrument for determining temperature - but it won't work for air speed, certain thermometers won't measure certain temperatures, all thermometers must be used correctly to obtain valid assessments and, if misused, the results determined on the basis of the invalid assessments cannot be assumed to be correct. One could examine whether a thermometer is a scientifically valid instrument or the best instrument for a particular task if used in a particular way (analogous to the Commission's task of determining whether the one-in-a-million standard is scientifically valid or the best standard for remediation of past discharges). Simply stating that it is a valid instrument would be misleading.

While the one-in-a-million standard is not an instrument per se, here the Legislature proposes its use as an instrument of political and legal policy. (While at first blush comparing centigrade or fahrenheit standards to the one-in-a-million standard might seem a better analogy, it should be clear that

that comparison is not appropriate precisely because there is universal acceptance of their definitions, utilization and measurement; further the best analogy would be whether or not a particular temperature will or will not be a problem, just as the real issue is whether or not one part per billion of di-ethyl-methyl-bad-stuff is or is not a problem - all analogies break down somewhere). Many issues similar to those outlined with regard to the use of thermometers are presented by NJDEPE's requirements surrounding the use of cleanup standards they have calculated. The Legislature needs to know whether NJDEPE's chosen path is the right one, the only one, the best one- is it scientifically necessary to go so far? NJDEPE and some in the environmental community have argued that the one-in-a-million standard is scientifically required. Your Commission exists to advise the Legislature without passion or political agenda whether scientifically NJDEPE was right.

III. Observations:

1. Key elements of risk formula: Examination of risk without accounting for rewards and benefits (as one formula) and costs (as another) will necessarily result in bad decision making, both as a matter of policy and science. Similarly other factors commonly considered in toxicology must be evaluated as part of the process of deciding when and how to investigate and remediate a site. Considering these factors, one-in-a-million risk may be far too conservative.

1.1 Rewards & Benefits: All human activity involves risk. Accompanying those activities are rewards or benefits. To prohibit or regulate risk without a better understanding of the benefits to be obtained, and the loss of benefits that may accompany the prohibition or regulation may, in hindsight, prove to be a serious mistake. ISRA happened precisely because the Legislature recognized the possibility that New Jersey's aggressive environmental strategy of the 1980's had undermined, more than the environmental gains justified, New Jersey's economy.

(a) Associated with risk-creation:

(i) Without trying to divert from the central point for too long, I note that our transportation system carries with it known and measurable costs and benefits. Yet, interestingly, although we regulate transportation heavily, we limit regulation at a point that continues significant risks and measurable human losses. For example, we make choices in the design of our roads (we allow 55-65 mph speeds, even though statistically that design

allows a certain measurable risk), traffic signals (we don't put a light on every intersection, nor do we design every intersection as a cloverleaf to avoid the use of traffic lights), and police activities (we don't put a policeman in every car; we don't test every driver every day for drunk driving). As a society we draw the line, among other reasons, because there is a real benefit to the transportation system that is important to us.

It would not be difficult to economically estimate the losses to society from the many accidents and injuries related to our choices (although admittedly far more difficult to weigh the intangible pain and suffering of the individuals and their families). Nor would it be difficult to weigh the considerable advantages obtained by the sophisticated and flexible transportation system our country has fostered (although admittedly more difficult to measure the intangible benefits in human pain and suffering avoided by the ability to quickly deliver goods, services, medical treatment and supplies, and intangible benefits obtained such as greater freedom to live where one chooses, or to share in greater experiences such as education, the arts or nature, all through the sophisticated system). Those losses or risks may in the abstract exceed our one-in-a-million standard, yet they are accepted in exchange for the benefits received. While many less risky alternatives might be available, there is little doubt that our present choice for the transportation system is justifiable.

(ii) All life pollutes. The very existence of the mass of human beings on this planet strains its resources. The laws of entropy apply to our very existence. One way to reduce the strain significantly would be to eliminate or reduce humanity, an obviously unacceptable alternative. The more realistic approach is to search for a balance of conflicting goals, recognizing the existence of limited resources, achieving measurable benefits with an understood loss of other values.

Some argue that pollution has no benefit and, therefore, any cost is justified if any risk is reduced by any amount. I think this is too simple a statement. Historically, we accepted many benefits of our industrial society (including a better transportation system) and one of the long-term costs, regrettably, has proven to be an environmental cost. We now better understand and regulate this cost. We seek to avoid further deterioration in our regulation of new products and operations. Society also seeks to remediate past pollution in order to

achieve justifiable levels of ongoing risk (i.e. to the right standard, for the right benefits and at the right costs).

(b) Associated with risk-reduction:

(i) Similarly at issue is whether we are prepared to accept the cost of environmental regulation (the loss of economic benefits associated with lost business ventures in New Jersey and application of scarce economic resources to pay remedial costs) in order to attain the benefits of such regulation. The question must be asked- "What benefits?" Unlike our transportation system, there is surprisingly little evidence of demonstrable benefits obtained from the expenditure of vast sums of moneys for remediation of past discharges proportionate to those costs. Although NJDEPE often argues otherwise, it should be clear that the mere fact of money having been spent and contaminants reduced is not a demonstrated benefit. There is considerable doubt as to whether we are in fact more safe by this expenditure of remediation dollars, whether actual lives have been saved and whether expenditures of dramatically lower amounts might have achieved equivalent or otherwise justifiable levels of protection.

The obvious benefits of environmental regulation come from regulation of new or ongoing discharges to air and water and related operations. Also, there have been inactive waste sites that needed immediate attention to prevent catastrophic releases, or control and prevention of continued releases from significant sources. Importantly, those are not the sites that have involved the vast bulk of expenditures of concern for investigation and remediation under ISRA. Resolution of those sites has not been dependent on establishing the right soil or water standards. In many ISRA/ECRA cases, once the major and obvious contamination sources have been controlled, cogent arguments can be made that through the effective use of engineering and institutional solutions, exposures to remaining contaminants can be so reduced that actual risks are negligible. If this is correct, and I believe it is, why require expensive investigations, analyses, arguments, meetings, reports and often meaningless remediations (e.g. investigations and remediations of volatile organic contamination of aquifers from which no one drinks)?

Regulators and environmentalists engage in a search for reductions in risk to the lowest possible level, calculated on a hypothetical basis. They are willing to conclude that any reduction in hazardous substances must always be "safer" than the existence of a higher number. More pristine is better than less

pristine. It is difficult in the abstract to argue they are wrong, but on that logic all costs will be justifiable, no matter how little the risk. The standard to be applied must consider whether the benefits outweigh the cost- it must be a balancing test. If no weight can be measured on each side of the equation, the standard cannot be meaningfully applied. At present there is an assumed benefit from remediation to the one-in-a-million standard, with little supporting evidence. I believe in such circumstances high costs should be avoided, particularly when more reasoned assumptions support less stringent standards, investigations and remediations as providing substantial benefits with the incremental cost increases to reach more stringent standards providing disproportionately lower gains.

1.2 Costs & Scarce Resources:

(a) Despite the bias of regulators to the contrary, I conclude that not every risk that can be identified must be eliminated. As discussed above, the benefits from risk-reduction must be considered. But even when costs to remediate may be justified as against the benefits to be gained, some risks will be left unremediated. Life involves a series of choices. Society lacks sufficient resources to eliminate all risks, even those that are unaccompanied by sufficient benefits. Science recognizes that costs and resources must be considered in the formula of when and how to deal with many risks. Sometimes costs are considered as a matter of prioritizing which risks to deal with (sometimes to be dealt with in order, sometimes not to be dealt with ever); othertimes it is considered as a matter of selecting among various choices for remediating risks, reducing risks or even accepting risks.

I believe it to be unscientific and irrational to say that all one-in-a-million risks, one-in-a hundred-thousand, one-in-ten-thousand, one-in-a-thousand or even one-in-hundred risks from pollution must be eliminated without regards to the costs. The costs of such an approach for remediation would be astronomical. I conclude that society can, would and should accept many risks that could exceed NJDEPE's chosen standard because the relative costs and risks of the remedy are not justified by the benefits of the risk reduction.

I have been advised that NJDEPE's own calculations suggest that there are real world exposures in New Jersey from background natural and man-made exposures to contaminants that exceed the one-in-a-million standard. Indeed it is my

understanding that background radiation risks may exceed one-in-a-hundred risks. Presumably steps can be taken to deal with these risks. The costs of taking those steps may be appropriate for the benefits. Yet we have not done so. Why? And whether the decision to ignore such risks is right or wrong, should society spend so much on the assumed risks involved at so many of the New Jersey sites now under investigation? Our lack of concern for such calculated risks confirms that we do not really want or need the high level of imagined risk-reduction sought through adoption of the one-in-a-million standard, or alternatively we are wastefully diverting energies and resources from more serious problems (such as radon in homes).

The process of evaluating whether a site is or is not "clean" should proceed similarly. The actual expenditures required to be made in order to pursue a strategy of reducing risk by investigation and remediation should be weighed against the benefits to be obtained from the project itself. Frankly the field of environmental investigation and remediation regularly challenges my sensibilities of how best to use resources. I believe NJDEPE should objectively inquire: are the dollars for the effort being spent appropriately to protect against our most important priorities of health, safety and the environment? Could more be gained by approaching the problems differently, with a better sense of priorities, and a recognition that there are many ways to spend a million dollars, some of which will better protect important goals, and others of which will be wasteful?

Since there are not unlimited resources to do everything, one cannot conclude whether imposition of a one-in-a-million standard is scientifically justified without considering whether the money could accomplish more meaningful and measurable benefits if spent elsewhere. In the larger sense it is appropriate to consider whether those same dollars might be best spent by treating radon risks, researching cancer cures, reducing tobacco smoking, treating water supplies, or eliminating exposures at superfund sites?

(b) Consider also that those in business in New Jersey legitimately fear the result of a future examination of their activities in the harsh light of NJDEPE's search for ideal risk reduction without adjustment for costs or benefits and regularly consider whether to make new investments in New Jersey. Some choose to go elsewhere and the accompanying loss of benefits must be seen as a cost of our environmental policy. As jobs are lost, and our economic health is impacted, it is my understanding that

there is a direct measurable adverse impact to human health brought about by the stress to the affected individuals and families and society's loss of scarce resources (reduced taxes) to provide social services. The loss of business to less conservative jurisdictions is not compelled by any scientific imperative: the citizens of those locales are not less protected than the citizens of New Jersey.

1.3 Risks of Remediation: Interestingly, rarely accounted for in the NJDEPE's assessment of risks are the risks of actual injury or death associated with the remedial process itself. NJDEPE is all too willing to assume that with proper care, worker safety is assured, while making opposite assumptions as to exposures to the contaminants themselves. While I know of no easy way to calculate the matter, I suspect that there have been significant injuries, and perhaps fatalities, from the construction, excavation, demolition and related activities associated with the investigations and remediations conducted under CERCLA, Spill Act, ECRA and Underground Storage Tank programs in New Jersey. Similarly, considering the many miles traveled by trucks carrying debris removed from such sites there are likely a statistically significant associated number of accidents, injuries and perhaps deaths. I am uncertain of whether the hypothetical risks eliminated by the remediations justified the actual injuries so caused.

Similarly, NJDEPE excludes from its risk calculus the reality that any remedial strategy that moves contaminated soils from one location to another creates future risks for the day when the new landfill leaks.

If all of these risks were included in the calculation of whether particular levels of contaminants could be left unremediated, I suspect much less soil would have been removed over the years. Can science require the use of the one-in-a-million risk standard without accounting for the other risks associated with adoption of that standard? I think not.

1.4 Dose, Pathways & Exposure: I will rely on the remarks of those more competent than I to note the relevance of dose, pathways and exposure as concepts of risk analysis, particularly when evaluating rewards/benefits and costs. Although NJDEPE gives some consideration to the concepts, many experts with whom I have been associated have often been frustrated by the lack of real application of the concepts by NJDEPE in its decision making.

1.5 In order that I not be misunderstood, I emphasize that I do not urge a return to the days of unregulated discharges. Nor do I urge that industry be immunized from liability for their breaches of legal duties. Remember that at all times the State and third parties retain the right to sue for their actual damages to person and property from improper pollution. Also at present NJDEPE is armed with appropriate laws and enforcement powers to prevent the creation of new problems. But New Jersey's investigative and remediation system is not about actual damage, it is about deciding to what level and with what procedures to remediate sites strictly without regards to fault or actual harm. NJDEPE has chosen to use hypothetical risk calculations hypothetically reducing risks to one-in-a-million. I do not think that is the right approach.

2. When is enough, enough?

2.1 Once NJDEPE adopts a standard of clean, one of the major friction points between regulated and regulator is the quest for sufficient data to assess whether a site meets the standards and whether a particular remedial strategy is adequate. NJDEPE's formula and practices use the most stringent standards calculated for all exposure pathways, whether really present or not, to require expensive, time-consuming and comprehensive data collection, and often remediation. I believe that in many instances NJDEPE could have and should have greatly reduced this data collection effort because the benefits to be obtained were outweighed by the costs. (Like the hospital that allows temperature readings to be taken at a low frequency or by particular techniques notwithstanding the risk that something will be missed). This is a particularly troubling problem in the environmental sphere precisely because of the scientific and statistical problems inherent in the chemical analyses upon which so much decision making relies.

The Commission must consider this phenomenon in its deliberations of the appropriateness of the standard. While some hope that site specific standards or the use of engineering and institutional controls will provide considerable relief from stringent generic standards, NJDEPE's present practices reduce the value of that relief. The generic standard must be well chosen because the relief itself is difficult to obtain. When the standard is chosen NJDEPE will require ever increasing certainty that particular activities or events or conditions are within the acceptable risk standard. Yet is there ever enough data? NJDEPE's power to require increasing levels of certainty that an area is "clean" (i.e. that it is adequately "delineated"

horizontally and vertically) is the power to compel actual remediation (because business will prefer to spend dollars excavating a supposed problem rather than spend dollars testing for and arguing about a problem). An overly strict application of any overly strict standard will result in doubly wasted resources.

2.2 As part of any risk assessment process, scientists evaluate risks by considering the duration of exposures. The impact of duration is presumably accounted for in NJDEPE's formula. Less obvious is a recognition that timing of risk is relevant for consideration in the degree of risk that is acceptable. Many activities have both imminent and consequential long term risks arguably greater that one-in-a-million, but society tolerates (or embraces) these risks because of their benefits: consider the risks associated with our space program, drug testing, police enforcement, and military activities. We also routinely recognize that while studies may allow better understanding of costs & benefits and risks & rewards, the delays necessitated by such studies may cost more than they are worth through transactional costs, delays or denials of products to market, denial of needed benefits due to delays, and reduced innovation. Absence of certainty cannot justify the delays so routinely observed in NJDEPE matters; nor can it be used to be improperly conservative on the justification that one can never protect health, safety and the environment too much. That overly conservative philosophy can cost too much for the benefit, precisely because it diverts scarce resources from other activities.

3. Other concerns: While not expressly included in its mandate, the Commission must accept that its recommendations must consider ordinary human behavior as relevant to what standard or approach is right. But the Commission also must recognize the possibility, for good and for ill, that its opinion may have far ranging consequences on risk assessment outside the genre of remediation of contaminated sites.

We have already seen NJDEPE attempt to use its cleanup standards as relevant to the question of what products can be safely used as recycled products. Is that appropriate? Should macadam and concrete and fertilizer and pesticides be assessed in the same manner as contaminated soils? (I think not- the risk-reward formula is different). Indeed, should we consider the scientific validity of redesigning highways, cars and bridges so that risks from transportation are reduced to less than one-in-a-million? And what impact will such conservative thinking, in the

guise of science, have on the future of our culture (and indeed our science itself)?

Policy pronouncements of risk affect public perception and decision making. A statement that one-in-a-million is the scientifically right standard for remediation will necessarily tell the public that they are not safe if the risks are more than that standard. Is this really justified? I believe that by making such statements we encourage decisions motivated more by politics and bureaucratic processes than by science. Consider how politically driven publicity encouraged the public to become outraged by the solution, proposed in the Montclair radiation waste matter, of blending to reduce radiation risks and using soils outside on a baseball field (to eliminate radon risks) because in the abstract the public perceived the pollution and risk would still be there. Government publicized the contamination problem as being a threat to the point that the science of risk reduction became irrelevant and, I believe, $100 million were wasted. We cannot adopt a mere standard, or instrument (like a thermometer), without adopting the processes and practices that govern its use. You do not want to encourage NJDEPE to stand in court and testify, as they will, that the mere existence of 50 ppm of arsenic in soils is dangerous and poses a threat to public, health, safety and the environment. The Legislature and the public need to understand that the answer is more complex than establishing a simple risk level. We must focus on actual risks, not hypothetical risks.

IV. Conclusion:

I believe that the use of a one-in-a-million standard to generate cleanup numbers used by the NJDEPE as the basis for data collection and guidance for remediation decisions is flawed because it ignores most of the key elements of risk decision making discussed above. In essence the bureaucratic mentality adopts the numbers as a cult-like talisman around which all other decisions are mechanistically made. The correct approach recognizes that the mere existence of contamination is not automatically risky; risk must be analyzed based on exposure and dose over time using realistic assumptions. While copper and many metals are a hazardous substance, and copper pipe and coins are concentrated forms of those substances, few would seriously argue that there mere presence in a pocket, house, or yard is dangerous. Yet often NJDEPE's theory of investigating and remediating sites is based on mere presence of "contaminants" without regard to essential concepts of risk.

Paradoxically, I believe that although the regulated community must be allowed the option of focusing on site specific issues (costs, benefits, exposures, timing), the regulated community would benefit from the option of a defined set of numbers that, if they were used, would economically allow the investigation and remediation of a site with minimum oversight from the NJDEPE. Hopefully those numbers can be created without being too conservative. I do not know with certainty how best to calculate such "safe harbor" numbers, but I believe many toxicologists have proposed using more realistic formula and assumptions than used by NJDEPE to reach risk ranges of one-in-ten-thousand to one-in-a-million (depending on whether or not there is actual scientifically accepted data showing human carcinogenicity).

Thus, I recommend and urge that the Commission apply its best judgment and provide an opinion to the Legislature of how best to devise and use an objective set of numeric criteria that could be used without bureaucratic oversight of NJDEPE to investigate and remediate. If the approach that best succeeds is a one-in-a-million risk level using the NJDEPE's approach, then say so. But, if as I suspect, that approach is far too conservative and mechanistic, and some other objective approach succeeds better, than the Legislature needs the guidance that the Commission can provide. I believe the Commission should strongly suggest that the presence of levels in excess of the calculated "safe harbor" numbers does not mean that unacceptable risk is present, but rather might require a focus on site specific conditions and exposure pathways to build an understanding of real risks.

I further urge that the Commission comment on the extent to which NJDEPE's application of rules for investigation and remediation is or is not scientifically valid, necessary or advisable and justifiable on a cost-benefit analysis.

I would be pleased to provide further information to the Commission if it has any questions about these comments or the practices of NJDEPE, the regulated community or their respective experts and scientists.

I eagerly await your conclusion and opinion.

Sincerely Yours,

RICHARD J. CONWAY, JR.

Note: 15 Copies enclose

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April 11, 1994

Ms. Judith L. Horowitz
Aides to the Commission
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Legislative Office Building
CN-068
Trenton, New Jersey 08625-0068

Dear Ms. Horowitz:

Hoffmann-La Roche Inc. welcomes the opportunity given by the Environmental Risk Assessment and Study Commission to submit comments on the scientific basis for the selection of the risk level of an additional cancer risk of one in one million for the remediation of contaminated sites. Hoffmann-La Roche Inc. is also grateful to the commission for holding public hearings on the above subject.

Hoffmann-La Roche has reviewed, in depth, the comments prepared by the American Industrial Health Council (AIHC). Hoffmann-La Roche Inc. believes that it is a very comprehensive, scientifically-based document which analyses the current approach used by the New Jersey Department of Environmental Protection and Energy (NJDEPE) and provides alternate approaches to the risk assessment method utilized by the NJDEPE. Hoffmann-La Roche agrees in principle with the scientific basis provided in the comments by the AIHC.

Hoffmann-La Roche believes that the current method utilized by the NJDEPE is extremely conservative. Many times, the assumptions made by the NJDEPE are not based on real life scenarios because NJDEPE assumes continuous intake of material throughout the life time of a person in the risk assessment process. The NJDEPE also uses data from very high dose level studies and extrapolates to low level intermittent exposure in the risk assessment process. We believe that the quantitative risk assessment methodology is not a biologically meaningful approach for the extrapolation of a potential cancer risk. In our opinion, the minimum remediation standard for chemicals in soil should be determined on a case-by-case or site-specific basis by experts based on the appropriate biological data and the real-life exposure scenario, rather than an arbitrarily selected number such as 10^{-6}.

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Other factors, such as type of chemicals present, bioavailability of these chemicals, half lives of chemicals, type of land and its proximity to the general population, type of exposure, ultimate use of the reclaimed land, and current technology and remedial cost should be considered in the overall risk assessment process to determine the minimum remedial standard for chemicals in soil.

A one-in-one million cancer risk factor is used by the United States Environmental Protection Agency (USEPA) for cancer risk for a carcinogenic chemical ingested daily by the entire population of this country. In soil remediation, ingestion is not the route of exposure to the chemicals present, and only a limited population may have potential for exposure. In many cases, these chemicals may be tightly bound to the soil particles and exposure is unlikely to occur. Many State and Federal regulatory agencies have recognized these parameters and have often used different factors. Even a more "pro-active" state like California has often used 10^{-5} or 10^{-4} numbers in the risk assessment process.

In conclusion, we believe that the minimum remediation standards for chemicals in soil must be determined on a case-by-case basis and not on the basis of a one-in-one million cancer risk factor. If the NJDEPE must use some number, then we believe that 10^{-4} is a more realistic number for estimating the risk of chemicals present in soil.

Once again, thank you very much for giving me the opportunity to express our views on the minimum remediation standards for chemicals in soil.

Sincerely,

Theodore J. Berger

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Jersey Central Power & Light's Comments to the Environmental Risk Assessment and Risk Management Study Commission

Introduction

Jersey Central Power & Light Company (JCP&L) is pleased to provide comments to the Environmental Risk Assessment and Risk Management Study Commission (Commission). JCP&L feels very strongly that the importance of placing risks in their proper perspective is a critical issue facing society today. How successful we are in doing so will have a major impact on our ability to properly prioritize and utilize limited available resources.

The Commission requested input on three specific areas, the scientific basis for selecting a risk level of one-in-a-million for remediation of a contaminated site; alternative scientific standards and criteria; and risk assessment methodologies and their efficacy and applicability for setting remediation standards. These comments will address each of these areas in detail.

Scientific Basis for the Acceptability of a One-in-a-Million (10^{-6}) Risk and Alternative Criteria

The selection of an acceptable level of cancer risk is a societal decision and not a scientific one. In this regard, the acceptable level of cancer risk is no different from the acceptable level of any other risk, such as the acceptable level of work place safety, automotive safety or airplane safety. Thus, science cannot determine an acceptable level of cancer risk, but a historical review of the evolution of the "one-in-a-million" criterion can be informative and a discussion of regulatory precedents with regard to acceptable risk can place the "one-in-a-million" criterion in an appropriate context.

The Food and Drug Administration, which is responsible for guaranteeing the safety of the nation's food supply, originated the one in one million excess cancer risk level nearly two decades ago. In the 1970's, when the FDA was first regulating meat additives, they needed to determine a degree of risk that could be regarded as "essentially zero" for the U.S. population as a whole (i.e., about 230 million people) (Graham, 1993). In fact a "one-in-a-million" lifetime risk of

cancer in a population of 230 million people translates into 3 cancer cases a year. When compared to the actual number of cancer cases in a year (2 million), this number is inconsequential.

The "one-in-a-million" risk level continues to be the defacto standard used by some regulatory agencies. However, this choice seems excessive for many situations. There are few long term activities that have a lifetime risk of less than 10^{-6}. In particular, the lifetime risk of death from accidents is on the order of 10^{-3} for even the safest occupation, white collar workers (Milvy, 1986). Also, a recent investigation of risks due to background exposures to xenobiotics suggests that lifetime risk is on the order of 10^{-3} to 10^{-2} (Travis and Hester, 1990).

While the FDA precedent suggested that a "one-in-a-million risk is an acceptable level of risk for activities that can potentially expose the entire U.S. population (such as meat additives), other regulatory precedents suggest that the acceptable level of risk is inversely related to the population at risk. In particular, an excess cancer risk level of one-in-ten thousand has been deemed to be acceptable when small populations are exposed. This viewpoint is supported by the work of Dr. Curtis Travis and associates who in 1987 examined the basis for the most recent 132 health-based regulatory decisions made by the Federal government (Travis, 1987).

The regulatory decisions evaluated in Travis's study covered the broad spectrum of both public and occupational exposures for populations ranging from 9,700 to 230 million people. Dr. Travis found that where the estimated risk to a small population was less than 1 in 10,000, regulatory action was never taken. Conversely, for effects resulting from exposures to the entire U.S. population, the level of acceptable risk was often set at one in one million. Clearly, the size of the potentially exposed population, as well as the level of individual risk, is considered by public officials when making regulatory decisions.

Paul Milvy of EPA reached a similar conclusion when he evaluated the basis for regulating potential exposures to carcinogens (Milvy, 1986). His analysis suggested that the typical regulatory acceptable risk level is about 10^{-4} for populations between 1,000 and 100,000 people and 10^{-5} for populations between 100,000 and 10,000,000 people. Since the number of people who are likely to ever live or work on a former industrial or disposal site is relatively small (most certainly substantially less than 100,000), a risk level of 10^{-4} would therefore be appropriate.

A directive from the Assistant Administrator of the U.S.EPA's Office of Solid Waste and Emergency Response (OSWER Directive 9355.0-30), noted that "where the cumulative

carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}" then "action is generally not warranted" (Clay, 1991). These data are critical when examining the issue of acceptable risk levels for contaminated sites in New Jersey, since impacts from these sites typically affect a limited geographic area, where the total potentially affected population is small. These Federal decisions and directives also support the viewpoint that an appropriate risk for contaminated sites in New Jersey is 1 in 10,000.

Another major finding of the Travis study is that when the cancer risk is estimated to be between 10^{-6} and 10^{-4}, the primary determinant for regulation became cost effectiveness. A guidance document prepared by the EPA Deputy Administrator to EPA Regional Administrators on risk management, states that decision-makers should not be a captive of the numbers and should expect the same level of rigor from the economic analysis as they receive from the risk analysis (Habicht, 1992). Clearly, the EPA feels that cost is an important consideration in determining which levels of risk should trigger remedial actions. JCP&L believes that the Commission must closely examine the cost benefit issues associated with setting state wide standards.

In addition to the course set by the federal government, some states have recently modified the view that the one in one million level should be universally applied. For example, in Massachusetts (Massachusetts Contingency Plan 310 CMR 40.0902), a site is considered to pose no significant risk if the excess lifetime risk level is less than 1 in 100,000. Other states vary the acceptable risk level according to the carcinogenic classification of the chemicals detected (Texas) or the future use of the site. All of these initiatives by the states and Federal government help to illustrate that alternatives to the traditional one in one million risk level are now being incorporated into the policy making processes.

Based on the preceding discussion, JCP&L believes that a target risk level of 1 in 10,000 provides an adequate level of protection of human health in relation to contaminated sites in New Jersey. However, since there is more compelling toxicological evidence that some chemicals are human carcinogens, specifically the Class A carcinogens, it would be acceptable to JCP&L to provide an additional safety factor of 10 by setting the target risk level of 1 in 100,000 for Class A chemicals. A target risk level of 1 in 10,000 is recommended for Class B and C chemicals.

Review of Risk Assessment Methodologies

We would now like to turn the discussion to issues related to risk assessment methodology. JCP&L believes the regulated community would derive enormous benefit from a universal set of risk assessment methodology guidelines and we urge the Commission to develop these guidelines for all environmental media. Although much of the oral testimony regarding this issue has focused on the risk assessment methodology and issues associated with the development of surface soil standards JCP&L feels very strongly that the Commission must also evaluate appropriate risk assessment methodologies for subsurface soils and ground water.

JCP&L believes that establishing appropriate methodologies for obtaining subsurface soil and ground water standards are especially critical because, the establishment of an overly conservative risk assessment process for subsurface soils which may impact ground water, and ground water itself have equal or greater potential to impact the viability of remediating sites in a responsible and cost effective manner. For example, more than 50% of NJDEPE's proposed Subsurface Soil Cleanup Standards are lower than the proposed Surface Soil Cleanup Standards.

Although NJDEPE did not promulgate the Cleanup Standards for ground water proposed on February 3, 1992, NJDEPE has promulgated a set of regulations entitled Ground Water Quality Standards N.J.A.C. 7:9-6. These Ground Water Quality Standards are currently being inappropriately applied by the NJDEPE as defacto ground water cleanup standards for contaminated sites throughout New Jersey. These criteria were developed by the NJDEPE using the excessively conservative methodologies discussed above and employing a target risk level of 10^{-6}. In addition, as stated in the original Basis and Background document for the Ground Water Quality Standards, these criteria were developed to be "applicable to the protection of ground water quality outside the boundaries of permitted discharge sites and pollution cleanup sites." Consequently, they lack the appropriate scientific basis and the necessary flexibility for application to remediation sites.

The Basis and Background document for the February 3, 1992 proposed Cleanup Standards (7:26 D) contained the following statements demonstrating the planned relationship between the proposed Ground Water Quality Standards and the proposed Ground Water Cleanup Standards. "The New Jersey Ground Water Quality Standards regulate permissible discharges and set the goals for the quality of New Jersey ground water, they do not address whether active or passive means are used to reach the desired goals. The Cleanup Standards regulate the remediation of

contaminated sites." However, in addition to the proposed Surface Soil Standards, the Ground Water Cleanup Standards and Subsurface Soil Standards were not promulgated by the NJDEPE pending the outcome of the Industrial Site Recovery Act (ISRA). Clearly, the legislators as well as the NJDEPE expect the Commission to evaluate and recommend appropriate risk assessment methodologies to be used to determine subsurface soil (i.e. impact to ground water) and ground water remediation standards.

JCP&L further recommends that the Commission focus their attention on the excessively conservative methodology that is too often employed by regulators in risk assessments. JCP&L discussed this excessive conservatism in detail in our comments to the NJDEPE's Feb. 3, 1992 proposed Cleanup Standards (7:26 D). JCP&L feels that the NJDEPE's previously proposed approach to developing standards is overly protective and will lead to excessively costly remediations with infinitesimal impact on the incidence of cancer in the target population.

There are several major contributing factors to the excessive conservatism. First, the NJDEPE assumptions used to estimate exposure and toxicity were upper bound values. As a result, intakes are likely to be over predicted by at least an order of magnitude and toxicity values (i.e., reference doses and cancer slope factors) may over estimate actual toxicity by an order of magnitude or more. Consequently, the risk associated with a given cleanup standard (e.g., 0.66 ppm for benzo (a)anthracene in surface soil) is likely to be much lower than the target risk level of 10^{-6}, possibly on the order of 10^{-8} or 10^{-9}. The reason for this is because a 95th percentile target (the value at which 95% of the population will be below) can quickly become an unreasonably conservative 99.999 percentile when the above described redundant conservative assumptions are used.

An unfortunate outcome of using all upper bound exposure estimates (such as those used by the NJDEPE in developing their proposed Cleanup Standards) is that it leads to the regulation of phantom risks and the inappropriate diversion of scarce resources to insignificant problems. JCP&L does not believe that the excessive cost of remediation associated with the use of such a high percentile is an appropriate use of resources.

Suggested Alternative Methodology

JCP&L suggests the Commission recommend a tiered approach to setting remediation standards. The first tier would provide generic screening criteria for various media and land uses.

The second tier would employ a site-specific risk assessment. A critical element in both tiers is the methodology utilized in the risk assessment, whether generic or site-specific.

Tier 1. A Tier 1 evaluation involves a comparison of site analytical data with Tier 1 generic screening levels to be developed for various media. If none of the applicable Tier 1 screening levels are exceeded, the site would not require remediation. Tier 1 screening levels should be established based on conservative yet reasonable assumptions for all environmental media since they would potentially be applied to a wide variety of sites and circumstances.

In application of Tier 1 screening levels, it should be emphasized that these levels are not cleanup levels but rather levels where at least some additional study and possible remedial action should occur. Excessive risks due to elevated concentrations can be addressed by remediation methods which are designed to mitigate the potential exposure pathways (for instance, the installation of a cover system to prevent direct contact or, where warranted, remediation methods intended to reduce concentrations, such as, excavation and off-site treatment).

Tier 1 screening levels should also be devised based on the intended use of the property as mandated by ISRA. For example, Tier 1 screening levels for surface soils which are developed based on exposure assumptions for residential uses, should be applied only if either the current or anticipated future use is in fact residential. Former industrial properties that will be used in the future for industrial/commercial purposes should not be required to meet soil standards calculated based on improbable future residential exposures. It is totally unrealistic to establish one set of soil standards that would apply to both a residential and industrial setting. It is common sense, therefore, that industrial soil standards should be based on assumptions applicable to commercial/industrial exposure conditions. In addition, the development of Tier 1 screening levels for subsurface soil and ground water should take into account the actual, current or anticipated future use of impacted ground water beneath the site.

In order to help in the development of a reasonable standard setting process, JCP&L recommends to the Commission that the following elements be incorporated into the risk assessment methodology used to determine possible Tier 1 screening levels.

1) Background - The Tier 1 screening levels should not exceed background levels for naturally occurring inorganics. Background levels could be set as the 95th percentile of the distribution of background data, for example. Background levels could be determined

for different parts of the state to account for spatial variation in natural levels of compounds. For inorganics and organics that have numerous sources (such as lead or PAHs) background levels should reflect the ubiquitous and possibly anthropogenic nature of these chemicals. It is important to recognize the existence of both naturally occurring and anthropogenically introduced compounds because it is futile to clean up sites below these levels. The risk associated with background levels of naturally occurring compounds is a risk we must all live with. The reduction of anthropogenically generated compounds requires regional action. Without such regional action, the removal of such compounds from a site will lead, with time, to the gradual return of the chemical. Obviously such action is for the most part unrealistic and unnecessary, but these examples serve to illustrate the importance of recognizing background levels in developing standards.

2) Aerial Volume Considerations - One area of excess conservatism in applying cleanup standards is in assuming that all exposure on a site (in a specific medium) occur at locations where contaminants are in excess of the risk based criteria rather than assuming an exposure to the entire medium i.e., the average contamination level for a given medium. If an aerial average is not employed, but rather every location of a particular medium that exceeds a cleanup standard is remediated, the average areal residual concentration could be far less than a cleanup criteria, resulting in risk levels far lower than the target risk level.

3) Toxicity - The quantitative indices of toxicity used in health risk assessments (i.e., cancer slope factors and reference doses) are conservative estimates of the relationship between dose and response. The cancer slope factor, in particular, is estimated from animal data using the linearized, multi-stage model. There are many mathematical models that can be used to fit dose-response data, but the linearized, multi-stage model is used because it provides a conservative, linear relationship between dose and response at low doses. In addition to using a conservative model, the cancer slope factor is selected so that it provides an upper bound estimate of this critical parameter in the model. Thus, not only is a conservative model used, but a conservative estimate of this critical parameter in the model is also used. This whole procedure is so conservative, that the cancer risk estimated using the cancer slope factor may overestimate cancer risks at low doses by several orders of magnitude. To partially account for this conservatism, we propose that the Commission should recommend two actions. First, the Commission should recommend that the upper bound point estimates for the cancer slope factor be replaced with the probability

distribution that is developed for this parameter when the linearized multi-stage model is fit to animal data. When the distributions are used in a probabilistic analysis, the result will be a distribution of remediation standards, as opposed to a single value. This issue of probabilistic analysis is discussed in more detail in the section on Monte Carlo analysis. Second, toxicity equivalency factors published by the federal government for various compounds including polycyclic aromatic hydrocarbons and (PAHs) polychlorinated biphenyls should be taken into account. For example, the EPA office of Research and Development has issued a document titled "Provisional Guidance For Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons" which recommends the use of relative potency values for the carcinogenic PAHs. The basic assumption of this method is that not all of the carcinogenic PAHs are as equally potent at causing cancer as benzo (a) pyrene.

4) Exposure Assumptions - A major problem with the current practice of risk assessments is that conservative point estimates are used in the risk calculations. When several conservative exposure assumptions are combined (such as ingestion rate, absorption, exposure frequency and exposure duration), the resulting estimate of intake has an almost vanishingly small probability of occurring. Such an intake is unnecessarily conservative, overly protective, and it does not make sense that such improbable intakes should be the basis of a regulatory policy. A more reasonable approach is to replace upper bound estimates of exposure assumptions with probability distribution and use a probabilistic analysis to generate a distribution of intakes. This issue of probabilistic analysis is discussed in more detail in the section on Monte Carlo analysis.

5) Biodegradation and Chemical Transformation - There are a number of natural biological and chemical transformation processes that can reduce the concentration of a chemical over time. Biodegradation is one of the most important environmental processes that cause the breakdown of organic compounds. It is a significant loss mechanism in soil and aquatic systems. Other transformation processes that are known to reduce the levels of chemicals in various media includes: hydrolysis, photolysis, and volatilization. Because of these transformation mechanisms, the assumption that concentrations of chemicals remain constant over time is totally unrealistic. It is more realistic to assume a conservative level of transformation and assume that exposure occurs to the average concentration over the period of exposure, not the initial concentration for the entire duration of the exposure. For example, various studies have shown that the half life of benzene in surface soil ranges

from a few days to several months with an upper bound half life of 365 days. In an typical evaluation of residential exposure, the benzene concentration is assumed to remain constant at its initial value for 30 years. Using the upperbound half life of 365 days, virtually all the benzene would be gone in 30 years and the average concentration over this period of time would be 20 times lower than the initial concentration.

6) Bioavailability - Incorporation of the most recent information from empirical studies, on the bioavailability of various chemicals through either inhalation, oral, or dermal routes of exposure should be allowed. This is particularly pertinent for chemicals in soil. There are physical interactions of chemicals, such as matrix effects, that can reduce the release of chemicals from soil and subsequent absorption either across the gastro-intestinal tract or skin. The assumption that all chemicals are totally assimilated, despite compelling evidence to the contrary, provides a distorted evaluation of the chemicals which can mistakenly identify these chemicals as major contributors to site risks.

7) Monte Carlo Analysis - As discussed above, parameters in a risk equation (such as cancer slope factor, ingestion rate, absorption factor, exposure frequency, exposure duration and biodegradation rate) are often conservatively approximated as an upper bound value in risk calculations. The result is so conservative that it has a very small probability of ever actually occurring. Another problem with selecting upper bound values is that such activity is highly subjective and requires judgments about what is meant by upperbound for a number of parameters. To circumvent the issues of redundant conservatism, these point estimates can be replaced with probability distributions and the Tier 1 screening level calculated by carrying these distributions through a Monte Carlo or probabilistic analysis. The resulting screening level is selected as an appropriate percentile value in the resulting probability distribution. Monte Carlo analysis has two significant benefits. By replacing point estimates with distributions, a range of potential Tier 1 screening levels is generated. The characteristics of this range (e.g., the difference between the minimum and maximum value; the location of the expected value and median; the variance) are indicative of the uncertainty associated with the screening level. If the minimum and maximum differ by orders of magnitude, this suggests that a screening level set at the minimum is overly restrictive given our expectation about actual exposure. The second benefit of Monte Carlo analysis is that the input distributions used in the analysis are based on actual data. The risk assessors judgement comes at the conclusion of the analysis when a Tier 1 screening level is selected from the resulting distribution.

Tier 2. In addition to the development of appropriate Tier 1 screening levels, it must be recognized that an additional evaluation of potential risk may be warranted for more complex sites. A responsible party may determine that Tier 1 screening levels are not appropriate. In these cases, a responsible party should be permitted to use a Tier 2 approach, which involves performing a site-specific risk assessment and the development of site-specific remediation criteria.

A Tier 2 evaluation would involve a risk assessment that would identify and quantify the potential risks on a site-specific basis to the most plausible population groups based on the current and anticipated future uses of the site. A Tier 2 evaluation would then be used to identify the exposure pathways of concern and to calculate site-specific remediation criteria to be achieved by the remedial activities.

In a Tier 2 site-specific risk assessment an additional level of refinement is possible. The elements that should be allowed to be incorporated into a Tier 2 site-specific risk assessment should include those previously described for developing Tier 1 screening levels such as background and volume considerations, toxicity, biodegradation, bioavailability, and Monte Carlo analysis. However, because a Tier 2 analysis is site specific, site specific information such as receptor activity patterns, intrinsic biodegradation rates and bioavailability can be incorporated into the analysis. A number of organizations, including the Gas Research Institute and Electric Power Research Institute, are performing research in some of these areas. An outcome from this research could be methods for better determining site-specific and chemical-specific values for properties such as biodegradation rates and bioavailability fractions.

Conclusion

JCP&L suggests the Commission recommend a tiered approach to setting remediation standards. Tier 1 screening levels should be based upon conservative yet reasonable assumptions for all environmental media. Tier 2 would employ a site-specific risk assessment. In order for the result of the Commission's efforts to be truly meaningful, JCP&L strongly urges that key elements including Monte Carlo analysis, biodegradation, background and volume considerations, realistic toxicity indices and exposure assumptions and bioavailability be incorporated into the methodology used to establish such standards. Failure to carefully address these elements could

lead to a lost opportunity to effect meaningful reform in the development of realistically based remediation standards.

Although JCP&L believes that a target risk level of 1 in 10,000 will protect human health, we would support a more stringent risk level of 1 in 100,000 for Class A carcinogens only (given the toxicological evidence denoting them as known human carcinogens). A target risk of 1 in 10,000 is the most stringent level which should be used for Class B and C chemicals.

JCP&L greatly appreciates the opportunity to provide written comments and we offer our services to assist the Commission as it continues to work on this critically important process.

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Mobil Oil Corporation

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Judy Horowitz, Associate Counsel
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April 11, 1994

File: 13.0
ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY

Dear Ms. Horowitz:

Mobil U.S. Marketing and Refining, a division of Mobil Oil Corporation, appreciates the opportunity to submit comments on the development of minimum remediation standards for chemicals in soil. We would like to express support for the State of New Jersey and the Commission in their efforts to seek public input for this very important issue. Allowing a forum for open discussion of these issues will result in improved public policy decision making.

Within the State of New Jersey, Mobil owns a refinery and other facilities integral to the petroleum industry operations, including distribution terminals and service stations. Therefore, Mobil is extremely interested in this rule. Mobil is also committed to ensuring the protection of human health and the environment.

As can be seen from the attached comments, Mobil is very concerned about the imposition of an unnecessarily conservative standard for soil and subsoils in New Jersey. Mobil asks that the commission consider recommending that revisions to the subsurface soil cleanup standards also be made based on the use of improved and more reasonable risk assessment standards. Excessively conservative risk levels like the proposed one in one million cancer risk standard coupled with conservative risk calculations result in spending scarce societal resources for what, scientifically, is truly a deminimus risk. Mobil understands that the commission has received detailed comments from many sources including the Chemical and Industry Council, and the American Industrial Health Council of which Mobil is an active member. Mobil agrees with these comments and would like to incorporate them by reference.

Yours very truly,

Deborah J. Campbell

D. J. Campbell
Regulatory Affairs Advisor

Attachment

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GENERAL COMMENTS

1. How can Risk be fairly assessed?

The use of a conservative bright line standard, although administratively easy to manage is not the most realistic or effective way to manage risk. Site specific data provides a more accurate characterization of potential human and environmental exposure and in turn significantly improves the validity of the resulting risk assessment. Risk assessment methodology which does not take into account individual site characteristics may result in unnecessary cleanup remedies and the misallocation of resources without any real benefit.

The use of actual site specific leaching tests will be extremely useful in assessing any potential effects to groundwater. Soil conditions, if available, will also be helpful in determining the bioavailability and potential biodegredation of both organic and inorganic constituents since they are effected by soil particle size, organic carbon and clay content, ion exchange capacity and contaminant speciation. Site specific data information, if it exists, on groundwater flow, contaminant fate and exposed populations would be very useful in properly assessing the individual sites risk.

2. Risk assessment must be conducted using the best available scientific information available, in a realistic and reasonable way.

An evaluation of NJDEPE's withdrawn 1992 cleanup standard proposal shows the need to build flexibility in to a New Jersey risk assessment program. This proposal used conservative ingestion rates, exposure rates, assumed that 100% of the chemical is bioavailable, and did not recognize the tendency of some chemicals to biodegrade. The following summary discusses several of these concerns.

- NJDEPE used outdated soil ingestion rate data. Recent studies have shown a four fold decrease in expected soil ingestion by both adults and children.
- NJDEPE assumed that residents live at home 365 days per year and reside in the same location for 30 years. Recent housing survey data suggest that the actual total residence time in the United States was 4.6 years. Mobil would recommend that current demographic data be used to get a more accurate representation of both time spent at home and the average years spent at the same residence.
- NJDEPE assumed that workers are in the same job for 25 years and are off work for only 3 weeks. It would seem reasonable to adjust this information to account for holidays and sick days and to use recent demographic data regarding the average length of employment in the United States.
- NJDEPE assumed that people would be exposed to soil for 365 days. A more accurate representative would take into account rainy days, days with snow cover and days that the ground is frozen.
- NJDEPE did not take into account that bioavailability varies by chemical and site condition. In addition many chemicals, particularly organic, naturally degrade in the environment. This important fact should be considered in any risk assessment methodology.

Risk assessment technology is a rapidly evolving field. Many of the above proposed methodologies by NJDEPE used outdated information underscoring the need to allow risk assessment guidelines to advance with the addition of new scientific data. Research groups worldwide are improving our understanding of chemical carcinogenesis, fate and transport modeling and exposure assessment. It is necessary that the NJDEPE be encouraged to develop guidelines which will allow risk assessment techniques to be scientifically current.

Mobil would suggest that up to date methodologies be applied in site specific risk assessment. Allowing current peer reviewed scientific data to be used will ensure that the best available information and assessment methods are being used. This will ensure that New Jersey citizens and the environment will be protected without unnecessary expenditures of the limited resources of both government and industry.

3. Recommended Risk assessment methods

The use of a bright line standard should be avoided as no single range of risk can realistically portray a site. A more accurate method would include ranges of risk with an indication of the degree of certainty associated with the various risk estimates. One class of methods that may be used to describe the range and statistical certainty associated with these risks are quantitative uncertainty analysis like the Monte Carlo simulation. This computer program allows the consideration of a complete range of parameter inputs rather than placing undue credence on point estimates of exposure which can result in overestimating the risk associated with the site.

The proposed use of a one in one million cancer risk standard is much more stringent than the many voluntary and involuntary risks that New Jersey citizens face every day. Allowing a range of risks between 10^{-4} and 10^{-5} cancer risk for the majority of cleanups would compare more favorable to many involuntary risks that citizens believe to be essentially zero. In addition, EPA has chosen not to regulate risks of less than 10^{-4} in small geographic areas according to a 1987, review of 132 EPA regulatory decisions by Travis, Crouch, Wilson, Klema published in the Journal of Environmental Science and Technology.

4. Reasonable risk assessment procedures will protect New Jersey and help conserve jobs, state and local resources.

The use of an extremely conservative risk assessment standard would preclude the use of more environmentally benign cleanup techniques like insitu bioremediation techniques. To remediate a site to the low levels of organics, for example, required by a one in one million cancer risk standard would necessitate incineration of the soil. That would be a prohibitive cost to industry and society in this state. Incineration can cost between $300/ton to $1,000/ton to reduce total petroleum hydrocarbons to a 1 ppm in soil as opposed to bioremediation which could achieve a level of 10 ppm at the greatly reduced cost of $20/ton - $50/ton.

New Jersey Business & Industry Association

NJBIA

March 17, 1994

Mr. Raymond Cantor
Environment Risk Assessment
and Risk Management Study Commission
Legislative Office Building, CN-068
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Dear Ray:

We would like to present this testimony on behalf of the 13,500 member companies of the New Jersey Business and Industry Association (NJBIA). The Environment Risk Assessment and Risk Management Study Commission was charged by the New Jersey Legislature in S-1070, to study the New Jersey Department of Environmental Protection and Energy's (NJDEPE's) proposed methods for the development of minimum remediation standards for chemicals in soils.

The business community has been very concerned about the adoption of the NJDEPE's proposed risk level factor for carcinogens of one in 1 million (10^{-6}) additional cancer risks. Our review of the relevant scientific literature indicates that a vast majority of risk experts agree that this factor is an overly conservative baseline number. Regulated parties trying to remediate to residential standards using the department standards derived from this overly conservative figure may be saddled with unnecessary and unproductive costs.

In the design of the proposed cleanup standards the NJDEPE rejected the federal Environmental Protection Agency's procedure of using the range of 10^{-4} to 10^{-6} as the baseline risk number. No one, including NJDEPE, presented the Legislature with valid scientific reasons on why 10^{-6} should be the baseline number for New Jersey. Clearly, the Legislature did not have sufficient scientific input to make this fundamental policy decision. That is why S-1070 has established the Environmental Risk Assessment and Risk Management Commission to determine what risk level is appropriate for setting cleanup standards. The Commission is instructed to revisit this legislative policy decision regarding the baseline risk number and make recommendations, using scientific evidence available, on an appropriate risk management level and the methods to be used in reaching this level. This is not a trivial issue, and it is an important policy consideration in the development of soil cleanup standards.

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I am enclosing a copy of a wonderful report prepared by Dr. Kathryn E. Kelly entitled "The Myth of 10^{-6} As a Definition of Acceptable Risk." This extensively cited paper was presented at the 84th Annual Meeting of the Air and Waste Management Association in Vancouver in June 1991. The bottom line of Dr. Kelly's findings is that **there is no sound scientific, social, economic or other basis for the selection of 10^{-6} as a cleanup goal for hazardous waste sites.**

Using 10^{-6} in concert with the other redundant conservative assumptions (cancer slope factors, soil ingestion rates, body weights, and time correction factors) gives an unworkable soil standard. This will damage the environment because appropriate cleanups will not take place and will continue to damage our economy because urban industrial land will not be reused for productive purposes. Unemployment and poverty are a far greater health risk to society than a few additional parts per million of even the most toxic ingredient.

New Jersey's business community has provided a significant amount of technical information supporting the adoption of a tiered approach to risk which is based on chemical group type. NJBIA supports this approach. We hope that the Commission will carefully analyze the scientific information and will provide the technical and scientific basis for the development of a rational and workable public policy which will allow our site remediation program to progress.

Sincerely,

Dr. Jim Sinclair, P.E.
First Vice President

Enclosure

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Environ
Toxicol
Internationa

The Myth of 10^{-6} As a Definition of Acceptable Risk

(Or, "In Hot Pursuit of Superfund's Holy Grail")

Kathryn E. Kelly, Dr.P.H.

Presented at the

84th Annual Meeting of the
Air and Waste Management Association

Vancouver, B.C., Canada

June 1991

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INTRODUCTION

It is difficult to imagine a criterion in wider use in U.S. environmental legislation than 10^{-6}. It guides the use of pesticides and food additives; it defines our allowable exposure to groundwater contamination and incinerators. It is the most influential determinant we have in deciding what emissions should be allowed from stacks, how a hazardous waste site should be cleaned up, and how much Alar to leave on apples.

10^{-6} is a shorthand description for an increased lifetime chance of 0.000001 in one (or one chance in 1,000,000) of developing cancer due to lifetime exposure to a substance. It is an upper-bound limit which is not likely to underestimate risk. 10^{-5} represents 1 chance in 100,000, and so on. 10^{-6} numerically represents an increase of approximately 0.0003% over our current chance of one in three (or 3.33×10^{-1}) from developing cancer from all causes in the U.S.

Background level of exposure to environmental contaminants is estimated at 10^{-3} to 10^{-2}.[1] The vast majority of our exposure to carcinogens is thought to be due to those that occur naturally in our foods.[2] 10^{-6} is therefore 1,000 to 100,000 times less than our current risk of background exposure to environmental contaminants or developing cancer from all causes. As 10^{-6} is an upper-bound estimate of risk, not an absolute or average value, the difference may actually be much greater.

The past, present, and future costs of achieving compliance with such a stringent criterion are virtually incalculable; certainly many billions of dollars have been spent in attempting to achieve this goal for cleanups at hazardous waste sites in the U.S. As a result, determining the origins of 10^{-6} is of considerable social, scientific, and economic interest.

Recent research has revealed that there is no sound scientific, social, economic or other basis for the selection of 10^{-6} as a cleanup goal for hazardous waste sites. Remarkably, this criterion, which has cost society billions of dollars, has never received widespread debate or even thorough regulatory or scientific review. It is an arbitrary level proposed 30 years ago for completely different regulations (animal drug residues), the circumstances of which do not apply to hazardous waste site regulation. As a result, implementing it consistently has frequently been socially, politically, technically, and economically infeasible. Although the benefits of 10^{-6} generally have not been shown to outweigh the significant costs of attaining this goal, many state cleanup guidelines still advocate or require the use of 10^{-6}.

Under these circumstances, communicating the meaning of 10^{-6} and the definition of "acceptable risk" poses considerable challenges to those responsible for explaining risk. The origin of 10^{-6} relative to its use as a criterion of "acceptable risk" is explored below.

THE SURPRISING ORIGINS OF 10^{-6}

Recently, we conducted an extensive review to determine the origin of 10^{-6} as a criterion of "acceptable risk."[3] We began with an informal telephone survey of affected agencies and an extensive literature search. The conclusions of this survey include the following:[3]

1. *None of the officials contacted at any federal or state agency currently using 10^{-6} as a criterion knew the basis of this criterion, nor is there any readily available documentation that specifically describes the origin of 10^{-6}.*

The extensive literature search included numerous toxicological, medical, regulatory, pollution, environmental, and governmental databases, that were queried back to the origin of each database (usually the mid-1970's). Not finding any written documentation, the authors began calling a "Who's Who" of the environmental industry. The contacts included:

- The White House
- The U.S. Environmental Protection Agency
- The EPA's Science Advisory Board
- The EPA's Risk Assessment Forum
- The Food and Drug Administration
- The U.S. Department of Agriculture
- The U.S. Conference of Mayors
- Oak Ridge National Laboratories
- The Congressional Office of Technology Assessment
- The Natural Resources Defense Council
- Citizen's Clearinghouse for Hazardous Waste
- Greenpeace
- Two former EPA Administrators
- A former state environmental commissioner
- Rockefeller University
- Environmental divisions of major law firms
- Staff members of several Congressmen
- And many other contacts in government and industry

Despite widespread use of this criterion, none of the agencies could cite the source of 10^{-6}, although there was almost universal surprise that the origin of 10^{-6} was not readily available. We were offered many good theories, but no written documentation. A sample of the responses:

- "My mind is a complete blank."
- "My, what an interesting question!"
- "I think it came from pesticides legislation or the Delaney Clause."
- "It came from the FDA in the 1950's."
- "It was derived from the Virtually Safe Dose used in the Safe Drinking Water Act."
- "It's an economic criterion."
- "It's based on the chance of being hit by lightening which is one-in-a-million."
- "I just assumed it was because one-in-a-million sounded like such a nice phrase."
- "It was selected because it was 'doable'. Or at least that's what we thought at the time."
- "It was a purely political decision made by several of the major agencies behind closed doors in the 1970's. I doubt very much you'll get anyone to talk to you about it."
- And our favorite, "You really shouldn't be asking these questions" (this from one of the federal agencies).

2. *The concept of 10^{-6} was originally an arbitrary number, finalized by the U.S. Food and Drug Administration fourteen years ago as a screening level of "essentially zero" or* de minimis *risk. This concept was traced back to a 1961 proposal by two scientists from the National Cancer Institute regarding determining "safety" levels in carcinogenicity testing.*[3]

The proposal for *de minimis* risk was contained in a 1973 notice in the Federal Register entitled "Compounds Used in Food-Processing Animals: Procedures for Determining Acceptability of Assay Methods Used for Assuring the Absence of Residues in Edible Products of Such Animals," commonly called the "Sensitivity of Method" regulations.[4] The term *de minimis* is an abbreviation of the legal concept, "*de minimis non curat lex*: the law does not concern itself with trifles." In other words, 10^{-6} was developed as a level of risk below which was considered a "trifle" and not of regulatory concern.

The purpose of these proposed rules was to set forth guidelines with regard to appropriate assay methods for carcinogenic animal drugs "which may be administered to food-producing animals, but for which no residue is permitted in human food" under the Delaney Clause of 1958. The rules were specifically prompted by the use of diethylstilbestrol (DES) as a growth promoter in cattle.

In adopting a threshold of safety, the FDA referred to a 1961 article by Nathan Mantel and Ray Bryan, originators of the well-known Mantel-Bryan equation, on the subject of safety testing in animal studies. Mantel, a biostatistician at the National Cancer Institute, had been asked by the Director of the Institute to develop guidelines for the number of laboratory animals required to establish the safety of a substance. This in turn was in response to a request by the Secretary of the Department of Health, Education and Welfare to the NCI to help establish which cancer-causing substances were "safe" and at what levels following the Thanksgiving cranberry scare of 1959. (Trace residues of a cancer-causing herbicide were found in supplies of cranberries shortly before the holiday, prompting the Secretary to recommend against buying cranberries that year. This in turn set off a mild panic which nearly devastated the cranberry industry.)

In their 1961 article, Mantel and Bryan reasonably pointed out that to define the parameters of safety testing, one must first come up with a definition of safety. For the purposes of discussion, they said, we'll assume "safe" is equal to one chance in 100,000,000 of developing cancer. Asked how he came up with the number of one in one hundred million, Mantel replied, "We just pulled it out of a hat." After all, defining "safe" was not the focus of their article. But this is the ultimate origin of 10^{-6}.

FDA initially adopted this "one in 100,000,000" in their 1973 proposal, but changed this value to one in 1,000,000 by the time the final rule was issued in 1977. "One in one million" was thus established as the "maximum lifetime risk that is essentially zero", or the level below which no further regulatory consideration would be given regarding the safety of residues of a carcinogenic animal drug. Only two comments were received on these proposed rules, despite a specific request from the FDA Commissioner for public comment on the setting of one-in-a-million risk as a threshold of "essentially zero" risk.

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3. *In the FDA legislation, the regulators specifically stated that this level of "essentially zero" was not to be interpreted as equal to an acceptable level of residues in meat products.*[4]

Nevertheless, many current regulations and guidance documents have done exactly that: interpreted this "essentially zero" level developed by the FDA, a level below which there would be no regulatory consideration given regarding safety, as a maximum "acceptable" level of risk.

An analogy to automobiles is that if we could not measure when a car were standing completely still, the FDA might consider one mile per hour a "virtually safe" rate of speed. Below this rate either speed is unmeasurable, or the costs of such measurements outweigh the benefits of the information gained.

In a sense, this criterion of one mile per hour has been misinterpreted to be a maximum "acceptable" rate of speed for driving a car on the highway without risk of dying in a car crash. The former is a *screening* level below which no regulatory consideration would be given to risks; the latter is a *safety* decision that takes into account cost-benefit considerations of highway safety, the road conditions, type and weight of automobile, etc.

Cleaning up all hazardous waste sites to a 10^{-6} level of "essentially zero" risk is therefore comparable to limiting highway traffic to 1 mph. The cost-benefits tradeoffs need to be evaluated more carefully in selecting a final cleanup number, using 10^{-6} as a starting point instead of a goal.

HOW IS 10^{-6} USED?

A review of the evolution of 10^{-6} reveals that *perception* of risk is a major determinant of the circumstances under which this criterion is used.

1. *10^{-6} is not consistently applied to all environmental legislation. Rather, it seems to be applied according to the general perception of the risk associated with the source being regulated. Specifically, 10^{-6} has been applied almost exclusively to hazardous waste sites, pesticides, and selected carcinogens, but not to air, drinking water, or other sources perceived to be of less risk.*

Cleanup levels for a given contaminant are not consistent and vary by orders of magnitude. From these past site cleanup decisions, we can see that what is determined to be "acceptable" is not a set value; the threshold of "acceptability" varies among countries, among states, and among different cities of the same state. Furthermore, the lack of consistent quality among risk assessments has resulted in similar sites with widely differing cleanup levels, all claiming to have been cleaned up to 10^{-6}.

Less well known are the extreme differences even among various divisions of the same agency for the same substance. For example, there are six orders of magnitude (one million-fold) difference in target risk within different EPA regulations for arsenic.[5] We suggest the differences are in part due to the *perception* of risk associated with the particular regulatory decision: the greater the perceived risk, the narrower the gap between "essentially zero" and what the public

will allow as "acceptable risk." As a result, some sources that actually pose a higher risk to society, such as automobile emissions, are regulated less stringently simply because they are *perceived* to pose less risk than such sources as hazardous waste management facilities, whether or not the data support that assumption.

2. *Although it has been in widespread use for hazardous waste sites for many years, the concept of 10^{-6} as a criterion of acceptable risk has never been legislatively mandated in any EPA regulations. In fact, the target range of 10^{-6} to 10^{-4} as a range of "generally acceptable risk" was not actually codified into EPA Superfund legislation until 1990 with the passage of the revised National Contingency Plan.*

How did this misconception arise? As the concept of risk assessment was broadened over two decades from carcinogenic animal drugs at the FDA to a host of other decisions and agencies (including food, water, air, hazardous waste, and others), the 10^{-6} concept was carried along as well. In the opinion of a former FDA counsel, the concept of 10^{-6} was repeated so often that it took on the stature of a firm regulatory policy, although the record clearly indicates otherwise. Unfortunately, in adopting 10^{-6} for other purposes, the original intent of 10^{-6} as a screening level was lost and still is not recognized today.

We could find no reference to 10^{-6} as a criterion for "acceptable risk" in any published EPA regulation or guidelines. The guidance published in 1984 by the Office of Science and Technology Policy[6] made no mention of any target risk whatsoever with which to compare results of health risk assessments, nor did EPA's proposed or final Guidelines for Carcinogenic Risk Assessment.[7,8]

The first use of "acceptable risk" in any environmental guidance appears to have been a part of the Superfund Public Health Evaluation Manual, issued in 1986 and now superseded by the 1990 National Contingency Plan.[9] The original Superfund guidelines stated: "... remedies considered should reduce ambient chemical concentrations to levels associated with a carcinogenic risk range of 10^{-4} to 10^{-7}." This range was modified to 10^{-4} to 10^{-6} in the final NCP.

3. *In codifying 10^{-6} for the first time in hazardous waste site rules, the National Contingency Plan specifically designates 10^{-6} as a starting point for discussion of acceptable target risk at a site or "point of departure," not the ultimate goal.[9] This is consistent with the original intent of the use of 10^{-6} as a level below which regulatory consideration was not warranted, i.e., as a starting point for discussion.*

The plan specifically states 10^{-6} should not be presumed to be the final target risk for hazardous waste sites, but a "point of departure" for deciding an appropriate target level. 10^{-6} to 10^{-4} is given as a range of "generally acceptable risk," with the option given for even 10^{-4} to be exceeded in some circumstances.

Because no two sites are alike, the guidance then lists several site-specific or remedy-specific factors that can be used to assist in the selection of a final risk level. This approach is consistent with EPA's requirement to develop protective strategies for hazardous waste sites, not eliminate risk.

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4. *The use of a single value of "acceptable risk" has never been used in EPA hazardous waste site regulation -- only a range of values.*

In an analysis of the final NCP by one of the EPA attorneys who drafted the rule, the attorney states:

> "The use of a *range of* acceptable risk is general practice for most government programs...[It] affords the Agency the flexibility to take into account different situations, different kinds of threats, and different kinds of technical remedies. If a single risk level had been adopted (e.g., at the more stringent end of the risk range), fewer alternatives would be expected to pass the protectiveness threshold and qualify for consideration in the balancing phase of the remedy selection process."[10]

The use of 10^{-6} as a definition of acceptable risk thus has no scientific or regulatory basis. Its use appears to be arbitrary and generally applied where risks are perceived to be high relative to other risks, regardless of the available data.

SO WHAT IS AN ACCEPTABLE LEVEL OF RISK?

Much has been written about determining the acceptability of risk. The general consensus of the literature is that "acceptability" of a risk is a judgment decision properly made by those exposed to the hazard or their designated health officials. It is not a scientifically-derived value or a decision made by outsiders to the process. Acceptability is based on many factors, such as the number of people exposed, the consequences of the risk, the degree of control over exposure, and perhaps 40 or so other factors. The degree of risk acceptable at hazardous waste sites has never been formally quantified, but it does vary with each site, and it is clear that the public tolerates a very low threshold of acceptable risk at hazardous waste sites in part because hazardous waste ranks very high with many of these factors.

Travis *et al.* attempted to answer this question indirectly by quantifying the risk levels associated with 132 federal regulatory decisions, and thus determine a *de facto* level of acceptable risk.[11] If a consistent threshold of risk could be shown in other federal health and safety decisions, that could provide guidance for comparable protection of hazardous waste sites. From this effort they rather convincingly concluded that the *de facto* level of acceptable risk in federal regulatory decisions has been shown to be approximately 10^{-4}.

This level, which is 100 times greater than 10^{-6}, is likely due to several factors. We suggest that chief among those reasons is that *perception* of risk drives the regulatory decision on what constitutes the level of "acceptable" risk. This notion is supported by recent findings of the U.S. EPA Science Advisory Board,[12] which ranks hazardous waste near the bottom of its list of actual risks to the public, but near the top of the agency's priorities, which in turn are dictated by public perceptions and Congressional funding. In response to these findings, U.S. EPA Administrator Reilly has undertaken a major reorganization of the EPA to refocus its efforts on the major sources of actual risk and their reduction.[13]

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A second reason we believe 10^{-6} has been so widely applied to hazardous waste sites is that unlike decisions about air contamination, pesticides, and other agency reviews made at the federal level, hazardous waste site cleanup decisions are made on a very local and site-specific basis. What seems "doable" at the local level, such as spending a million dollars for cleaning up a site in return for virtual elimination of risk, often does not seem "doable" on a larger scale, as when thousands of sites at perhaps several million dollars per site are the cost of reducing risk to levels well below those considered "acceptable" by other public health standards.

What does this mean for current and pending state environmental policy? We suspect that many agencies will begin to adopt policies such as that established by the New Jersey Department of Environmental Protection, Division of Environmental Quality (DEQ), in their guidance for risk assessments for municipal solid waste incineration facilities. This policy quite succinctly states:

> "Incremental risks from a new source which are less than one in a million are considered by the DEQ to be negligible. Incremental risks greater than one in ten thousand are deemed unacceptable. Risks between these two limits are judged on a case-by-case basis."[14]

SUMMARY AND CONCLUSIONS

It has been nearly two decades since the FDA introduced the concept of risk assessment in its efforts to deal with DES as a growth promoter in cattle. As part of this effort, the threshold of one-in-a-million risk of developing cancer was established as a screening level to determine what carcinogenic animal drug residues merited further regulatory consideration.

Since then, the use of risk assessment and 10^{-6} (or variations thereof) have been greatly expanded to almost all areas of chemical regulation, to the point where today clearly one-in-a-million risk means different things to different agencies. What the FDA intended to be a *lower* regulatory level of "zero risk" below which no consideration would be given as to risk to human health, many federal and state agency decisions somehow came to consider a *maximum* or *target* level of "acceptable" risk.

As 10^{-6} seemed like a reasonably conservative level (or "doable," according to many of those we spoke with), it was adopted first for a few chemicals and exposure pathways, then more chemicals and exposure pathways, and so forth. Not until the rule came into widespread use or until everyone was limited to one mile per hour on the freeway, so to speak, and it was costing billions of dollars to eliminate risk -- did it become readily apparent that the "zero risk" screening criterion was not intended to be interpreted as "acceptable risk." Accordingly, the benefits of the 10^{-6} criterion applied to hazardous waste sites will rarely exceed the risks and costs, and the criterion is thus unsuitable for regular implementation or enforcement.

Furthermore, 10^{-6} as a criterion for "acceptable risk" has not been applied to other sources of exposure that pose considerably more risk to public health than hazardous waste, such as automobile emissions, radon, or sources of benzene. The primary reason for the inconsistent application of this criterion appears to be that public perception of risk has driven the regulatory management of these sites

to a greater degree than supported by the actual data. Reorganizing the EPA's priorities towards issues of actual rather than perceived risk is a major goal of EPA Administrator Reilly.

A lack of a sound basis for extrapolating the use of 10^{-6} from its very specific origins to a wide variety of other non-related applications partly explains the extreme difficulty agencies have had in implementing 10^{-6} as a goal. Such extrapolations face costs and benefits that are often not in balance (e.g., OMB's unwillingness to approve recent hazardous waste incineration rules because of EPA's inability to fully account for and justify the costs of implementing these rules -- i.e., $288 million dollars per case of cancer avoided).[15]

The discovery of a lack of a sound basis for the choice of 10^{-6} offers opportunities for introducing health-based considerations into the discussion of how to clean up hazardous waste sites, particularly when so many sites demand attention for cleanup and funds are limited. As the federal and state agencies review their position on the "Holy Grail" of 10^{-6} as a goal that is frequently sought but rarely found, it's interesting to know that in the absence of a well-established basis for 10^{-6}, the door is wide open for discussion about the appropriateness of 10^{-6} or any other criterion. Of particular interest is the need for clarification of 10^{-6} as a screening level of "essentially zero" risk, as it was originally intended, vs. its frequent use at hazardous waste sites as a goal of maximum "acceptable risk."

This is an opportunity to create cleanup criteria with a more sound basis, instead of presenting an obstacle to further decision-making regarding important health and environmental matters. The solution to developing better criteria for environmental contaminants is not to adopt arbitrary thresholds of "acceptable risk" in an attempt to manage the public's perception of risk. Rather, the solution is to standardize the *process* by which risks are assessed, and to undertake efforts to narrow the gap between the public's understanding of actual vs. perceived risk. A more educated public with regard to the sources of real environmental risk will greatly facilitate the regulatory agencies' ability to prioritize their efforts and standards to reduce overall risks to public health.

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April 15, 1994

Environmental Risk Assessment
and Risk Management Study Commission
Michael A. Gallo, Ph.D., Chairman
Legislative Office Building
CN-068
Trenton, NJ 08625-0068

Attention: Judith L. Horowitz

RE: Industrial Site Recovery Act (ISRA)

Dear Chairman Gallo:

The New Jersey Public Health Association supports the concept and spirit of environmental risk assessment and risk management in general, and more specifically, as it is outlined in the State's Industrial Site Recovery Act (ISRA).

We must, however, caution the Commission in reviewing available technical knowledge and in accessing appropriate risk methodologies that the one germane issue should remain paramount in the deliberations of the Commissioners—that is, the protection of public health must not be compromised by expediency, especially the expediency of rationalization that clean-up of hazardous substances and sites can be negotiated or compromised because "after all the sites are just industrial sites"—some sites are actually in or near residential areas.

As guardians of public health in New Jersey, our Association, our State Legislature, our State health and environmental officials, and you, as Commissioners charged with this awesome responsibility, must not shirk from the endless vigilance and protection of the very lives of the residents, workers and visitors to our great State of New Jersey.

Sincerely,

James W. Brown

James W. Brown, Ph.D.
President

Sincerely,

John Surmay

John N. Surmay, H.O., R.P.
Environmental Health Chair

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Shell Oil Company

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April 8, 1994

Ms. Judith L. Horowitz
Aides to the Commission
Environmental Risk Assessment and
Risk Management Study Commission
Legislative Office Building
CN-068
Trenton, New Jersey 08625-0068

Re: Environmental Risk Assessment

Dear Ms. Horowitz:

Enclosed please find fifteen copies of written testimony applicable to the above-referenced subject to be presented to the Environmental Risk Assessment and Risk Management Study Commission.

Specifically, the enclosed includes testimony on a risk-based approach to corrective action presented by Paul C. Johnson, PH.D, to the Groundwater Protection Task Force in California at a public meeting on March 17, 1994. Mr. Johnson is a Senior Research Engineer for Shell Development Company. Also, enclosed is a general overview of "Risk-Based Corrective Action" and a copy of the second draft of the "ASTM Guide for Risk-Based Corrective Action at Petroleum Sites." I would like to mention that this standard was officially approved as an ASTM Emergency Standard on March 10, 1994.

I will be very happy to discuss this very important issue with you or to arrange a meeting with anyone from Shell's staff. I can be reached at (703) 707-5656. Thank you for the opportunity to make this submission.

Very truly yours,

L. M. Polocheck
Environmental Engineer

Enclosures

cc: J. S. Spinelle, Manager, Environmental Engineering - East
D. M. Maxson, Manager, Garden State District
P. C. Johnson, Senior Research Engineer, Westhollow
D. J. Farrier, Hydrogeologist, Environmental Engineering - East
Kevin F. Kratina, Chief, BUST, NJDEPE

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External Program Review:
Groundwater Protection Task Force
Public Meeting - March 17, 1994

Testimony from:
Paul C. Johnson, Ph.D.
Shell Development Company

Opening Comments:

I would like to thank the Groundwater Protection Task Force for allowing the opportunity to provide input for their consideration. I am a senior research engineer for Shell Development Company, and I am responsible for conducting research related to soil remediation and risk and exposure assessment. As a recognized expert in these areas, I am often invited by the USEPA and state agencies to provide training and external peer review related to these subjects. I am also a member of the Underground Storage Tank Technical Advisory Committee (USTTAC) for the revision of the California Leaking Underground Fuel Tank (LUFT) Manual. I am here today at the request of Shell Oil Company and the Western States Petroleum Association (WSPA).

Issues

I would like to address the following issues being considered by the Groundwater Protection Task Force:

- target groundwater cleanup levels
- target soil cleanup levels
- well-head, or point-of-use treatment of groundwater

Background

The Groundwater Protection Task Force has already received testimony from concerned parties who feel that current State policies do not promote prompt and cost-effective remediation of soils and groundwater. Shell Oil and WSPA agree with these views. First, experience and fundamental considerations point to the conclusion that remediation to very low soil and groundwater concentrations is not practicable in many cases. Secondly, evaluation of the true risks posed by soil and groundwater contamination in many settings leads to the conclusion that it is not necessary to uniformly achieve very low soil and groundwater concentrations in order to be sufficiently protective. In addition, when forced to respond to, and remediate all sites uniformly, then limited resources are diverted from those sites with the greatest potential threat and there is little incentive for responsible parties to support the development of more innovative technologies. Consequently, the economic burden resulting from current State policy is great relative to benefits realized by California residents and businesses.

The Groundwater Protection Task Force is now considering a number of issues, including recommendations to the State that:

- State policies be amended to reflect inherent technology limitations with achieving very low levels of contaminants in groundwater and soils,
- alternate points of compliance be used for establishing locations where groundwater quality criteria are to be met, and
- policy should not dictate that uniform state-wide cleanup levels be applied regardless of characteristics of the site and surrounding area, and the source of the contaminants.

Shell Oil Company and WSPA support these recommendations, and the progression towards risk-based corrective action policy. Furthermore, I propose that the Groundwater Protection Task Force urge the State to adopt policy consistent with the *ASTM Guide for Risk-Based Corrective Action at Petroleum Release Sites*. This standard was developed over the past two years in response to needs expressed by government regulatory agencies and industry. It was drafted by a fairly diverse working group that considered a range of solutions to the same issues addressed today by the Groundwater Protection Task Force. The ASTM standard represents the concensus of a fairly diverse working group that included representatives from:

State Agencies:	Dennis Rounds - South Dakota State Petroleum Storage Tank Compensation Fund Manager (and Task Group Chairman)
	Ron Pedde - Texas Natural Resource Conservation Commission,
	Chet Clarke - Texas Natural Resource Conservation Commission,
USEPA:	Gerald Phillips - USEPA Region V UST Program Manager, and
	Matt Small - USEPA Region IX
Insurance Industry:	Tom Schruben - Reliance Reinsurance (and formerly of USEPA OUST),
Banking Industry:	Nona Hancock - Boatman's Bancshares,
Consulting:	Dr. Robert Schofield - ENVIRON,
Petroleum Industry:	Mark Malander - Mobil Oil Company, and Erik Hansen - Shell Oil Company

The standard was officially approved as an ASTM Emergency Standard on March 10, 1994. In the history of ASTM very few emergency standards have been issued, and this status was allowed in this case due to the very high interest expressed by the regulatory and regulated communities.

Contents of the ASTM Guide

In general, The ASTM standard provides the framework for building a streamlined and technically-defensible "risk-based" corrective action program, which will promote the prompt and cost-effective management of contaminant release sites. It embodies many of the recommendations under consideration by the Groundwater Protection Task Force. While the ASTM standard focuses on petroleum release sites, the process is generally applicable to any contaminant and release scenario.

The main body of the ASTM standard describes a logical sequence of activities and decisions to be followed from the time contamination is suspected until regulatory closure is achieved. At all times the decisions and required actions are based on insuring that human health and beneficial uses of environmental resources are protected. Key components of the process are:

- **Site Classification:** Based on the results of an initial site assessment, sites are classified in order to insure that resources are immediately applied towards those sites posing the greatest threats to human health and environmental resources. In some states, the classification process is also used to identify sites where agency oversight is not necessary and the corrective action is self-directed, or conducted under the oversight of "licensed site professionals".

- Associated with each site classification is a prescribed **immediate response action** to insure that human health and safety and environmental resources are protected. These actions range from

emergency response activities necessary for sites posing short-term threats, to monitoring programs appropriate for those sites having a low potential for current or future impacts.

- **Look-Up Table of Screening Level Concentrations:** The "Look-Up Table" containing screening level concentrations, is used to determine if site conditions satisfy the criteria for a quick regulatory closure, or if conditions exist that warrant a more site-specific evaluation of corrective action goals. Groundwater, soil, and vapor concentrations may be presented in this table for a range of site descriptions and types of contaminant sources (e.g. gasoline, crude oil, etc.). The values in this table may be a combination of health-risk-based screening levels, aesthetic (taste, odor, etc.) criteria, or ecologically-based criteria. Tools such as CALTOX (currently under development by the CA DTSC), or results from the upcoming LLNL LUFT manual contract, may be appropriate for developing some of the health-risk-based values appearing the Look-Up Table. It is urged that these levels be established based on realistic exposure scenarios and the latest scientific evidence available.

- **Site-Specific Compliance Goals:** The ASTM standard incorporates the flexibility to pursue the development of soil, groundwater, and vapor concentrations based on characteristics of the site and surrounding area. Specifically, alternate points of compliance may be negotiated. While the use of alternate points of compliance may be a new shift in State policy for groundwater, the use of negotiated zones of compliance has been common in California in the regulation of air and surface water discharges. The ASTM standard recommends that monitoring data be required to support the development of site-specific corrective action goals.

- **Corrective Action Options:** The selected remedy may be a combination of traditional remedial techniques, the natural attenuation of contaminants due to biodegradation and dispersion, point-of-use (well-head) treatment, and institutional and migration controls. The objective is to choose a remedy that satisfies the requirements for risk reduction, as opposed to a strict focus on mass reduction.

Benefits of the ASTM standard include:

In summary, I urge the Ground Water Protection Task Force to recommend that the state adopt a risk-based approach to corrective action, and that the policy be built on the framework presented within the *ASTM Guide for Risk-Based Corrective Action at Petroleum Release Sites*. In doing this, I believe that the following benefits will be realized by the State:

- human health and beneficial uses of environmental resources will be protected,

- policy will be technically-defensible, can be applied consistently, and embodies those recommendations under consideration by the Groundwater Protection Task Force,

- the approach will promote the prompt and cost-effective closure of sites, and

- a number of activities that have been invested in by the State of California, including CALTOX and LUFT Manual revisions can be combined and taken advantage of within the risk-based corrective approach.

What Is Risk-Based Corrective Action?

"Risk-Based Corrective Action" (RBCA - pronounced like "Rebecca") is a term that is used quite liberally in the environmental industry. To many, RBCA is synonymous with "risk assessment" - the scientific process for quantifying risks associated with exposure to chemicals in the environment. To others, RBCA refers to a new philosophy for managing contaminant release sites. In this new approach, decisions related to resource allocation, urgency of response, target cleanup levels, and remedial measures are based on current and reasonable potential risks to human health and environmental resources. It is this broader definition of RBCA that is utilized in the ASTM "Guide for Risk-Based Corrective Action at Petroleum Release Sites". As we shall see, applying the RBCA process to a given site may or may not involve the preparation of a formal risk assessment.

How Does RBCA Differ From Current Corrective Action Programs?

Many of the components of the RBCA process are similar to those already practiced under current state and federal corrective action programs (site assessment, remedial measure selection, etc.). However, the philosophy underlying traditional and RBCA approaches is quite different. Historically, the focus of corrective action programs has been to reduce the amount of contaminants present at a given site, with the ultimate goal being the achievement of background, or very low criteria (such as Maximum Contaminant Levels in groundwater). On the other hand, RBCA decisions are dictated by current and potential risks posed by a site, and corrective action goals are based on reducing these risks to some low, acceptable level. This may be achieved by reduction of contaminant concentrations, but it may also involve reducing the potential of exposure through the application of institutional controls, point-of-use water treatment, and the natural attenuation of contaminants.

Are There Other Approaches for Managing Contaminant Release Sites?

So far we have mentioned two approaches for managing contaminant release sites. In the traditional approach, the goal is to reduce contaminant concentrations below prescribed numerical standards, independent of site characteristics. In the RBCA approach, the goal is to reduce current and reasonable potential risks of adverse impacts to below some low, acceptable level. There is a third approach advocated by some, and this approach is often referred to as the "technology-based limits" approach. Here the goal is to reduce contaminant concentrations as much as is "technically feasible", given current technologies and practical constraints. Each of these three approaches has benefits and limitations. The more traditional approach is the easiest to consistently manage; however, the numerical standards are applied independent of site characteristics. The RBCA approach is better equipped to handle the diverse nature of sites, but assumes that we can indeed assess risks posed by sites. The technology-based approach is attractive as it provides an outlet for those parties who want to turn-off ineffective remedial systems. However, detractors will argue that this approach also forces the installation of remedial systems at all sites not meeting generic numerical criteria, and it inherently assumes that the most appropriate technologies will be applied correctly at every site. In addition, not all parties will easily agree on what "technically feasible" means, and that the approach will be applied inconsistently, depending more on the financial resources of the responsible party than risks posed by the site.

What is Risk Assessment, and How Has It Been Used?

As stated above, the RBCA process is based on considerations of risk and exposure. While we shall see that this does not imply that formal risk assessments are prepared for each site, it is useful to review the sequence of risk/exposure assessment activities prescribed by most guidance documents (e.g. Risk Assessment Guidance for Superfund; USEPA 1989); these include:

a) identifying chemicals of concern,
b) receptor identification,
c) exposure analysis,
d) dose-response analysis,
e) risk and sensitivity/uncertainty quantification, and
f) risk management.

These basic activities are performed for all human health and ecological risk/exposure assessments, independent of whether the site of concern is a relatively small underground storage tank release site or a large-scale mixed-waste Superfund site. By their nature, these activities require a multi-disciplinary approach involving people with a range of expertise, including site assessment, fate and transport of compounds in the environment, and human health and ecological effects. The degree of complexity required for steps (a) - (f) varies greatly depending on the goal of the assessment and complexity of the site and surroundings.

The use of formal risk assessment has been a major component of the CERCLA program for some years, but its acceptance and use at the state and local level has been limited to date. There are many reasons for this; a) most existing guidance has been written for complex assessments focussed on large-scale sites, b) in some cases regulators do not feel adequately trained to review formal risk assessments, c) policy does not explicitly allow their use, or d) it is perceived that the multitude of possible approaches will make the review process less manageable. In addition, in many cases there is a distrust resulting from the perception that a risk assessment is necessarily a complex mathematical exercise in which parameters can be adjusted to get the answer of choice. Risk assessment has also been viewed by some as an opportunity to delay implementing corrective action. In the authors' experience, risk assessment has only been used in underground storage tank programs to justify the closure of sites where technology limitations have been encountered.

Can Risk Assessment Be Incorporated Into the Corrective Action Process?

Considering the experience gained to date, the diverse nature of sites likely to be encountered, and the questions that must be answered (prioritization, immediacy of response, target levels, compliance zones, etc.), it is clear that a new risk assessment paradigm is needed. For this reason, the ASTM "Guide for Risk-Based Corrective Action at Petroleum Release Sites" is based on a "tiered" approach to risk and exposure assessment, where each tier refers to a different level of complexity. For example, in a three-tiered approach the first tier consists of a *qualitative* risk assessment; this might require a site visit to identify obvious environmental impacts (if any), potentially affected sensitive receptors (schools, homes, water bodies, etc.), and significant exposure pathways (drinking water wells, recreational use of streams, vapor transport, etc.). When gathered for a number of sites, this information is typically sufficient to help prioritize and negotiate an acceptable time frame for corrective action (immediacy of response), if

necessary. This first tier is consistent with the philosophy of site ranking programs used by federal and some state regulatory agencies (e.g. the National Priority List for Superfund sites). In the second tier, the *reasonable maximum site-specific impact* is evaluated through the use of site-specific characterization and monitoring data, conservative mathematical models (e.g. maximum emission rates, maximum soluble plume travel distance), and reasonable maximum exposure scenarios. This information is used to set conservative corrective action objectives that are generally regarded as overly-protective. In the third tier, more sophisticated mathematical descriptions of transport phenomena are used and sometimes probabilistic descriptions of the range of possible exposures/risks are generated. At this level of complexity, site-specific transport and exposure models are developed and distributions for each of the parameters are usually input (e.g. exposure parameter distributions given by The Exposure Factors Handbook; USEPA 1989). Experience has shown that it is currently more expedient in most cases to make decisions based on the first and second tier analyses, if responsible parties and regulators can agree on a "reasonable maximum exposure scenario".

Can the "Tiered" Concept Be Used to Build a Technically-Defensible and Practical Corrective Action Process?

The RBCA process outlined in Figure 1 also utilizes a tiered approach, in which assessment and remedial activities are appropriately tailored to site-specific conditions and risks. This flexibility allows RBCA to be more technically-defensible, protective, and cost-effective than traditional approaches under which all sites conform to uniform standards and procedures. While the RBCA process outlined in Figure 1 is not limited to a particular class of compounds, this guide emphasizes the application of RBCA to petroleum fuel releases.

The RBCA process is based on three tiers of possible activities, where the user begins at the first tier and then progresses to higher tiers, if warranted. As we shall see, by progressing through each tier, the activities of subsequent tiers become more focussed and efficient. A discussion of each tier appears below:

Tier 1: Conservative, But Efficient

In Tier 1, sites are assigned a **Classification** based on information collected from historical records, a visual inspection, and minimal site assessment data. The user is required to identify contaminant sources, obvious environmental impacts (if any), the presence of potentially impacted humans and environmental resources (e.g. workers, residents, water bodies, etc.), and potential significant transport pathways (e.g. groundwater flow, atmospheric dispersion, etc.). Sites are classified in order to insure that resources are immediately applied towards those sites posing the greatest threats to human health and environmental resources. In some states, the classification process is also used to identify sites where agency oversight is not necessary and the corrective action is self-directed, or conducted under the oversight of "licensed site professionals".

Associated with each site classification is a prescribed **immediate response action** to insure that human health and safety and environmental resources are protected. These actions range from emergency response activities necessary for sites posing short-term threats, to monitoring programs appropriate for those sites having a low potential for current or future impacts.

In addition, as part of Tier 1,a **Look-Up Table** containing screening level concentrations, is used to determine if site conditions satisfy the criteria for a quick regulatory closure, or if conditions exist that warrant a more site-specific evaluation of corrective action goals. Groundwater, soil, and vapor concentrations may be presented in this table for a range of site descriptions and types of contaminant sources (e.g. gasoline, crude oil, etc.). The values in this table may be a combination of health-risk-based screening levels, aesthetic (taste, odor, etc.) criteria, or ecologically-based criteria. These values are applied consistently from site to site, but are "evergreen" in that they will change as new methodologies and parameters are developed. It is urged that these levels be established based on realistic exposure scenarios and the latest scientific evidence available.

Tier 2 and Tier 3: Site-Specific Corrective Action Goals - Increasing Site-Specific Data

Tiers 2 and 3 provide the user with options for determining site-specific target levels (SSTLs). In most cases the decision to move to a higher tier is based on answers to the following questions:

Are the assumptions used in a lower tier appropriate, relative to site-specific conditions?,
Are the goals established from a higher tier's analysis likely to be less costly to achieve?, and
Is the cost for additional analyses low relative to the cost required to achieving the lower tier's goals?

It is important to note that the goal of all tiers is to achieve similar levels of protection. The only difference is that in moving to higher tiers the user is able to develop more cost-effective corrective action plans because the conservative assumptions of earlier tiers are replaced with more realistic site-specific assumptions. Additional site assessment data may be required. While both Tiers 2 and 3 involve developing site-specific goals, the major distinction between Tiers 2 and 3 is that Tier 2 analyses tend to be consistent with the level of site characterization data most often available, and Tier 3 often involves a much more significant increase in site-specific data requirements. Tier 2 analyses may involve the use of screening-level predictive models coupled with site assessment and monitoring data, and sometimes Tier 2 SSTLs are derived from the same equations used to calculate Tier 1 RBSLs, except that site-specific parameters are used in the calculations. At other sites, The Tier 2 analysis may involve applying Tier 1 RBSLs at more probable points of exposure. These points are often referred to as "alternate points of compliance", and may be physically located at property boundaries or the edge of areas where access has been restricted by physical or institutional barriers. Tier 3 analyses often involve the use of complex numerical models and probabilistic analyses.

Corrective Action Selection

If exceedences of the selected target levels occur and corrective action is necessary, the user develops a corrective action plan in order to reduce the potential for adverse impacts. One option is to utilize traditional remediation processes to reduce contaminant concentrations below the target levels. Another equally viable option is to achieve exposure reduction (or elimination) through the use of institutional or physical barriers. Again, the goal here is risk reduction.

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"What is Contained Within the ASTM Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites?"

In general, The ASTM standard describes the framework for building a streamlined and technically-defensible "risk-based" corrective action program. While the ASTM standard focuses on petroleum release sites, the process is generally applicable to any contaminant and release scenario.

The main body of the ASTM standard describes a logical sequence of activities and decisions to be followed from the time contamination is suspected until regulatory closure is achieved. At all times the decisions and required actions are based on insuring that human health and beneficial uses of environmental resources are protected.

Appendices are also included that contain supporting information on topics such as: a) characteristics of refined petroleum fuels, b) the approach used to develop the example Tier 1 Look-Up Table, c) the role of predictive modeling in the RBCA process, d) institutional controls, and e) example applications of the RBCA process.

Where Do We Go From Here?

The ASTM standard describes the framework for a corrective action process that needs to be "customized" before application in a particular state or region. Specifically, the parties involved need to develop a classification system, and a Tier 1 Look-Up Table. Beyond that, guidance may be required for specific aspects of higher tiers, such as rules for establishing alternate points of compliance. The ASTM standard was written in such a way that only minor modifications of many current programs are needed to conform with the ASTM approach.

Committee E-50 ON ENVIRONMENTAL ASSESSMENT

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TO : **ASTM E50.01 Storage Tank Subcommittee Members**

FROM : **Dennis D. Rounds, Chairman** D. Rounds
ASTM Risk-Based Corrective Action Task Group

SUBJECT: ASTM Guide for Risk-Based Corrective Action

Enclosed is the second draft of the ASTM Guide for Risk-Based Corrective Action at Petroleum Release Sites. This standard was balloted last summer under the title "Practice for Conducting Exposure and Risk Assessment for Petroleum Contamination in the Corrective Action Process". It has been substantially revised to take into account the comments received from last summer's balloting and peer review. Due to the current high level of activity and profuse expenditures being made on petroleum release cleanups, this standard has received the endorsement of Executive Subcommittee to be balloted as an emergency standard.

This standard was developed in response to needs expressed by both private industry and government regulatory agencies. It was prepared by a diverse, well balanced task group of professionals involved both directly and indirectly in the corrective action at petroleum release sites. The task group is represented by members of state regulatory agencies, the US EPA, state cleanup funds, environmental consultants, the petroleum industry, banking and insurance. With state funds and regulatory agencies being the driving force, all individual members of the task group remained committed throughout the standard's development. Of particular benefit was the experience and technical support provided by private industry.

While this document may appear somewhat voluminous, note that the standard itself is only 26 pages, including tables and figures. The remainder of the document consists of five important appendices which provide abbreviated, yet thorough descriptions of some of the more technical and administrative aspects that may be associated with risk-based corrective action, including examples. This standard is not intended to replace existing state regulations. However, it is the goal of the task group to produce a standard that is accepted by state regulatory agencies and can be incorporated into corrective action programs.

The ASTM Guide for Risk-Based Corrective Action at Petroleum Release Sites offers a three tiered approach to incorporating risk assessment in to the corrective action process. It explains a streamlined, step-by-step logical procedure for selecting the level of complexity necessary to assess exposure pathways and risk on a site-specific basis. Emphasizing specific components of concern, the standard also offers methods for determining risk-based target cleanup levels by using both simple mathematical calculations and complex fate and transport models.

You are encouraged to review the standard and offer support with a positive ballot. I recommend that the emphasis of your review and vote be on the 26-page standard itself. Any suggestions or comments on the appendices will also be appreciated, but should not be the overriding factor in your ballot decision.

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Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites

1. Scope

1.1 This is a guide to risk-based corrective action (RBCA), which is a consistent decision-making process for the assessment and response to subsurface contamination, based on the protection of human health and environmental resources. Sites with subsurface contamination vary greatly in terms of complexity, physical and chemical characteristics, and in the risk that they may pose to human health and environmental resources. The RBCA process recognizes this diversity, and utilizes a tiered approach where assessment and remediation activities are appropriately tailored to site-specific conditions and risks. This flexibility allows RBCA to be more cost-effective than traditional approaches under which all sites conform to uniform standards and procedures. While the RBCA process is not limited to a particular class of compounds, this guide emphasizes the application of RBCA to petroleum fuel releases.

1.2 The decision process described in this guide integrates risk and exposure assessment practices, as suggested by the United States Environmental Protection Agency (USEPA), with site assessment activities and remedial measure selection to ensure that the chosen action is protective of human health and environmental resources. The following general sequence of events is prescribed in RBCA, once the process is triggered by the suspicion or confirmation of hazardous hydrocarbon levels:

- 1.2.1 a Tier 1, or preliminary, site assessment,
- 1.2.2 classification of the site by the urgency of initial response,
- 1.2.3 implementation of an initial response action appropriate for the selected site classification,
- 1.2.3 comparison of site conditions with Tier 1 screening levels given in an evergreen "look-up" table containing conservative risk-based screening levels and other relevant criteria (drinking water standards, aesthetic criteria, ecological criteria, etc.),
- 1.2.4 deciding if Tier 1 screening target levels are appropriate, and if not, then
- 1.2.5 collect additional site-specific information as required, and
- 1.2.6 develop site-specific target levels and points of compliance (Tiers 2 and 3).
- 1.2.7 comparison of the negotiated target levels with site conditions at the appropriate points of compliance, and if any exceedences are noted, then
- 1.2.8 develop a corrective action plan to achieve the negotiated target levels in an appropriate time period (based on risks posed by the site). Alternatives to be considered include combinations of traditional remedial methods (~~e.g.,~~ for example, excavation, pump and treat, soil vapor extraction) with institutional controls and natural attenuation.

1.3 This guide describes the process outlined ~~above~~ previously in more detail. For those interested only in becoming familiar with RBCA, the short main body of text provides a brief overview of the RBCA process (Section 4.0), and then presents RBCA procedures in a step-by-step fashion (Section 5.0) followed by a discussion of ways in which the process can be

misapplied (16). For those interested in additional background information, appendices have been included. These are focussed on:

- 1.3.1 characteristics of petroleum fuels (Appendix X1)
- 1.3.2 derivation of the example Tier 1 RBSL Look-Up Table (Appendix X2)
- 1.3.3 uses of predictive modeling relative to the RBCA process (Appendix X3)
- 1.3.4 considerations for institutional controls (Appendix X4), and
- 1.3.5 RBCA examples (Appendix X5)

2. Referenced Documents

USEPA, "Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual, Part A", EPA/540/1-89/002, December 1989.

USEPA, "Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual, Part B: Development of Risk-Based Preliminary Remediation Goals", OSWER Directive No. 9285.7-01B, NTIS No. PB92963333, USEPA, December 1991.

USEPA, "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors", OSWER Directive No. 9285.6-03, NTIS No. PB91921314, March 1991.

USEPA, "Risk Assessment Guidance for Superfund, Volume 2: Environmental Evaluation Manual", EPA/540/1-89/001, NTIS No. PB90155599, March 1989.

USEPA, "Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference Document", EPA/600/3-89/013, NTIS No. PB89205967, March 1989.

USEPA, "Integrated Risk Information System (IRIS)", October 1993.

USEPA, "Health Effects Assessment Summary Tables (HEAST)", OSWER OS-230, March 1992.

USEPA, "Exposure Factors Handbook", EPA 600/8-89/043, July 1989.

Johnson, P.C., G.E. DeVaull, R.A. Ettinger, R.L.M. MacDonald, C.C. Stanley, and T.S. Westby, "Risk-Based Corrective Action: Tier 1 Guidance Manual", Shell Oil Company, July 1993.

3. Significance and Use

3.1 The allocation of limited resources (for example, time, money, regulatory oversight, qualified professionals) to any one petroleum release site necessarily influences corrective action decisions at other sites. This has spurred the search for innovative and cost-effective approaches to corrective action decision making, which still insure that human health and environmental resources are protected.

3.2 The risk-based corrective action (RBCA) process presented in this guide is a rational and consistent, streamlined decision process for selecting appropriate corrective actions at petroleum release sites. Advantages of the RBCA approach are:

3.2.1 decisions are based on reducing the risk of adverse human or environmental impacts to appropriate levels,

3.2.1 assurance that site assessment activities are focussed on collecting only that information which is necessary to making risk-based corrective action decisions,

3.2.2 assurance that limited resources are focussed towards those sites that pose the greatest risk to human health and environmental resources at any time,

3.2.3 assurance that the preferred remedial option is the most economically-favorable one that has a high probability of achieving the negotiated degree of exposure and risk reduction, and

3.2.4 compliance can be evaluated relative to site-specific standards applied at site-specific points of compliance.

3.3 This guide is intended to be consistent with USEPA guidance for risk and exposure assessment.

4.0 A Tiered Approach to Risk-Based Corrective Action (RBCA) at Petroleum Release Sites

4.1 In risk-based corrective action, traditional components of corrective action programs (site assessment, remedial action selection, and compliance monitoring) are integrated with USEPA-recommended risk and exposure assessment practices to create a process by which corrective action decisions are made in a consistent and cost-effective manner that is protective of human health and environmental resources.

4.2 In order to streamline the RBCA process, it is implemented in a tiered approach, involving increasingly sophisticated levels of data collection and analysis. The conservative assumptions of earlier tiers are replaced with site-specific assumptions. Upon completion of each tier, the user reviews the results and recommendations, and decides if more site-specific analysis is required. The following forms the basis for a three-tiered RBCA planning process:

4.2.1 *Tier 1: Site Classification and Non-Site-Specific Screening-Level Corrective Action Goals* - In Tier 1, sites are classified by the urgency of need for initial corrective action, based on information collected from historical records, a visual inspection, and minimal site assessment data. The user is required to identify contaminant sources, obvious environmental impacts (if any), the presence of potentially impacted humans and environmental resources (e.g. workers, residents, water bodies, etc.), and potential significant transport pathways (e.g. groundwater flow, atmospheric dispersion, etc.). Associated with site classifications are prescribed initial

response actions that are to be implemented prior to proceeding further with the RBCA process.

4.2.1 In addition, as part of Tier 1, conservative corrective action goals are based on an evergreen list of non-site-specific, risk-based screening levels (RBSLs), aesthetic criteria, and other appropriate standards such as Maximum Contaminant Levels (MCLs) for potable groundwater use. Tier 1 RBSLs are typically derived for standard exposure scenarios using current reasonable maximum exposure (RME) and toxicological parameters as recommended by the USEPA, and conservative contaminant migration models. These values are "evergreen" and will change as new methodologies and parameters are developed. Tier 1 RBSLs may be presented as a range of values, corresponding to a range of risks, and a risk management decision is made to select the screening levels to be used. This evaluation may include a cost-benefit analysis, where the user considers the costs associated with achieving various levels of risk reduction

4.2.2 *Tier 2: Site-Specific Corrective Action Goals* - Tier 2 provides the user with an option for determining site-specific target levels (SSTLs) and appropriate points of compliance when it is judged that Tier 1 corrective action goals are not appropriate. This decision is typically based on comparing the cost of achieving Tier 1 corrective action goals with the cost for Tier 2 analyses, considering the probability that the Tier 2 site-specific goals will be significantly less costly to achieve than Tier 1 goals. It is important to note that both Tier 1 and Tier 2 screening levels are based on achieving similar levels of human health and environmental resource protection (~~e.g.,~~ 10^{-4} to 10^{-6} risk levels); however, in moving to higher tiers the user is able to develop more cost-effective corrective action plans because the conservative assumptions of earlier tiers are replaced with more realistic site-specific assumptions. Additional site assessment data may be required, but minimal incremental effort is usually required relative to Tier 1. In some cases the Tier 2 SSTLs are derived from the same equations used to calculate Tier 1 RBSLs, except that site-specific parameters are used in the calculations. At other sites, The Tier 2 analysis may involve applying Tier 1 RBSLs at more probable points of exposure, such as property boundaries and negotiated points of compliance, and then deriving Tier 2 corrective action goals for the petroleum source areas based on demonstrated and predicted attenuation of hydrocarbon compounds with distance (~~as is discussed in~~ §5.6.3). Again, Tier 2 corrective action goals are considered conservative and are consistent with USEPA-recommended practices.

4.2.3 *Tier 3: Site-Specific Corrective Action Goals* - Tier 3 provides the user with an option for determining site-specific target levels (SSTLs) and appropriate points of compliance when it is judged that Tier 2 corrective action goals are not appropriate. As in §4.2.3, this decision is typically based on comparing the cost of achieving Tier 2 corrective action goals with the cost for Tier 3

analyses, considering the probability that the Tier 3 site-specific goals will be significantly less costly to achieve than Tier 2 goals. The major distinction between Tier 2 and Tier 3 analyses is that a Tier 3 analysis is generally a substantial incremental effort relative to Tiers 1 and 2, as the analysis is much more complex and may include detailed site assessment, probabilistic evaluations, and sophisticated chemical fate/transport models.

4.3 If ~~exceedences of~~ the selected target levels are exceeded and corrective action is necessary, the user develops a corrective action plan in order to reduce the potential for adverse impacts. One option is to utilize traditional remediation processes to reduce contaminant concentrations below the target levels. Another equally viable option is to achieve exposure reduction (or elimination) through the institutional controls discussed in Appendix D, or through the use of containment measures, such as capping and hydraulic control. X4

5.0 Risk-Based Corrective Action (RBCA) Procedures

5.1 The sequence of principal tasks and decisions associated with the RBCA process are outlined on the flowchart shown in Figure 1. Each of these tasks and decisions is discussed ~~below~~ as follows.

5.2 *Step 1: Initial Site Assessment* - Collect and assemble the data necessary to complete the Tier 1 analyses. In the interest of minimizing costs and expediting the RBCA process, it is important to focus initial site assessment activities on gathering that information which is necessary for the Tier 1 evaluation ~~(as discussed below)~~. As needed for Tier 2 or Tier 3 analyses, additional information (aquifer hydraulic properties, site-specific contaminant attenuation parameters, etc.), can be collected as the RBCA program proceeds. Tier 1 requirements and activities include:

5.2.1 *Source Characterization* - Historical records of site activities and past releases, and chemical analyses results are used to identify contaminants of concern and to locate major sources of these compounds. The field sampling program is then focussed toward identifying maximum concentrations of those most prevalent, toxic, and mobile compounds, and towards identifying if both soil and groundwater have been impacted (see X1 Appendix A for a discussion of the properties of common petroleum fuel products, as well as a summary of the relevant chemical and toxicological properties of key constituents). Initially, chemical analyses may include a wide range of suspected contaminants; however, as the investigation proceeds, the list of analytes can be narrowed to those compounds that consistently exceed the values given in a Tier 1 Look-Up Table (~~discussed below in §~~ see §5.4). Most investigations will encompass the sampling of all media (soil, groundwater, soil gas) to some degree; although, the analyses conducted on each may be very different. For example, soil samples may be sent to a laboratory for detailed GC analyses, while soil gas samples from a utility conduit may be analyzed by a portable explosimeter when the

goal is to verify if immediately hazardous levels exist. The amount of information necessary for the Tier 1 assessment is generally less than that collected for Tier 2 and Tier 3 analyses.

5.2.2 *Potential for Exposure and Degradation of Beneficial Uses* - The locations of humans and environmental resources that could reasonably be impacted ("receptors"), identification of potential significant transport and exposure pathways (groundwater transport, vapor migration through soils and utilities, etc.), and current and potential future uses of the surrounding land, groundwater, surface water and sensitive habitats is recorded. This information can be obtained from visual inspections, well inventory records, engineering drawings, and hydrogeological assessment data, and is used to determine the potential for continued near term and future impacts to human and environmental receptors.

5.2.3 *Extent of Migration* - In addition to the sampling of source areas, concentrations are measured at potential points of exposure or concern (~~e.g.~~ for example, dissolved concentrations in nearby drinking water wells, or vapor concentrations in nearby conduits or sewers). If it is already known that maximum source area concentrations exceed the Tier 1 non-site-specific risk-based screening levels (RBSLs), aesthetic criteria, or other relevant criteria (~~e.g.~~ for example, explosive limits), then it is useful at this point to also define the boundaries where these criteria are exceeded. The investigation should assess any potential preferential migration pathway, such as sewers, electrical conduits, etc..

5.2.4 *Summary of Site Characterization Results* - The site characterization data should be summarized in a clear and concise format. This can be accomplished through the use of pre-formatted tables and figures - this has the added advantage that the consistent presentation of results for many sites often speeds the review process. Tables 1 and 2 present outlines for tables and figures, respectively, that can be used to effectively present the site characterization results.

5.3 *Step 2: Site Classification and Initial Response Action* - As the user gathers data, site conditions should be compared with the scenarios listed in Table 3, and the scenario/classification most representative of actual site conditions should be selected, beginning with Classification 1 scenarios. Then an appropriate initial response action should be implemented, consistent with site conditions. This process is repeated every time additional data is collected at a site.

5.3.1 The classification scheme given in Table 3 is based on the current and projected degree of hazard to human health and environmental resources. "Classification 1" sites are associated with immediate threats to human health and environmental resources, while "Classification 4" sites are associated with no reasonable potential threat to human health or to

environmental resources. Classification levels falling between the two extremes are representative of varying degrees of potential impacts.

5.3.2 Associated with each classification in Table 3 is a potential initial response action; the initial response actions are implemented in order to eliminate any potential immediate impacts to human health and environmental resources as well as to minimize the potential for future impacts that may occur as one proceeds with the RBCA process, or while limited resources are focussed on higher priority sites. Note that initial response actions do not always require active remediation; in many cases the initial response action is to monitor or further assess site conditions to insure that risks posed by the site do not increase above acceptable levels with time. The initial response actions given in Table 3 should be regarded as recommendations, and the user is free to negotiate other appropriate alternatives.

5.3.3 The site classification should be re-evaluated whenever additional site information is collected or whenever implementation of an interim corrective action causes a significant change in site conditions.

5.4 *Step 3: Comparison of Site Conditions with Tier 1 Risk-Based Screening Levels (RBSLs) and Tier 1 Corrective Action Selection* - Select the reasonable potential exposure scenario(s), (if any), most appropriate for the site from a list of pre-defined exposure scenarios. At a minimum the list of pre-defined exposure scenarios includes residential and commercial/industrial scenarios; however, in some cases it may also be desirable to supplement these with an infrequent construction worker scenario.

5.4.1 The Risk Evaluation Flowchart presented in Figure 2 is a tool that can be used to guide the user in selecting appropriate exposure scenarios based on site characterization information. ~~Later~~ this worksheet is also used in the evaluation of corrective action alternatives. To complete this flowchart, a step-wise process is followed:

5.4.1.1 *Exposure Pathway Characterization:* Identify primary sources, secondary sources, transport mechanisms, and exposure pathways.

5.4.1.2 Using the data summarized from Tier 1, customize the Risk Evaluation Flowchart for the site by checking the small checkbox for every relevant source, transport mechanism, and exposure pathway.

5.4.1.3 *Exposure Scenario Characterization:* Select appropriate receptors (if any) and exposure scenarios based on current and projected reasonable use scenarios.

5.4.1.4 For each exposure pathway selected, check the most appropriate exposure scenario description (residential, commercial, etc.). Consider land use restrictions and surrounding land use when making this selection.

Residential exposure scenarios (the most conservative) are appropriate for residential, or unrestricted future land use. Commercial exposure scenarios are used to characterize current and projected future commercial and light industrial land use. Do not check any boxes if there are no receptors present, or likely to be present, or if institutional controls prevent exposure from occurring, and are likely to stay in place.

5.4.2 For each compound and selected exposure scenario, use Tier 1 RBSL "Look-Up Tables" to identify the corresponding risk-based screening levels (RBSLs) for a range of carcinogenic risk levels (10^{-6} to 10^{-4} are often evaluated) and hazard quotients (HQ) equal to unity. **After considering aesthetic, ecological, other relevant criteria, and background levels, select appropriate Tier 1 screening level(s).** Then compare these values with site conditions and identify any exceedences. If there is sufficient site characterization data, the user may opt to compare screening level values with statistical limits (~~e.g.~~ upper confidence levels) rather than maximum values detected. for example

5.4.3 Note that when the potential for carcinogenic human health effects is of concern, an acceptable risk level is selected to complete this step, and this value must be negotiated between all parties involved, and may involve using results from a cost-benefit analysis. One approach is to select target risk levels that reflect the probability of exposure; more conservative risk levels are selected for actual exposures and less conservative risk levels are chosen for potential exposure scenarios. For reference, risks in the 10^{-6} to 10^{-4} risk range are generally considered acceptable at this time. When selecting a target risk level it is important to be aware of background concentrations; for example, as shown in Table 4, national ambient background benzene vapor concentrations exceed concentrations corresponding to the 10^{-6} risk level (as calculated using USEPA RME parameter values). Note that additivity of risks is not explicitly considered in the Tier 1 analysis, as it is expected that the screening levels are very conservative, and typically a limited number of chemicals is considered to be of concern at most sites. Additivity is addressed in Tier 2 and Tier 3 analyses.

5.4.4 Tier 1 "Look-Up Tables" contain conservative, non-site-specific risk-based screening levels (RBSLs) for a range of prescribed scenarios, and may also include aesthetic criteria, and other appropriate standards. The RBSLs are calculated according to methodology suggested by the USEPA. For each exposure scenario the RBSLs are based on current USEPA Reasonable Maximum Exposure (RME) parameters, and current toxicological information given in the USEPA Integrated Risk Information System (IRIS) Database, Health Effects Assessment Summary Tables (HEAST), or peer-reviewed source(s). Consequently, the RBSL Look-Up Table is an "evergreen" set of values that is continually updated whenever new

methodologies and parameters are developed. Where required, hydrocarbon fate and transport estimations are based on conservative fate and transport models.

5.4.5 Table 4 is an example of an abbreviated Tier 1 RBSL Look-Up Table for compounds of concern associated with petroleum fuel releases. The exposure scenarios selected in this case are for residential and industrial/commercial scenarios characterized by USEPA Reasonable Maximum Exposure (RME) parameters for adult males. The assumptions and methodology used in deriving Table 4 are discussed in Appendix [illegible]. Note that not all possible exposure pathways are considered in the derivation of Table 4, which is presented here only as an example. **The user should always review the assumptions and methodology used to derive values in a look-up table to make sure that they are consistent with reasonable exposure scenarios for the site being considered as well as currently accepted methodologies.** The value of creating a standard look-up table is that users do not have to repeat the conservative exposure calculations for each site encountered, except when RME parameters, toxicological information, or recommended methodologies are updated. Many states have compiled such tables for direct exposure pathways, and for the most part many of these tables contain identical values (as they are based on the same assumptions). Values for the cross-media pathways (e.g. volatilization and leaching), when available, often differ; because these involve coupling exposure calculations with predictive equations for the fate and transport of chemicals in the environment. As yet, there is little agreement in the technical community as to conservative non-site-specific values for the transport and fate model parameters, or as to the choice of the models themselves. **Again the reader should note that Table 4 is presented here only as an abbreviated example of a Tier 1 RBSL Look-Up Table for typical compounds of concern associated with petroleum fuels. It should not be interpreted as a list of proposed standards .**

5.4.6 *Use of TPH Measurements* - Various chemical analysis methods commonly referred to as "Total Petroleum Hydrocarbons" (TPH) are often used in site assessments. These methods usually determine the total amount of hydrocarbons present as a single number, and give no information on the types of hydrocarbon present. Such TPH methods are useful for identifying the boundaries of contamination and for locating "hot spots", and may be useful for risk assessments where the whole product toxicity approach is appropriate. However in general, TPH should not be used for "individual constituent" risk assessments because the general measure of TPH provides insufficient information about the amounts of individual compounds present.

5.4.7 *Corrective Action Assessment:* Identify potential Tier 1 corrective measures that will remove sources, limit release mechanisms, or block exposure pathways that are responsible for the screening level concentration exceedences. Record these on a Tier 1 Analysis Summary Sheet.

5.4.8 The Exposure Scenario Evaluation Flowchart (Figure 2) can be used to graphically portray the effect of the Tier 1 corrective action. Select the Tier 1 corrective measure or measures (shown as valve symbols) that will break the lines linking sources, transport mechanisms, and pathways leading to the screening level concentration exceedences. Adjust the mix of corrective measures until no potential receptors have exceedences with the corrective measures in place. Show the most likely Tier 1 corrective measure(s) selected for this site by marking the appropriate valve symbols on the flowchart and recording a corrective measure abbreviation (defined by the user on the right-hand-side of ~~this~~ figure).

5.5 *Step 4: Evaluation of Tier 1 Results* - At this point, results of the Tier 1 assessment are reviewed and one of the following four options is selected:

5.5.1 *No Action:* If source concentrations do not exceed applicable screening level concentrations, no further action may be required. Compliance monitoring may be implemented, as appropriate, to confirm that current conditions persist or improve with time.

5.5.2 *Final Corrective Action:* If source concentrations exceed applicable screening level concentrations, a corrective action program may be designed and implemented to achieve the Tier 1 corrective action goals. This program may include some combination of source removal and containment technologies, as well as institutional controls.

5.5.3 *Interim Corrective Action:* If achieving the necessary risk reduction is impracticable due to technology or resource limitations, an interim corrective action, such as removal or treatment of "hot spots", may be conducted to address the most significant concerns, change the site classification and initial response, and facilitate reassessment of the corrective action plan.

5.5.4 *Tier Upgrade - Further Analysis:* If remediation, containment measures, and institutional controls are judged to be impracticable or inappropriate, additional site information can be collected as needed for reassessment of corrective action goals per Tier 2 of the RBCA process. This decision is typically based on comparing the cost of achieving Tier 1 corrective action goals with the cost for Tier 2 analyses, considering the probability that the Tier 2 site-specific goals will be significantly less costly to achieve than Tier 1 goals. It is important to note that both Tier 1 and Tier 2 screening levels are based on achieving similar levels of human health and environmental resource protection (~~e.g.,~~ for example, 10^{-4} to 10^{-6} risk levels); however, in moving to

higher tiers the user is able to develop more cost-effective corrective action plans because the conservative assumptions of earlier tiers are replaced with more realistic site-specific assumptions.

5.5.5 This decision and the scope of any proposed RBCA activities are now recorded and the Tier 1 analysis is complete.

5.6 *Step 5: Tier 2 - Expanded Site Assessment, Re-classification, and Site-Specific Corrective Action Goals (Optional)* - Tier 2 provides the user with an option for negotiating site-specific risk-based corrective action goals and points of compliance when there is an economic incentive to do so (see §5.5.4). Additional site assessment data may be required; however, the incremental effort is typically minimal relative to Tier 1. In most cases, only a limited number of pathways, exposure scenarios, and chemicals are considered in the Tier 2 analysis since many are eliminated from consideration during the Tier 1 evaluation. In Tier 2 the user negotiates compliance points and target concentrations at those points, and uses a combination of assessment data and predictive modeling results to determine target source area concentrations that correspond to compliance with the negotiated compliance point target levels. Examples of Tier 2 analyses include:

5.6.1 Application of Tier 1 RBSLs Look-Up Table values at reasonable points of compliance (as opposed to anywhere in an aquifer, geologic formation, or atmosphere as is done in Tier 1), such as property boundaries or negotiated compliance points located somewhere between source areas and reasonable potential receptors. Corrective action goals (site-specific target levels, time to achieve these values, etc.) for source areas are then based on the demonstrated and predicted attenuation (reduction in concentration with distance) of compounds that migrate away from the source area.

5.6.2 Applying the methodology for deriving values in the Tier 1 RBSL Look-Up Table, with the exception that site-specific parameters may replace the Tier 1 conservative assumptions. An example might be in the modeling of hydrocarbons leaching from soils to groundwater, where assumed infiltration rates, source sizes, and aquifer parameters are replaced with the actual values for a given site.

5.6.3 An example of a Tier 2 application is illustrated in Figure 3. Here, fuel has been released from a leaking product line and groundwater is impacted. The responsible party wishes to establish target concentrations for groundwater in the source areas based on assessment data that demonstrates the attenuation of contaminants down-gradient of the source area. A negotiated compliance point is selected down-gradient of the source area and upgradient of any actual potential receptors. Data from the site indicates that contaminant concentrations are observed, and predicted, to decline by a

factor of 100 between the source area and the compliance point, therefore the target source area groundwater concentration is established at 100 times the compliance point concentration.

5.6.4 Tiers 2 and 3 of the RBCA process involve the development of site-specific target levels (SSTLs) based on the measured and predicted attenuation of contaminants away from the source area(s). Tier 2 is based on the practical realization that our ability to characterize sites is limited; and, therefore, expectations for compound attenuation with distance from source area(s) are based on interpolating and extrapolating site-specific data through the use of relatively simplistic "screening" mathematical models. These predictive equations are characterized by the following

5.6.4.1 the models are relatively simplistic, and are often algebraic or semi-analytical expressions,

5.6.4.2 model input is limited to practicably attainable site-specific data, or easily estimated quantities (~~e.g.~~ for example, total porosity, soil bulk density), and

5.6.4.3 the models are based on descriptions of relevant physical/chemical phenomena. Any mechanisms that are neglected result in predictions that are conservative relative to those likely to occur (~~e.g.~~ for example, assuming constant concentrations in petroleum source areas, or neglecting attenuation due to natural biodegradation). In other words, these models are biased towards predicting exposure concentrations in excess of those likely to occur. Appendix C X3 discusses the use of predictive models and presents example screening level models that might be considered for Tier 2 analyses.

5.7 *Step 6: Evaluation of Tier 2 Results* - At this point, results of the Tier 2 analyses are reviewed and one of the following four options is selected:

5.7.1 *No Action:* If source concentrations do not exceed Tier 2 site-specific target levels (SSTLs), no further action may be required. Compliance monitoring may be implemented, as appropriate, to confirm that current conditions persist or improve with time.

5.7.2 *Final Corrective Action:* If source concentrations exceed Tier 2 SSTLs, a corrective action program may be designed and implemented. This program may include some combination of source removal, treatment, and containment technologies, as well as institutional controls.

5.7.3 *Interim Corrective Action:* If achieving the desired risk reduction is impracticable due to technology or resource limitations, an interim corrective action, such as removal or treatment of "hot spots", may be conducted to address the most significant concerns, change the site classification, and facilitate reassessment of the corrective action plan.

5.7.4 *Tier Upgrade - Further Analysis:* If remediation, containment measures, and institutional controls are judged to be impracticable, additional site information can be collected as needed for reassessment of corrective action goals per Tier 3 of the RBCA process. This decision is typically based on comparing the cost of achieving Tier 2 corrective action goals with the cost for Tier 3 analyses, considering the probability that the Tier 3 site-specific goals will be significantly less costly to achieve than Tier 2 goals. It is important to note that both Tier 2 and Tier 3 screening levels are based on achieving similar levels of human health and environmental resource protection (~~e.g.~~ for example, 10^{-4} to 10^{-6} risk levels); however, in moving to higher tiers the user is able to develop more cost-effective corrective action plans because the conservative assumptions of earlier tiers are replaced with more realistic site-specific assumptions.

5.7.5 This decision and the scope of any proposed RBCA activities are now recorded and Tier 2 is complete.

5.8 *Step 7: Tier 3 - Expanded Site Assessment, Re-classification, and Site-Specific Corrective Action Goals (Optional)* - In a Tier 3 assessment, SSTLs are developed on the basis of more sophisticated statistical and contaminant fate and transport analyses, using site-specific input parameters (~~e.g.~~ for example Monte Carlo simulations). Tier 3 corrective action assessments commonly involve collection of significant additional site information and completion of more costly modeling efforts than required for either a Tier 1 or Tier 2 planning effort. Examples of Tier 3 analyses include:

To-date not needed

5.8.1 The use of numerical groundwater codes that predict time-dependent dissolved contaminant transport under conditions of spatially varying permeability fields to predict exposure point concentrations,

5.8.2 The use of site-specific data, screening level models, and Monte Carlo analyses to predict a statistical distribution of exposures and risks for a given site, and

~~and~~

5.8.3 The gathering of sufficient data to refine site-specific parameter estimates (for example ~~e.g.~~ biodegradation rates) and improve model accuracy in order to minimize future monitoring requirements.

5.9 *Step 8: Evaluation of Tier 3 Results* - At this point, results of the Tier 3 analyses are reviewed and one of the following four options is selected:

5.9.1 *No Action:* If source concentrations do not exceed Tier 3 site-specific target levels (SSTLs), no further action may be required. Compliance monitoring

may be implemented, as appropriate, to confirm that current conditions persist or improve with time.

5.9.2 *Final Corrective Action:* If source concentrations exceed Tier 3 SSTLs, a corrective action program may be designed and implemented. This program may include some combination of source removal, treatment, and containment technologies, as well as institutional controls.

5.9.3 *Interim Corrective Action:* If achieving the desired risk reduction is impracticable due to technology or resource limitations, an interim corrective action, such as removal or treatment of "hot spots", may be conducted to address the most significant concerns, change the site classification, and facilitate reassessment of the corrective action plan.

5.9.4 This decision and the scope of any proposed RBCA activities are now recorded and Tier 3 is complete.

5.10 *Step 9: Implementing the Selected Corrective Action Program* - When it is judged that no further assessment is necessary, or practicable, an engineering feasibility study should be conducted to confirm the most cost-effective option for achieving the final corrective action levels. Detailed design specifications may then be developed for installation and operation of the selected measure. The corrective action must continue until such time as compliance monitoring indicates that contaminant concentrations no longer exceed the negotiated compliance levels. Corrective action options include mass removal (treatment, excavation, etc.) methods as well as containment and institutional controls (~~e.g.~~ for example, deed restrictions).

5.11 *Step 10: Compliance Monitoring and Site Maintenance* - In many cases, compliance monitoring for a limited time period is required to demonstrate the effectiveness of implemented corrective action measures. Upon completion of this monitoring effort (if required), no further action is required. In addition, some measures (~~e.g.~~ for example, physical barriers - capping, hydraulic control, etc.) require maintenance to insure integrity and continued performance.

5.12 *No Further Action and Site Closure* - When RBCA goals have been demonstrated to be achieved, and compliance monitoring and site maintenance are no longer required to insure that this condition persists, then no further action is necessary - except to insure that institutional controls (if any) remain in place.

6. Potential Problems

6.1 As with any process, the potential exists for misapplication of the RBCA process. In most cases the root cause will be a lack of understanding of the process and improper use of process components. In order to prevent misuse of the process, the following should be avoided:

6.1.1 use of Tier 1 risk-based screening levels as default remediation standards rather than conservative screening levels,

6.1.2 placing arbitrary time constraints on the process; for example, requiring that Tiers 1, 2, and 3 be completed within 30 day time periods rather than letting the time frame be based on risks posed by the site,

6.1.3 use of the process as a closure tool only, rather than a process that is applicable during all phases of corrective action,

6.1.4 requiring responsible parties to achieve technology-based remedial limits prior to requesting the approval for site-specific goals,

6.1.5 the inappropriate use of predictive modelling,

6.1.6 dictating that corrective action goals can only be achieved through source removal and treatment actions, thereby restricting the use of exposure reduction options, such as containment and institutional controls,

6.1.7 the use of inappropriate or unfounded exposure factors,

6.1.8 the use of antiquated toxicity parameters,

6.1.9 neglecting aesthetic and other criteria when negotiating target concentrations,

6.1.10 not considering the effects of additivity when screening multiple chemicals,

6.1.11 not negotiating institutional controls, compliance points, and target risk ranges before submitting corrective action plans, and

6.1.12 not honoring institutional controls.

Table 1. RBCA Tier 1 Summary Table Requirements.

Table #	Title	Contents
1	Executive Summary	• summary of visual & historic assessments • summary of receptor characterization • summary of tasks completed to date • results of classification exercise and selected interim response action • corrective action criteria exceeded • proposed/implemented corrective action
2	Site Description	• site address • site owner/contact • agency contacts • local land use • topography • surface water characterization • climatic information
3	Site Ownership & Activity Record	• describe past production and materials handling activities, waste disposal practices, chemicals used, and site ownership
4	Past Releases or Source Areas	• describe potential sources and spill events including: location, type and volume of materials released, time and duration of release, and affected media (soil, groundwater, surface water, etc.) • discuss past remediation efforts as appropriate • list any potential off-site sources
5	Summary of Current & Completed Site Activities	• describe all relevant ongoing and completed corrective action activities at the site (site investigation, emergency response, etc.)
6	Regional Hydrogeologic Conditions	• describe regional geologic framework through depth of principal aquifer and any other potentially impacted units

Table 1. RBCA Tier 1 Summary Table Requirements (cont.).

Table #	Title	Contents
7	Site Hydrogeologic Conditions	• describe site geologic framework through depth of principal aquifer and any other potentially impacted units • vadose zone thickness and geology • depth to groundwater • thickness of aquifer • maximum well yield • flow direction and gradient • description of any confining units • current groundwater quality (TDS) • off-site water quality
8	Beneficial Use Summary	• identify existing and reasonable potential beneficial uses for land, groundwater, and surface water
9	Receptor Survey (wells, utilities, basements, surface water, environmental resources, etc.)	• summarize relevant results (i.e. for well survey: well designation, distance from site, depth, construction details, age, etc. of wells for 0.5 mile radius around site) • Identify those receptors most likely to be impacted
10	Analytical Summary Sheets (these are intended for use as a tool to summarize analytical data and provide a tool for comparing site data with Tier 1 screening levels)	• compounds detected • analytical method(s) used • practical quantification limit • number of samples analyzed • compound detection frequency • maximum concentration detected • location of maximum concentration • sampling date • background concentrations • trend (stable, increasing, decreasing) • appropriate Tier 1 target levels (RBSLs, MCLs, etc.)
11	Ecological Assessment Summary Sheet	• observed impacts associated with site to vegetation, birds, fish, mammals, etc. • presence and description of any impacted sensitive habitats • ecological receptors (threatened or endangered species, economically or sport important species, etc.)

Table 2. RBCA Tier 1 Summary Figure Requirements.

Figure #	Title	Contents
1	Site Location Map	• show general vicinity. • identify surface water bodies • show groundwater supply wells and designation (e.g. drinking water, irrigation, etc.) • identify other potential receptors • show topography (use USGS quad maps, if available)
2	Extended Site Map	• show local land use including schools, hospitals, retirement homes, residential areas, commercial areas, and any groundwater supply wells
3	Site Plan View (this map should be developed from historical maps, plans, and aerial photos, and should encompass potentially impacted areas)	• location of all structures • location of buried tanks • location of buried conduits • location of suspected/confirmed sources • areas of ecological interest • areas of soil contamination
4	Site Photos	• provide photos of site, potentially contaminated areas, tank excavations, and surrounding property (show in chronological order)
5	Groundwater Elevation Map	• potentiometric surface contour map for any potentially impacted water-bearing units • date
6	Geologic Cross-Section(s)	• show site stratigraphy through full depth of potentially impacted water-bearing units, including underlying confining layer • prepare two cross-sections for each site (parallel and perpendicular to groundwater flow) • indicate contaminant concentrations • indicate subsurface piping, conduits, tanks, etc.
7	Dissolved Contaminant Plume Map(s)	• show lateral extent of impacted groundwater • indicate sampling locations and concentrations • show location of any free product • show time series data (if possible)

Table 3. Site Classification Scenarios and Potential Initial Response Actions (from Johnson et al. 1993).

Classification	Criteria & Prescribed Scenarios	Possible Initial Response Actions*
1	*Immediate threat to human health, safety, or sensitive environmental receptors*	*Notify appropriate authorities, property owners, and potentially affected parties, and evaluate the need to:*
1.1	• explosive levels, or concentrations of vapors that could cause acute health effects, are present in a residence or other building.	• evacuate occupants, begin abatement measures such as subsurface ventilation, or building pressurization.
1.2	• explosive levels of vapors are present in subsurface utility system(s), but no building or residences are impacted.	• evacuate immediate vicinity, begin abatement measures such as ventilation
1.3	• free-product is present in significant quantities at ground surface, on surface water bodies, in utilities other than water supply lines, or in surface water runoff.	• prevent further free-product migration by appropriate containment measures, institute free-product recovery, restrict area access.
1.4	• an active public water supply well, public water supply line, or public surface water intake is impacted or immediately threatened.	• notify user(s), provide alternate water supply, hydraulically control contaminated water, and treat water at point-of-use.
1.5	• ambient vapor/particulate concentrations exceed concentrations of concern from an acute exposure, or safety viewpoint.	• install vapor barrier (capping, foams, etc.), remove source, or restrict access to affected area.
1.6	• a sensitive habitat or sensitive resources (sport fish, economically important species, threatened and endangered species, etc.) are impacted and affected.	• minimize extent of impact by containment measures and implement habitat management to minimize exposure.

* - note that these are potential initial response actions that may not be appropriate for all sites. The user is encouraged to select options that best address the short-term health and safety concerns of the site, while the RBCA process progresses.

Table 3. Site Classification Scenarios and Potential Initial Response Actions (cont.).

Classification	Criteria & Prescribed Scenarios	Possible Initial Response Actions*
2	*Short-term (0 - 2 years) threat to human health, safety, or sensitive environmental receptors*	*Notify appropriate authorities, property owners, and potentially affected parties, and evaluate the need to:*
2.1	• there is potential for explosive levels, or concentrations of vapors that could cause acute effects, to accumulate in a residence or other building.	• assess the potential for vapor migration (through monitoring/modeling) and remove source (if necessary), or install vapor migration barrier.
2.2	• shallow contaminated surface soils are open to public access, and dwellings, parks, playgrounds, day care centers, schools, or similar use facilities are within 500 ft of those soils.	• remove soils, cover soils, or restrict access.
2.3	• a non-potable water supply well is impacted or immediately threatened.	• notify owner/user, evaluate the need to install point-of-use water treatment, hydraulic control, or alternate water supply.
2.4	• groundwater is impacted and a public or domestic water supply well producing from the impacted aquifer is located within two years projected groundwater travel distance downgradient of the known extent of contamination.	• institute monitoring, then evaluate if natural attenuation is sufficient, or if hydraulic control is required.
2.5	• groundwater is impacted and a public or domestic water supply well producing from a different interval is located within the known extent of contamination.	• monitor groundwater well quality and evaluate if control is necessary to prevent vertical migration to the supply well.
2.6	• impacted surface water, storm water, or groundwater discharges within 500 ft of a sensitive habitat, or surface water body used for human drinking water or contact recreation.	• institute containment measures, restrict access to areas near discharge, and evaluate the magnitude and impact of the discharge.

* - note that these are potential initial response actions that may not be appropriate for all sites. The user is encouraged to select options that best address the short-term health and safety concerns of the site, while the RBCA process progresses.

Table 3. Site Classification Scenarios and Potential Initial Response Actions (cont.).

Classification	Criteria & Prescribed Scenarios	Possible Initial Response Actions[1]
3	*Long-term (> 2 years) threat to human health, safety, or sensitive environmental receptors*	*Notify appropriate authorities, property owners, and potentially affected parties, and evaluate the need to:*
3.1	• subsurface soils (>3 ft BGS) are impacted and depth between impacted soils and the first potable aquifer is less than 50 ft.	• monitor groundwater and determine the potential for future contaminant migration to the aquifer.
3.2	• groundwater is impacted and potable water supply wells producing from the impacted interval are located >2 years groundwater travel time from the dissolved plume.	• monitor the dissolved plume and evaluate the potential for natural attenuation and the need for hydraulic control.
3.3	• groundwater is impacted and non-potable water supply wells producing from the impacted interval are located >2 years groundwater travel time from the dissolved plume.	• identify water usage of well, assess the effect of potential impact, monitor the dissolved plume, and evaluate whether natural attenuation or hydraulic control are appropriate control measures.
3.4	• groundwater is impacted and non-potable water supply wells that do not produce from the impacted interval are located within the known extent of contamination.	• monitor the dissolved plume, determine the potential for vertical migration, notify the user, and determine if any impact is likely.
3.5	• impacted surface water, storm water, or groundwater discharges within 1500 ft of a sensitive habitat, or surface water body used for human drinking water or contact recreation.	• investigate current impact on sensitive habitat or surface water body, restrict access to area of discharge (if necessary) and evaluate the need for containment/control measures.
3.6	• shallow contaminated surface soils are open to public access, and dwellings, parks, playgrounds, day care centers, schools, or similar use facilities are more than 500 ft of those soils.	• restrict access to impacted soils.

[1] - note that these are potential initial response actions that may not be appropriate for all sites. The user is encouraged to select options that best address the short-term health and safety concerns of the site, while the planning process progresses.

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Table 3. Site Classification Scenarios and Potential Initial Response Actions (cont.).

Classification	Criteria & Prescribed Scenarios	Possible Initial Response Actions*
4	*No demonstrable long-term threat to human health, safety or sensitive environmental receptors* Priority 4 scenarios encompass all other conditions not described in Priorities 1, 2, and 3, and that are consistent with the priority description given above. Some examples are:	*Notify appropriate authorities, property owners, and potentially affected parties, and evaluate the need to:*
4.1	• non-potable aquifer with no existing local use impacted.	• monitor groundwater and evaluate effect of natural attenuation on dissolved plume migration.
4.2	• impacted soils located more than 3 ft BGS and greater than 50 ft above nearest aquifer.	• monitor groundwater and evaluate effect of natural attenuation on leachate migration.
4.3	• groundwater is impacted and non-potable wells are located downgradient outside the known extent of contamination, and they produce from a non-impacted zone.	• monitor groundwater and evaluate effect of natural attenuation on dissolved plume migration.

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* - note that these are potential initial response actions that may not be appropriate for all sites. The user is encouraged to select options that best address the short-term health and safety concerns of the site, while the RBCA process progresses.

Note: for the purpose of this site classification process, an aquifer is considered to a potential potable water supply if it has the potential to yield >200 gal/d, and meets local water quality criteria (i.e. total dissolved solids (TDS) < 10,000 mg/L).

that is

move to top of table

Table 4. Example Tier 1 Risk-Based Screening Level (RBSL) Look-Up Table*.

AIR									
SOIL									
GROUND WATER									

* - This table is presented here only as an example set of Tier 1 RBSLs. It is not a list of proposed standards. The user should review all assumptions prior to using any of the values. Appendix B describes the basis of these values.

[1] - As benzene soluble coal tar patch volatiles.
[2] - American Industrial Hygiene Assoc., 1989: Odor Thresholds for Chemicals with Established Occupational Health Standards.
[3] - From: Shah and Singh, 1988. Env. Sci. Technol. Vol. 22, No. 12; ATSDR, 1988, Toxicology Profiles, U.S. Public Health Service; and Wallace, L.A., 1986. Journal of Occupational Medicine, Vol. 28, No. 5.
"RBS" - selected risk level is not exceeded for pure compound present at any concentration.
"> S" - selected risk level is not exceeded for all possible dissolved levels (≤ pure component solubility).

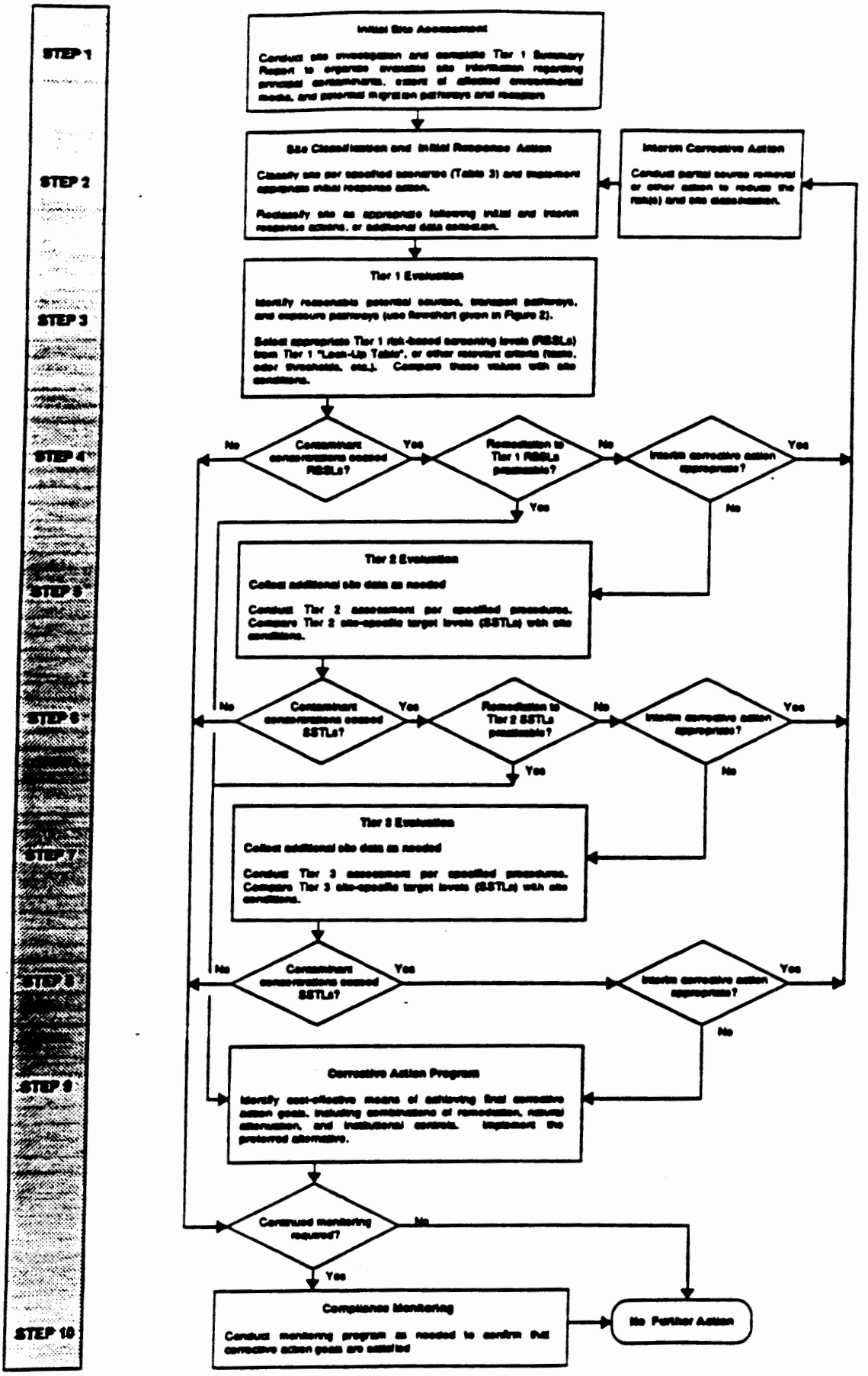

Figure 1. Risk-Based Corrective Action Process Flowchart (Johnson et al. 1993).

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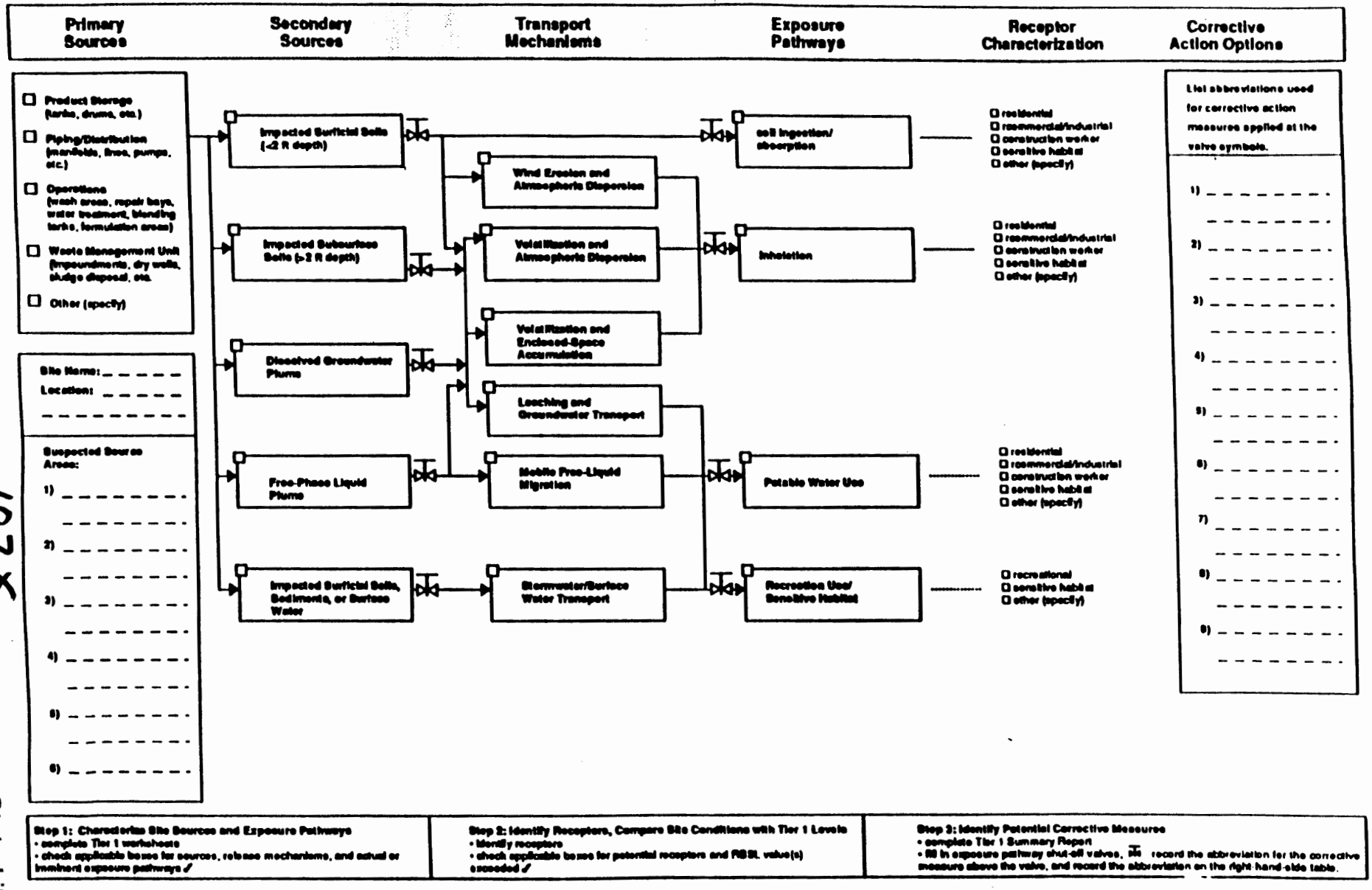

Figure 2. Exposure Scenario Evaluation Flowchart (Johnson et al. 1993).

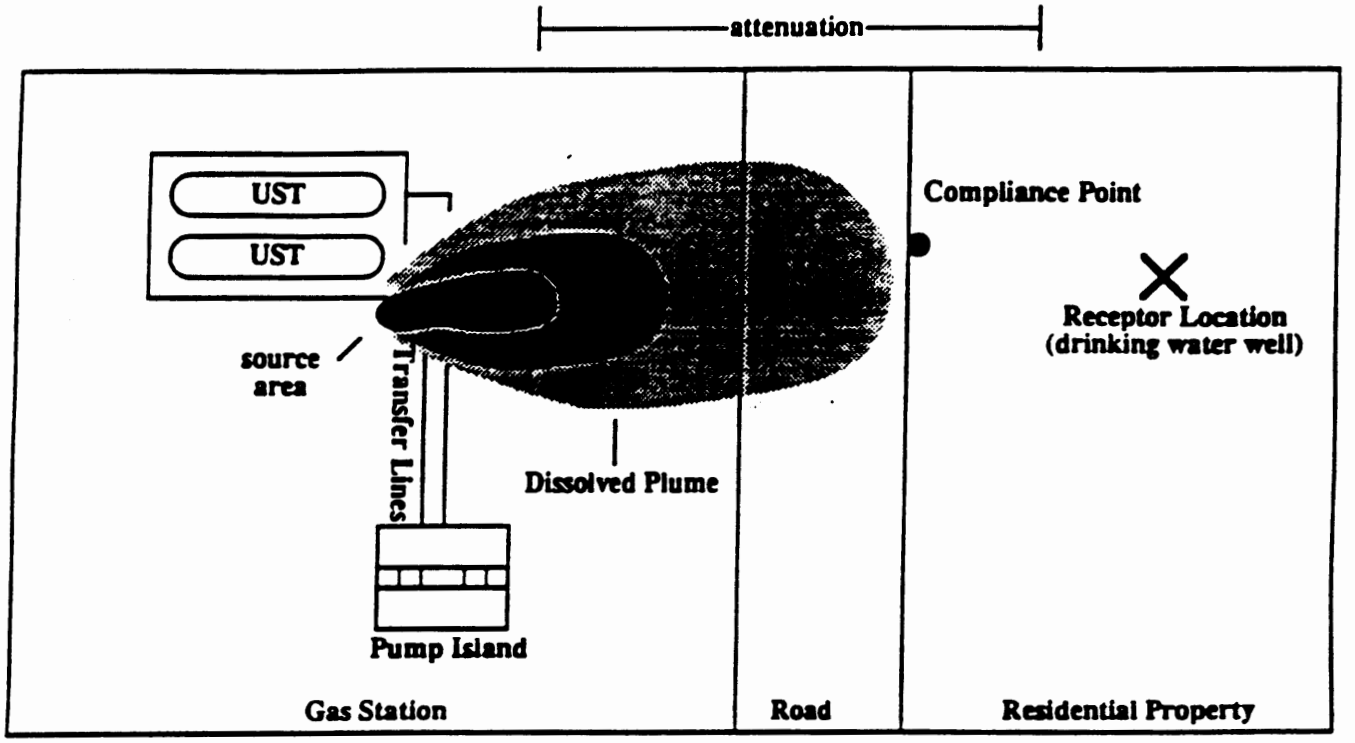

Figure 3. Attenuation of contaminants dissolved in groundwater with distance downgradient of source area

THE UNION COUNTY ALLIANCE

A Coalition for Action

April 8, 1994

Environmental Risk Assessment
and Risk Management Study Commission
c/o Ms. Judy Horowitz
Office of Legislative Services
CN-068
Trenton, NJ 08625

Dear Sirs:

The *Union County Alliance* is submitting comments on risk-based site remediation cleanup standards and methodologies for use under ISRA.

These matters are considered by the *Union County Alliance* to be of the highest importance to our mission of restoring economic and quality-of-life momentum for the citizens of the County.

ECRA/ISRA has had a very deleterious effect on the economy and the quality of life in Union County by contributing to business stagnation and joblessness.

The *Union County Alliance*, a coalition for action, was formally inaugurated in June 1993. Its mission is two-fold - to fight for the survival and recovery of Union County and to formulate a long-range vision of the County's major needs and priorities. Leading political, business, civic, academic and labor leaders joined forces as a result of current trends (flight of industry, loss of high wage jobs, deterioration of the revenue base, reduced educational attainment, and decline in the quality of life) that have imposed unacceptable costs on all parts of Union County.

It has become crystal clear to those of us who live or work in Union County that continued inaction guarantees that these conditions will inevitably worsen. This is why major organizations and groups within the County decided to strengthen teamwork and cooperation.

Through the *Alliance*, Union County has committed itself to developing a long-range plan and we consider ourselves uniquely positioned to participate with others throughout the State in partnerships for economic renewal.

Too often only a narrow range of special-interest parties comment on proposed policies and regulations. This can lead to excessive conservatism when a relatively small but conspicuous and politically vociferous segment of the public claims to represent the interests of the entire public.

We wish to help you overcome this excessive conservatism by offering the following comments from our broad-based organization. The *Union County Alliance* represents interests of a wide range of sectors of the public.

Our comments address several public policy issues pertaining to cleanup standards and risk assessment methodologies.

We have reviewed the testimony presented at your March 9-11 hearings. The arguments that were presented for 10-4 to 10-5 risk levels seem compelling. Also, the arguments for reforming the risk estimation methodologies and assumptions to eliminate excessive conservatism are likewise compelling.

Rather than repeat those arguments we simply state here that we strongly endorse them.

The NJDEPE has implemented New Jersey's site cleanup laws (first ECRA and now ISRA) in ways that render title transfers overly cumbersome and costly. Not surprisingly, title transfers have not occurred at nearly the level needed to support economic growth. That has contributed to the economic recession in the entire State, which has hit our County so heavily and delayed economic recovery. This in turn impacts upon joblessness and contraction of tax ratables and social service contributions.

One of the law firms associated with the *Alliance* have reported that complexity and costs have both escalated on cases since the passage of ISRA. ISRA has removed from the regulatory process any flexibility. The initiation of the ISRA process now requires a minimum expenditure of $4,000.00 to review all areas of potential environmental concern and to generate a report which NJDEPE then charges the business a large fee to review. These requirements are imposed upon every ISRA regulated business, even if there has been no adverse impact to the environment. In addition, the fees being charged for NJDEPE review are obscenely large and the fact that the review fees and fines are returned to NJDEPE's budget makes NJDEPE unaccountable to anyone but themselves. In one recent instance, NJDEPE attempted to charge a fee of $1,000.00 to review the data on one sample analyzed for total petroleum hydrocarbons. In several other recent instances, NJDEPE personnel have failed to adequately review submissions and requested the resubmission of data or explanations already provided.

With these burdens already in place, it is crucial that the risks being protected against be evaluated more carefully and realistically, and reconciled against the enormous costs the required protective measures would entail.

We can't afford as a State to pyramid excessive cleanup costs on top of excessive transaction costs and delays.

The policies that we urge you to recommend would:

- Specify a less restrictive standard than 10-6

We believe a range of 10-4 to 10-5 for various contaminants depending on their classification (unproven human carcinogens or proven human carcinogens) is amply protective.

- Require that better science be used in calculating risk levels.

  Data should be scrutinized for gaps and inadequacies before it is used. In the absence of valid data establishing a proven hazard, costly overremediation should be avoided.

- Eliminate use of overly conservative, upper bound assumptions in developing estimates of risk.

  Commonly used risk assessment assumptions are overly conservative. If multiple conservative assumptions are used the risk level is estimated to be far higher than it really is.

  It would be preferable to replace overly conservative assumptions with most likely values, or better yet by a probability-weighted range of values (as in Monte Carlo techniques).

- Recognize that there are huge cost penalties, which in the end the public must pay, associated with having to clean up to very small, overly conservative, risk levels.

  Society has only limited resources, and many needs are competing with remediation. A risk level of 10-6 is not only scientifically arbitrary, but it passes the point of diminishing returns for the use of funds and other resources.

We hope you will give these policy recommendations from the *Union County Alliance* serious consideration as you develop your report and recommendations to the legislature.

Sincerely,

The Union County Alliance

Henry Ross, Ph.D.
Executive Director

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Comments to

Environmental Risk Assessment and
Risk Management Study Commission
Legislative Office Building, CN-68
Trenton, New Jersey 086250068

on

The Risk Level
for
New Jersey Remediation Standards
April 11, 1994

by

Richard A. Davis, Ph.D. D.A.B.T
American Cyanamid Company
Princeton, New Jersey 08543-0400

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Introduction

The New Jersey Legislature charged the Environmental Risk Assessment and Risk Management Study Commission with the duty to examine and assess the scientific basis for selecting the appropriate cancer risk level for remediation standards. Much discussion of this issue has focused on the impact of conservative assumptions and default parameters used in exposure assessment that lead to an inappropriate overestimation of risk. Relatively little comment has focused on conservative assumptions employed in the determination of cancer potency factors that can overestimate risk, as much, if not more, than conservative exposure assumptions (1).

New Jersey remediation standards will probably be determined with EPA derived cancer potency factors. The methods used by EPA to derive these values from animal cancer studies were developed in the mid-1970s (see Crump *et al.* cited in Reference 1) and are designed to define a "plausible upper bound" on potency. It is well known that the linearized multistage (LMS) model, used for this purpose produces one of the highest potency factors (e.g., see Figures 1 and 2 from Reference 2). Potency factors from most other mathematical models are lower, even though these other models may fit the observed cancer data equally well. EPA often states that risk estimates based on upper bound potency factors are high and that the true risks are unknown but could be as low as zero.

The Commission should consider the degree to which EPA cancer potency factors and conservative exposure parameters overestimate risk, and account for the overestimate in the decision on an appropriate cancer risk level. To assist with this goal, we have compiled the following examples that illustrate the degree of overestimation by EPA cancer potency factors alone.

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Human Carcinogens

Cancer potency factors for human carcinogens are most often based on epidemiology data. Dose-response models other than LMS may be used. One may conclude, therefore, that such human cancer potency factors would be less likely to overestimate the true potency factor. However, there are several uncertainties in any epidemiology study that lead to the use of assumptions to determine a conservative upper bound on potency factors derived from such data.

An example of some of these uncertainties and how they are dealt with is presented in Allen *et al.* (Section 2.2 in Reference 3). They present the range and best estimates (Figure 1) of their cancer potency estimates for 23 chemicals shown to be carcinogenic in epidemiology studies. The ratio between the upper bound of the 90% confidence limits (not 95%) and the best estimate appears to vary from 5 to 1000 fold.

Schoof *et al.* (4) have recently completed a reanalysis of EPA's cancer slope factor for arsenic that is based on epidemiologic data. A critical assumption in EPA's determination was the amount of background arsenic intake in the study population. Using measured arsenic concentrations in food to better estimate background intake, Schoof *et al.* found a reduction in the cancer slope factor (CSF) of 1.75 $(mg/kg/day)^{-1}$ to a range of 1.13 to 0.044 $(mg/kg/day)^{-1}$ depending on how arsenic intake was determined. Risk estimates based on the EPA CSF compared to the revised CSF's are 0.6 to 39 fold higher.

Crouch conducted an evaluation of both human and animal cancer data on acrylonitrile and determined the probability distributions of unit risk based on separate and combined data sets (5). Unit risks at the 95th percentile were larger than the medians by 6 and 7

fold (2 data sets) for epidemiology data, 16 fold for animal data and 13 fold for combined human and animal data. EPA's upper bound unit risk was 45 times larger than the Crouch best estimate of unit risk (median value of the combined data distribution).

The above examples show that upper bound cancer potency factors based on human epidemiology data can be substantially higher than most likely or best estimates based on the same data. Risk estimates based on EPA CSF's can be 10 fold or more than most likely(e.g., AN) or less uncertain (e.g., arsenic) estimates. Greater differences that are overly conservative result in the calculation of remediation standards using EPA CSF's and conservative exposure parameters. Therefore, the Commission should increase the lifetime extra cancer risk level from 10^{-6} to 10^{-5} to account for overly conservative risk assessment of human carcinogens.

Animal Carcinogens

Cancer potency factors for humans derived from animal data, could be expected to overestimate the true risk by even greater amounts. The former head of the EPA Carcinogen Assessment Group, Elizabeth Anderson, evaluated the amount of overestimation for some of the assumptions used in this process, at a Harvard School of Public Health presentation in 1984 (Table attached). Her range of risk overestimation for individual assumptions was 1 to 12 fold, but she concluded an overall impact of 15–10,800 fold.

Beck *et al.* (2) provide a case study (pp. 15–17) to evaluate the difference in cancer potency estimates for TCDD and to determine how much of the difference was due to dose-response model, choice of animal bioassay and choice of data set. Choice of dose-response model produced a greater than 10^{13} fold difference in estimates! Choice of bioassay could also produce widely separated potency estimates. Even choice of data set

from the same bioassay and using the same dose-response model could produce a 10-fold difference. The authors concluded it is important "to recognize how much uncertainty may be hidden by science-policy decisions, and how this hidden uncertainty could affect the regulatory process."

Cyanamid has sponsored a project to further illustrate this point with additional data sets (Appendix I). The project goal was to compare the upper bound slope factor derived by the LMS model with the maximum likelihood estimate of the multistage model, in other words to further evaluate factor B in the Anderson table. The scope of this project was substantially limited by time and resources. The necessary data sets used by EPA were most readily available in EPA's IRIS. An initial list of 25 chemicals was selected from a New Jersey remediation site. Of these, six chemicals with 7 animal cancer data sets for which EPA used the LMS model were found in IRIS. Using the software employed by EPA (GLOBAL 86) the LMS upper bound potency factor (q_1^*) and best fit multistage model coefficients where calculated for each data set. The multistage coefficients were used outside of GLOBAL (which will not calculate MLE's) to calculate risk specific doses ($10^{-6}$and 10^{-4}) and compare them to the same doses based on q_1^*. The results are shown in Appendix Table 3. At 10^{-6} level, the upper bound potency factor produced doses 0.2 to 6400 fold greater than the maximum likelihood potency factor. At 10^{-4} risk the range was 0.2 to 64 fold. Differences at the high end of these ranges or even larger might be expected for trichloroethylene (6) and formaldehyde (1).

These results indicate Andersons's' analysis of the difference between upper bound and maximum likelihood estimates may be substantially low for some chemicals. As discussed by Wilson (1), this would be the case for any non-linear dose-response data set. The results for the two dichloromethane data sets in Appendix Table 3 further illustrate this point. Since non-linear carcinogenic dose responses are often seen in animal studies

(especially for non-genotoxic carcinogens), such large differences between upper bound and maximum likelihood potency factors might be quite common.

Therefore, use of EPA upper bound cancer potency factors for animal carcinogens can result in remediation standards that are orders of magnitude lower than the best estimate of the EPA methodology. Conservative assumptions and other factors in the EPA methodology have a multiplicative effect to make this difference even larger. Likewise, conservative exposure assessment parameters result in even lower remediation standards. The overall impact is that remediation standards for animal carcinogens are extremely conservative as shown by Lloyd *et al.* (7). The most practical way to remedy this situation is to select a higher target risk level. The information presented here supports 10^{-4} as an appropriate target risk when using EPA CSF's and conservative exposure parameters for animal carcinogens.

Conclusion

New Jersey remediation standards will probably be based on EPA CSF's determined by methods developed almost 20 years ago. Many conservative assumptions have been used in this process, which produces upper bound CSF's. These CSF's alone can produce overly conservative remediation standards by an order of magnitude for human carcinogens and many orders of magnitude for animal carcinogens. Coupled with the use of conservative exposure assessment parameters the remediation standards are too conservative. This problem can best be remedied by the selection of 10^{-5} and 10^{-4} as the target risk level for human and animal carcinogens, respectively.

FACTOR	RANGE OF POSSIBLE REDUCTION IN ESTIMATED CANCER RISK
A. WEIGHT vs. SURFACE AREA	2-12
B. MAXIMUM OR AVERAGE LIKELIHOOD vs. UPPER 95% CONFIDENCE	2-3
C. MALIGNANT TUMORS vs. MALIGNANT PLUS BENIGN TUMORS	1-2
D. AVERAGE ANIMAL SENSITIVITY vs. MOST SENSITIVE ANIMAL	2-5
E. PHARMACODYNAMICS vs. EFFECTIVE DOSE	1-6
F. RISKS AT SHORTER THAN EQUILIBRIUM BUILD-UP TIME	2-5
Total	15-10800

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Elizabeth L. Anderson, Ph.D.
"Risk Analysis in Environmental Health with Emphasis on Carcinogenesis"
Harvard School of Public Health, September 18-20, 1984

Appendix I

Step 5®

Strategic quantification for health and environmental risks

April 4, 1994

J.F. Terenzi, Ph.D.
Corporate Vice President for Environmental Affairs
American Cyanamid Company
1 Cyanamid Plaza
Wayne, NJ 07470

Richard A. Davis, Ph.D., DABT
American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, NJ 08543-0400

Dear Drs. Terenzi and Davis:

American Cyanamid asked *Step 5* Corporation to calculate the doses that would result in a 10^{-4} or 10^{-6} risk for the upper-bound (UB) and the maximum likelihood estimate (MLE) curves generated by the linearized multistage model used by EPA.

The chemicals selected by American Cyanamid were those of interest that had sufficient information in EPA's Integrated Risk Information System (IRIS) to replicate derivation of EPA's cancer potency factor. The IRIS files for these chemicals were provided to *Step 5*.

- Only one chemical, dichloromethane by the inhalation route of exposure, so screened was later found to have insufficient data in IRIS to replicate EPA's analysis. The cancer potency factor for this route was derived using pharmacokinetic modeling. Insufficient data and models were available in IRIS; thus, this route was excluded from further analysis in this preliminary study.

- In one case (benzo[a]pyrene), only one data set of several available passed the selection screen. Since EPA's analysis of this dataset was presented in IRIS (even though later combined with other data), this dataset was retained for evaluation.

Step 5 Corporation; 1101 17th Street, NW; Suite 501; Washington, DC 20036
Phone: (202) 429-8761 Fax: (202) 429-8762

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Step 5 used GLOBAL86 to produce the coefficients for the MLE and UB curves (Table 1). None of the curves were of higher order than quadratic. Thus, for a dose, d, the resulting curves were of the form:

$$Risk = P(d) = 1 - \exp(-q_0 - q_1 d - q_2 d^2)$$

The risk-specific doses based on the UB curve (Table 2) were calculated following the standard procedure used by EPA. The coefficient of the linear term of the UB curve, often designated the q_1^*, was used as a cancer potency factor, and the low-dose curves were assumed to be linear. The dose, d, for the risks of interest was calculated from the equation:

$$d = \frac{Risk}{q_1^*}$$

The risk-related doses (Table 2) for the MLE curves were estimated using the following procedures:

- One chemical, hexachlorobenzene, had no background incidence. In this case, the MLE curve was used directly to estimate the doses associated with a 10^{-4} or 10^{-6} risk.

- For all other analyses, the risk-related doses were calculated using the equation for extra risk:

$$Extra\ Risk = \frac{P(d) - P(0)}{1 - P(0)}$$

where P(d) is as defined above, and P(0), or the risk at zero dose, is:

$$P(0) = 1 - \exp(q_0)$$

For MLE equations where q_0, q_1, and q_2 are all non-zero, the equation for dose becomes:

$$d=\frac{-q_1+\sqrt{q_1^2-4(q_2)(q_0+\ln[(Risk)(1-P(0))+P(0)])}}{2(q_2)}$$

For MLE equations where only q_0 and q_1 are non-zero, the equation for dose becomes:

$$d=\frac{-q_0-\ln(1-[(Risk)(1-P(0))+P(0)])}{q_1}$$

For MLE equations where only q_0 and q_2 are non-zero, the equation for dose becomes:

$$d=\sqrt{\frac{-q_0-\ln(1-[(Risk)(1-P(0))+P(0)])}{q_2}}$$

The ratios of the risk-specific (10^{-4} or 10^{-6}) doses calculated based on the MLE curve to that from EPA's method of linear extrapolation using the q_1* are presented in Table 3. Differences are observed for those chemicals where the MLE linear component (q_1) of MLE curve is zero; this dataset did not include a chemical for which the linear coefficient was present but substantially smaller than the coefficient of the quadratic term.

One consequence of this analysis is of interest with regard to another procedure often used by EPA when estimating cancer potency factors when several data sets are available, i.e., the combining of various q_1*'s most frequently by use of a geometric mean. For the oral data of dichloromethane, IRIS states that EPA's cancer potency factor is based on the arithmetic mean of the two q_1*'s: 2.6×10^{-3} and 1.3×10^{-2}. While an analysis of the generic issues involved in the practice of averaging upper-bound values is beyond the scope of this assignment, we have addressed some of the issues previously (for example, see Figure 2 and related discussion in Putzrath, R.M. and Ginevan, M.E. 1991. Meta-Analysis: Methods for Combining Data to Improve Quantitative Risk Assessment. *Regulatory Toxicol. Pharmacol.* 14:178-188).

For this case, two topics require a brief mention. First, the MLE equations of the two dichloromethane datasets are quite different: the NTP is a pure quadratic on dose while the NCA is linear. Thus, the scientific basis for combining the results (based on the analysis provided by EPA) is questionable. Second, the effect of the

quadratic equation on the risk-based dose demonstrates that the "average" dose of the two data sets will be highly dependent on the point, i.e., the risk, at which the comparison is been made. We have also addressed this issue in a different context (Putzrath, R.M. and Ginevan, M.E. "How the Concept of Benchmark Doses Demonstrates Some Failings of EPA's Hazard Index for Mixtures." *Step 5* Working Paper 93-1, April 26, 1993). Copies of both citations are enclosed.

Sincerely,

Resha M. Putzrath, Ph.D., DABT
Principal

Enclosures

Step 5 Corporation; 1101 17th Street, NW; Suite 501; Washington, DC 20036
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TABLE 1

Coefficients of Maximum Likelihood Estimate (MLE)
and Upper-bound (UB) Equations

Chemical	q_0	q_1	q_2	Comments
Benzo(a)pyrene, Brune, MLE	4.7	0.0	341	
Benzo(a)pyrene, Brune, UB	3.0 E-02	11.8	0.0	EPA's q_1* is 11.7; rounding versus truncation?
Beryllium, oral, MLE	1.7 E-01	1.7	N/A	
Beryllium, oral, UB	1.2 E-01	4.3	N/A	Agrees with EPA q_1* of 4.3
Dichloromethane, NTP, oral, MLE	5.8 E-02	0.0	2.7 E-05	
Dichloromethane, NTP, oral, UB	5.2 E-02	2.6 E-03	1.4 E-5	Agrees with EPA q_1* of 2.6 E-03
Dichloromethane, NCA, oral, MLE	2.5 E-01	6.9 E-03	0.0	Fourth order equation, only q_0 and q_1 have coefficients
Dichloromethane, NCA, oral, UB	2.5 E-01	1.3 E-02	0.0	EPA's q_1* is 1.2 E-02. Fourth order equation, only q_0 and q_1 have coefficients
Hexachlorobenzene, MLE	0.0	1.4	2.4	
Hexachlorobenzene, UB	0.0	1.7	0.0	EPA's q_1* is 1.6
Polychlorinated biphenyls, MLE	2.1 E-02	5.3	N/A	
Polychlorinated biphenyls, UB	2.0 E-02	7.7	N/A	Agrees with EPA's q_1* of 7.7
1,1,2-Trichloroethane, MLE	1.1 E-01	5.8 E-03	3.4 E-03	
1,1,2-Trichloroethane, UB	7.4 E-02	5.7 E-02	3.7 E-04	Agrees with EPA q_1* of 5.7 E-02

N/A = not applicable because data set has only one dose other than control

TABLE 2

Doses for Risk Levels of Interest

Chemical/Classification	Equation	Dose at 10^{-4} Risk	Dose at 10^{-6} Risk
Benzo(a)pyrene/B2	MLE - ER	5.4 E-04	5.4 E-05
	UB	8.5 E-06	8.5 E-08
Beryllium(oral)/B2	MLE - ER	5.9 E-05	5.9 E-07
	UB	2.3 E-05	2.3 E-07
Dichloromethane/B2: NTP	MLE - ER	1.9	1.9 E-01
	UB	3.8 E-02	3.8 E-04
NCA	MLE - ER	1.4 E-02	1.4 E-04
	UB	7.7 E-03	7.7 E-05
Hexachlorobenzene/B2	MLE	7.1 E-05	7.1 E-07
	UB	5.9 E-05	5.9 E-07
Polychlorinated biphenyls/B2	MLE - ER	1.9 E-05	1.9 E-07
	UB	1.3 E-05	1.3 E-07
1,1,2-Trichloroethane/C	MLE - ER	1.7 E-02	1.7 E-04
	UB	1.8 E-03	1.8 E-05

Abbreviations:

MLE Solutions for the maximum likelihood estimate equation

MLE-ER Solutions for the extra risk equation using maximum likelihood estimate equation coefficients

UB Solutions for EPA's linear extrapolation using the q_1* (the q_1 from the upper-bound equation)

TABLE 3

Ratio of Dose Based on Maximum Likelihood Estimate
to Dose Based on Upper Bound Dose-response Curves

Chemical: Classification	Dose at 10^{-4} Risk	Dose at 10^{-6} Risk
Benzo(a)pyrene: B2	64	6400
Beryllium(oral): B2	2.6	2.6
Dichloromethane: B2: NTP	50	500
NCA	1.8	1.8
Hexachlorobenzene: B2	1.2	1.2
Polychlorinated biphenyls: B2	1.5	1.5
1,1,2-Trichloroethane: C	9.4	9.4

References Attached

1. James D.Wilson, "A Usually Unrecognized Source of Bias in Cancer Risk Estimations," Risk Analysis 11 (1): 11–12, 1991.

2. Barbara D, Beck, Edward J. Calabrese and Paul D. Anderson, "The Use of Toxicology in the Regulatory Process," Chapter 1, *Principles and Methods of Toxicology, Second Edition*, A.W. Hayes, Ed., Raven Press, New York, 1989.

3. Bruce C. Allen, Kenny S. Crump and Annette M. Shipp, "Correlation Between Carcinogenic Potency of Chemicals in Animals and Humans," Risk Analysis 8 (4): 531–544, 1988.

4. R. A. Schoof *et al.*, "Recalculation of the Oral Arsenic Reference Dose and Cancer Slope Factor Using Revised Assumptions of Inorganic Arsenic Intake from Food," The Toxicologist 14 (1): #51, p 36, 1994.

5. Edmund A. C. Crouch, "Uncertainty in the Unit Risk Estimate for Acrylonitrile (AN)," Draft report, March 11, 1992.

6. Resha M. Putzrath and Michael E. Ginevan, "Meta-Analysis: Methods for Combining Data to Improve Quantitative Risk Assessment," Reg. Toxicol. Pharmacol. 14: 178–188, 1991.

7. Kylie J. Lloyd, Kimberly M. Thompson and David E. Burmaster, "Probabilistic Techniques for Backcalculating Soil Cleanup Targets" in *Superfund Risk Assessment in Soil Contamination Studies, ASTM STP 1158*, Hoddinott and

Knowles, Eds., ASTM, Philadelphia 1992. Improvements to this methodology are under review - David Burmaster, personal communication.

ENVIRONMENTAL LIABILITY MANAGEMENT, INC.
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April 12, 1994

Ms. Sheryl Telford
NJDEPE
Site Remediation, 6th Floor
401 E. State Street
CN 028
Trenton, NJ 08625

Dear Sir/Madam:

The Environmental Risk Assessment and Risk Management Study Commission (Commission) has two duties:

(1) To examine and assess the scientific basis for selecting the risk management standard of one-in-one million for the purposes of Industrial Site Recovery Act (ISRA) and to consider and assess alternative standards and criteria for that purpose; and

(2) To examine and assess methodologies of risk assessment and their efficacy and applicability for the purposes of establishing remediation standards.

We are providing comments on both of these duties because they are related, but primarily on the one-in-one million risk management standard. In addition, we are providing references to scientific articles which support our recommendations; some of these articles are attached to our comments for the Commissions convenience. Any questions concerning our comments can be directed to either of us.

Sincerely,

ENVIRONMENTAL LIABILITY MANAGEMENT, INC.

Peter P. Brussock, Ph.D., CHMM
Vice President

Frederick W. Cornell, CHMM
Project Manager

PPB/gt

cc: J. Fallon, Environmental Liability Management, Inc.

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Brussock & Cornell Comments - Environmental Risk Assessment and Risk Management Study Commission

Comments on the One-In-One Million Risk Management Standards

The scientific basis for selecting the risk management standard of one-in-one million can be divided into two components: the theoretical basis for calculating risks and the empirical evidence for risk rates. Our recommendation is that the risk management standard be set based primarily on empirical evidence and generally accepted levels of risk encountered every day by New Jersey residents, rather than on theoretical calculations. Our scientific basis for this recommendation is as follows:

1. The current day methodologies of theoretically-based quantitative risk assessment are widely recognized as imprecise and burdened with uncertainty as well as the associated safety factors (1, 2, 3). Corresponding remediation standards derived from such methods are readily recognized as unrealistic (3, 4). For example, risk-based soil remediation standards commonly are lower than the Food and Drug Administration (FDA) acceptable concentrations in food products (Table 1) (3-7). Surely the dose a person receives from a food item is going to exceed the dose from soil exposure when the ingestion rate and bioavailability of the contaminants in the two materials are objectively evaluated.

   We encourage the Environmental Risk Assessment and Risk Management Study Commission to recognize this discrepancy between theoretically derived remediation standards and FDA food limits as a basis to abandon emphasis on theoretical calculations and anchor risk management standards to reality; empirically-derived standards that fall within a risk rate commonly accepted by New Jersey residents on a daily basis (see discussion below).

2. Purist risk assessors commonly reject consideration of relative risk. However, since any sound risk management decision must consider the cost-benefits of various levels of risk,

the risk manager must relate any proposed level of regulation to the generally accepted levels of risks for perspective (3). This step is a reality check.

Our recommended scientifically defensible basis for selecting a risk management standard would be a thorough review by the Commission of the literature to determine the relative frequency that various risk levels are generally accepted (3, 5, 6, 8, 9). For example, how many widely used machines (including automobiles) are designed to cause only one-in-one million deaths if used eight to twelve hours a days, 7 days a week? The answer is probably none. The reason is the cost far exceeds the perceived/actual benefits. Something closer to one-in-one thousand or one-in-one ten thousand is probably more accurate.

We suggest the risks posed by chemical residuals should be regulated at a level consistent with the mean level of risk commonly accepted by a population of people. Therefore, the Commission's objective should be to study generally accepted risks by residents in New Jersey. The baseline chemical residual risk level would be set by the most commonly accepted risk level. Concurrently, the analysis should include evaluation of the approximate relationship of costs-benefits with other forms of risks, and the analysis should compare information on the cost-benefits of various soil remediation standards. These two analyses would constitute a scientific basis for a risk management standard.

3. Some risk assessors argue that relative risks posed by chemical residuals are involuntary risks and can not be compared to voluntary risks such as driving a car (10). We feel such an opinion is ecologically naive.

As consumers of industrial products and natural resources, we are all voluntarily adding to the pollution pressure on our environment in order to enjoy the benefits of the products of advances in technology. Chemical residuals in soils would not be there if we, the consumers, did not buy the products.

Today more than ever, natural resources are in increasing short supply which adds to the truth of the phrase, "everything is related." In a world where all actions that influence use of natural resources have recognizable consequences, the distinction between voluntary and involuntary risks becomes little more than an artificial academic construct which distracts from the objective of developing rational remediation standards.

4. As risk assessors and risk managers of chemical residuals at hundreds of sites, our professional opinion is that one-in-one ten thousand is the appropriate level of risk to set remediation standards. Agencies such as OSHA, the EPA, and the FDA commonly regulate at this level (4, 5, 6, 11, 12).

An exception might be a few chemicals that are proven human carcinogens and widespread contaminants, such that millions of persons are routinely exposed. In these cases, epidemiologic data should be developed to determine if scientific evidence indicates a more stringent risk management standard may be desired. The opposite approach of adopting a more conservative standard when there is any uncertainty should be abandoned because the exorbitant increased costs are not justified by hypothetical benefits which probably do not really exist.

Comments On The Methodologies Of Risk Assessment And Their Efficacy And Applicability For Purposes Of Establishing Remediation Standards

The Commission's duty to develop recommendations on methodologies of risk assessment is far more difficult than addressing the one-in-one million question, because the number of details to be considered is staggering. Our point is a simple one, large uncertainties are going to remain a major factor in risk assessment for decades to come. Consequently, quantification of risks by agencies or using agency developed guidelines will be redundantly conservative and therefore unrealistic, unless the Commission takes this opportunity to recommend specific guidelines that ensure realistic exposure scenarios (see Gephart, et al. 1994 (13) for some examples).

A variety of simple common sense adjustments to exposure assumptions can be developed. For example, the Commission could recommend that NJDEPE in coordination with NJDOH Commission conduct an independent study of:

a. The number of days children and adults contact soil in their yards.
b. The number of hours spent in contact with soil on days spent outside.
c. The relative contribution of soils and other sources of contaminants in New Jersey populations through epidemiologic evaluations.

Then, with real scientific data for New Jersey, the theoretical estimates are far more likely to be realistic and not overly conservative in an effort to protect some sensitive receptor who probably does not exist.

Even if exposure assumptions are refined, tremendous uncertainties will remain in the risk assessment process due to uncertainties/safety factors in dose-response assessments. The effect of these uncertainty/safety factors is demonstrated below.

> The EPA reference dose for zinc is based on animal studies and is published in the IRIS database as 0.05 mg/kg/day, including a 5,000% uncertainty factor. An EPA risk assessment for a typical adult would determine that ingestion of more than 3.5 mg/day of zinc would present a toxicity concern.
>
> The U.S. Food and Nutrition Board has published Recommended Daily Allowances (RDA) which represent the minimum nutrition requirements for several minerals, including zinc. The RDA for zinc is 12.5 mg/day for a typical adult, which is five times higher than the toxic dose calculated using EPA risk assessment guidance. Obviously, eating Total cereal does not present a significant threat to human health.

These examples amplify the call for a reasonable risk management standard in order to avoid remediation concentrations which frequently are meaningless if driven solely by theoretical

quantitative risk assessment methodologies. Risk assessment is a tool to provide information for use by the risk manager. Risk assessment by itself is not the proper basis by which to set remediation standards.

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TABLE 1

Comparison of NJDEPE Health-Risk Based Soil Cleanup Criteria to Food and Drug Administration Tolerance/Nutrition Concentrations

Chemical	NJDEPE Health Based Cleanup Goal for Residential Soils	FDA Tolerance Concentration	Comments
PCBs	0.49 ppm	0.3 to 3 ppm	The FDA permits dairy products to contain 1.5 ppm, poultry to contain 3 ppm, edible fish to contain 2 ppm and eggs to contain 0.3 ppm PCBs.
Lindane	0.52 ppm	3 ppm	The FDA tolerance of 3 ppm has been established for several vegetables including lettuce, squash, and tomatoes.
Toxaphene	0.1 ppm	0.2 ppm	The FDA had established the 0.2 ppm action level for edible fish.