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; methodologies of risk assessment and their efficacy and applicability for the purposes of establishing remediation standards"

LOCATION: New Jersey Instititute of Technology
Newark, New Jersey

DATE: March 11, 1994
2:30 p.m.

MEMBERS OF COMMISSION PRESENT:

Michael A. Gallo, Ph.D., Chairman
Stephen T. Boswell, Ph.D.
Christopher P. D'Alleinne, Ph.D.
David S. Kosson, Ph.D.
Richard S. Magee, Sc.D.
Rita M. Turkall, Ph.D.

ALSO PRESENT:

Raymond E. Cantor
Office of Legislative Services
Aide, Environmental Risk Assessment and Risk Management Study Commission

Hearing Recorded and Transcribed by
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ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

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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 **Friday, March 11, 1994 at 2:30 PM at the New Jersey Institute of Technology, Hazell Student Center Ballroom, 2nd Floor, Newark, 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)

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MICHAEL A. GALLO, Ph.D. (Chairman): I'd like to get started, please. My name is Mike Gallo, and I'm the Chairman of this ISRA Commission. We're here this afternoon to take testimony from seven listed witnesses. Just as a word of introduction, this is the third of three public hearings on the first round of the ISRA Commission. The first was held night before last down in South Jersey; last night we had a hearing at Rutgers; and today, here at NJIT.

The format that we have followed -- and I would ask the witnesses to please follow this format -- is that you will be allowed to speak for five minutes, at which time an alarm will go off right here. I'll demonstrate the alarm in a moment. At this point you have one minute to sum up. We've been using this format all the way through, and we will use it again today.

The other piece of information is that this Commission will be receiving written testimony -- or will receive written testimony -- through the 11th of April. Upon receipt of all the written testimony and the verbal testimony of these three days, we will generate a report which will then become public. There will be one more public hearing, so you will get a second shot at us. At that point we will generate a final report.

Before we start, I'd like to introduce the Commissioners around the table. On my far right, Dr. Richard Magee. Next to Dick is Steve Boswell. On my far left, Dave Kosson, Dr. Rita Turkall, and Chris D'Alleinne.

What we're here today to do is just to listen, take notes, and then deliberate on your presentations. So again, just reiterating, a five minute-- This is what it's going to sound like. So you know when it goes off, we'll let it beep down. It takes about 10 seconds to get there. I don't know how to set a clock for 5 seconds. (timer beeps) That's it, and you have a minute from then, just so you know.

Okay, the first speaker -- the first witness -- is John Maxwell. Is he here? (affirmative response from audience)

Please speak into the two mikes, because it's being recorded and transmitted at the same time.

J O H N M A X W E L L: Okay. Is this okay?

DR. GALLO: Yes.

MR. MAXWELL: Good afternoon. I am John Maxwell, Associate Director of the New Jersey Petroleum Council. We appreciate the opportunity to submit testimony before the Environmental Risk Assessment and Risk Management Commission. We commend the Commission for holding three public hearings throughout New Jersey, and going even beyond their mandate to obtain public input.

We are a Division of the American Petroleum Institute, which represents approximately 300 member companies involved in the exploration, production, refining, transportation, and marketing of petroleum and petroleum products. Many of our members are here in New Jersey, and will be greatly affected by changes made to the risk assessment and risk management program.

All of our member companies are committed to promoting our environmental principles, which include operating our facilities in a manner that protects the environment, safety, and health of our employees and the public. We also conduct and support research on the safety, health, and environmental effects of our raw materials, products, processes, and waste materials.

We believe that current risk assessment methods are overly conservative and are based on hypothetical worst-case scenarios and unrealistic assumptions concerning exposure and toxicity. Such assessments are not always founded on the best available science, rather they reflect simplistic rules and default exposure assumptions that are often far removed from the actual factors at specific sites.

We recommend that the Commission require that new risk protocols are based on current, credible, and realistic scientific evidence and methodologies which have received peer review; actual site-specific data where it is available or reasonably obtainable; and a range of values using state-of-the-art statistical methods for exposure and toxicity, as opposed to just worst-case assumptions. Scientifically objective risk assessments based on all relevant data should be the central element in making cleanup decisions.

Risk management decisions are better made on the basis of actual site-specific factors. The risks posed, actual and potential water and land use, toxicity and exposure pathways, and degree and type of contamination are likely to vary widely from site to site. The New Jersey Petroleum Council believes that remedy selection is a critical and complex decision that should not be made automatically. The particular characteristics of a site should always be considered in determining whether to rely on generic cleanup standards or site-specific risk assessments.

The current preference for treatment and permanent remedies often precludes alternative remedies, such as containment and institutional and engineering controls. Those more expeditious alternative remedies offer the potential of providing greater overall protection of human health and the environment at significantly reduced costs. Containment remedies, which leave contaminated soil undisturbed, can pose less risk to human health and the environment than more active types of remediation, which involve excavation and subsequent transportation, treatment, and disposal.

The costs of remediation must be a factor if we are to increase the rate of progress and decrease inefficient use of societal resources. Selection of the lowest cost, appropriate remedy should be required whenever several adequate alternatives are available. This does not imply that the

requirement to protect human health and the environment should be relaxed. We believe that increased considerations of relative risk and cost will actually enhance protection of human health and the environment by allowing for a better prioritization of sites and allocation of resources.

We encourage the Commission to ensure that site-specific risk assessment -- as provided in Section 35(f) of ISRA -- remain a viable alternative for those responsible for cleanups. We think that 10 to the minus 5 (10^{-5}) and 10 to the minus 4 (10^{-4}) are more reasonable risk levels as site-specific standards, and are in line with risks we all face in our daily lives.

We have before us an historic opportunity to get beyond the gridlock of the well-intentioned, but seriously flawed former ECRA law by seizing the opportunities presented by last year's ISRA law, Senate Bill No. 1070. We respectfully ask the Commission to consider both new risk assessment methodologies, which are more realistic than previous overly conservative assumptions, and remediation standards that incorporate site-specific land use. Let's get New Jersey moving ahead.

Thank you very much.

DR. GALLO: Good timing. Thank you.

MR. MAXWELL: Thanks.

DR. GALLO: I don't see the next witness in the room. We'll come back to her.

DR. MAGEE: Maybe she sent a substitution?

DR. GALLO: Dolores Phillips? (no response) Go on to the next one. If she shows up, fine. Our next witness is Franklin Reick.

You have some written testimony, sir?

F R A N K L I N G. R E I C K: Yes. I already passed it out.

DR. GALLO: Okay, great. Thank you.

MR. REICK: I'm going to take a slightly different approach, because I know what the majority of people are going to tell you today. A little bit on myself: I'm an inventor. I'm also an alumnus of the Inventors Hall of Fame. You'll find my name on the wall down here. I was Inventor Of The Year five years ago in New Jersey -- one of several.

I've been very concerned about this ECRA situation for quite some time, and have raised bloody hell about it in the media and through various sources, in that I have contacts in the Legislature. My main concern has always been that there is an element of mindlessness that has entered into this whole thing, and that's really what upsets me. Everybody wants to clean up the environment. I don't know anybody that's not an environmentalist.

Now, I've prepared a one-page thing here to keep me on track, and then what I'll do is sort of ramble on from there.

DR. GALLO: You've got five minutes, though.

MR. REICK: Within limits.

DR. GALLO: Okay.

MR. REICK: Okay. First, please, nature is not benign. Plants and animals have spent billions of years trying to protect themselves from one another. Powerful toxic chemicals have evolved quite naturally in the process.

All life has evolved in a toxic environment. The background is normal. Small doses of some toxins are beneficial. For instance, vitamin A, aspirin, curare; large doses will kill you. It's a matter of degree and lifestyle. Some people can take more than others.

When the magic number, 10 to the minus 6 (10^{-6}), drifted into the bureaucratic awareness, the results were predictable unfortunately.

I have attached the cover sheets from a number of papers published by Bruce Ames showing the levels of toxins in

common foods. Most of the vegetables that are known to be good for you contain high levels of a vast array of chemical toxins and carcinogens.

Nobody wants a toxic environment; however, the definition of what and how much is toxic cannot be defined arbitrarily. I have to reinforce what the previous speaker said. This should be based on sound science. It should not be based on arbitrary bureaucratic fiat. It should be based on a peer review of that science, using the techniques well-established in the scientific fields. Incidentally, I've published many scientific papers. I know the review process.

I'm going to read you the parts per million and the names of some chemicals found in a variety of foods, just to keep this in perspective. Please keep this in mind when you pass this information on to the Legislature. Now, I'm taking this from Bruce Ames' paper, and this is just one of several papers that he has published. If you would like the full papers, all you have to do is call my secretary and she'll spend three hours copying them for you. The bibliography is extensive. It runs into the thousands of references on this. But here is an example now:

Concentrations of natural pesticide -- excuse me, yes, pesticide carcinogens. These are things that have been developed by the plants to help themselves against the bugs. Here we go: for parsley, methoxypsoralen, 14 parts per million; parsnips, cooked, 32 parts per million; celery, 0.8; celery, new, 6.2; and celery, stressed, 25.

You'll notice if you attack the plant, it puts out more harsh chemicals. This is well-known.

Mushrooms, hydrazinobenzoate, 11; mushrooms, commercial, 42. That's all parts per million. Cabbage -- get a load of this -- allyl isothiocyanate 35 to 590 parts per million; cauliflower, 12 to 66 parts per million; brussels sprouts, 110 to 1560. Now, those vegetables right there have

been published in the literature -- referenced literature -- in the last few years. If you have a high level of them in your diet, they give you very strong protection against certain types of cancer.

Mustard -- get a load of this -- 16,000 to 72,000. You better stay away from your hot dogs. Horseradish, 4500 parts per million; basil, 3800; fennel, 3000; nutmeg, 3000; mace, 10,000. Apple, pear, plum, cherry, carrot, lettuce, tomato, endive, grapes, and eggplant -- caffeic acid, 5 to 200 parts per million. Thyme, basil, anise, sage, dill, caraway, rosemary, tarragon, and coffee -- caffeic acid, 1000, greater than 1000 parts per million. Then we've got the last one down here is neochlorogenic acid, which, again, is caffeic acid in coffee, roasted beans, 11,600.

Now, if you're going to watch out for carcinogens in the environment, I hope you don't test the local supermarket or the local vegetable stores, because they are loaded with carcinogens. One of the most virulent carcinogens known grows on moldy peanuts. It's an alpha toxin. It's created by a fungus. It also grows on moldy corn. Those of you who eat peanut butter are consuming enormous quantities of peanut butter mold. (timer beeps)

DR. GALLO: You've got a minute.

MR. REICK: Okay, enough. My point here is, when you set up the standards for this, you had better know the facts. You cannot allow people to pull the numbers straight out of the air, make pontifical statements about them, and create laws based on that sort of nonsense. It's going to destroy our society sooner than the carcinogens do.

Thank you.

DR. GALLO: Thank you.

The next witness is John Whysner. (witness distributes literature) Oh, it's typed. I'm old. Okay.

Dr. Whysner.

J O H N W H Y S N E R, M.D., Ph.D., D.A.B.T.: Okay. Thank you.

My name is John Whysner. I'm a physician, a scientist, and a Board certified toxicologist speaking on behalf of the Chemical Industry Council of New Jersey. I thank the members of the Commission for this opportunity to address you this afternoon on this important issue.

My manuscript on the one-in-a-million risk-based standard has been submitted to the Commission as an attachment to this testimony. In the interest of the Commission's time constraints, my testimony will provide a distilled and excerpted version of this paper. However, I hope that you will have an opportunity to scrutinize the manuscript that contains the detailed rationale for my testimony.

In order to put different risk levels into perspective, government agencies often derive estimates of the annual risk reduction for a proposed law or regulation. Using such a calculation for Senate Bill No. 1070, the adoption of a one-in-a-million, one-in-a-hundred thousand, or one-in-ten thousand risk level results in risk reductions of only 0.0001, 0.001, or 0.01 of a hypothetical cancer case per year for the population of the State of New Jersey. This calculation is presented in detail in my attached paper. These hypothetical fractions can be compared to the actual annual incidence of 42,000 new cancer cases in the State of New Jersey, as reported by the American Cancer Society. Clearly, the choice of any of these different risk levels would not appreciably affect the public health of the citizens of New Jersey.

The one-in-a-million risk level has been chosen historically in an arbitrary manner as a basis for regulation. Also, there is an apparent historical trend for the use of greater acceptable risk levels as the conservative nature of risk assessment calculations has been recognized. One review

of these policies by Travis et al. has indicated that the EPA does not consider individual risks of less than one-in-ten thousand in small geographic areas to require regulation.

The choice of any risk-based standard should include health protective assumptions; however, the methods of risk assessment as developed by the EPA overestimate the risks in several ways. Consequently, there is plenty of room to correct assumptions and risk assessment methodology without jeopardizing the public's health, and allow for other possible concerns, such as the presence of several different chemicals at a site.

In order to illustrate the inflation of these risks, the naturally occurring levels of beryllium are present in soils at average levels that result in calculated risks above one-in-a-million using NJDEPE soil ingestion calculation methods. For 10 percent of both urban and rural soil samples, the naturally occurring levels of beryllium give between one-in-ten thousand and one-in-one hundred thousand cancer risks. Consequently, using these criteria, New Jersey soil is inherently carcinogenic. An alternative and more plausible conclusion is that the methodology used, and the choice of a one-in-a-million risk level greatly overestimates the public health concern.

The EPA classifies agents according to the weight of evidence of carcinogenicity. This classification system reflects important differences in the demonstrated abilities of chemicals to cause cancer in humans, and Senate Bill No. 1070 has recognized this distinction. The wording, "human carcinogens," as categorized by the United States Environmental Protection Agency, was a deliberate designation on the part of the Legislature, since earlier versions of Senate Bill No. 1070 did not include this language. Consequently, Senate Bill No. 1070 leaves open the question of

how to determine remediation levels for Groups B and C, and implies that these chemicals may be regulated according to another standard.

The designation of higher acceptable risk levels for Groups B and C is one method of taking weight of scientific evidence into account in the risk assessment process. There are many precedents for the establishment of distinct levels of risk for different groups of carcinogens that use a tenfold difference. It is proposed that the most important risk-based distinction should be between known human carcinogens and animal carcinogens.

Many past risk management decisions have chosen the most conservative risk numbers, because there were no perceived negative consequences for this decision. However, there has been an increasing awareness that these overly conservative decisions result in needless expenditure of hundreds of millions of dollars for little or no incremental reduction in real risk.

In conclusion, one-in-one hundred thousand is the lowest lifetime cancer risk level that should determine any soil remediation standard. Furthermore, a higher risk level such as one-in-ten thousand should determine the standards for Groups B and C. Alternatively, remediation levels for Group C chemicals can be developed using No Observed Effect Levels. The adoption of one-in-ten thousand or one-in-one hundred thousand risk levels will protect the citizens of New Jersey. I am concerned that the adoption of a one-in-one million risk level will make insignificant difference on public health, and will create remediation gridlock and huge, unnecessary costs.

Thank you.

DR. GALLO: Thank you very much.

Dwight Bedsole?

A N D R E W D W I G H T B E D S O L E: (distributes statement) Mr. Chairman, my name is Dwight Bedsole. I am Business Director of Remediation for DuPont's

facilities in New Jersey. I'm pleased to have the opportunity to come before this Commission to provide testimony on behalf of the Chemical Industry Council of New Jersey on these extremely important issues.

We commend the Commission for their efforts to deal with the question of what appropriate risk management standards should be used in the remediation of contaminated sites, and then to recommend risk assessment methodologies that should be used in defining, as accurately as possible, the nature and magnitude of potential risks presented by contaminated sites.

The CIC and its member companies are committed to protection of human health and the environment, and believe that such assessments by the Commission are in the best interest of the State's citizens and businesses. In several respects, the CIC believes that the currently used one-in-one million risk level, along with the overly conservative risk assumptions and methodologies used by the DEPE, go beyond that needed for protection of human health and the environment, and thus have the potential for misuse of society's limited resources.

The CIC also believes that there is no sound social, scientific, economic, or other basis for selecting a rigid one-in-one million risk level for human carcinogens in the remediation of a contaminated site. A one-in-one million risk level is needlessly stringent, does not match up with other societal risks, and has been chosen historically in an arbitrary manner.

At a recent lecture at Stanford University, Bill Reilly, former administrator of the EPA, stated that huge sums of money are being spent on hypothetical risks experienced by a few individuals. He went on to comment about the lifetime cancer risk of one-in-one million by saying the hazard of death by lightning is 35 times as great; by accidental falls, 4000 times as great; and in motor vehicles, 16,000 times as great. He emphasized that one-in-one million is a very remote risk.

An answer to the question: "Just how remote is a one-in-one million risk?" I believe has been answered very effectively in a paper coauthored by Commission member, Dr. Bernard Goldstein, that looked at the risk of death to people on the ground due to airplane accidents. Results of this study showed the lifetime risk of dying from being hit by an airplane is four times greater than a one-in-one million risk. It is concluded that the public would not make any significant change in personal behavior to reduce the risks of falling airplanes, such as living in their basements, since in their minds the risk is clearly too small to warrant such a lifestyle change. Yet with the imposition of a one-in-one million risk management standard, the regulated community is being asked to spend enormous sums to reduce calculated risks from contaminated sites to a level that the private individual would rightly judge to be inconsequential.

Whether orders of magnitude of conservatism find their way into the methodologies used to calculate risks or into risk management decisions of what constitutes an acceptable risk level, the result is the same: Scarce societal resources could be spent on issues of de minimus risk.

The CIC is concerned with the economic impact of overconservatism. The CIC finds that a one-in-one hundred thousand risk level is the lowest risk level required to accomplish the goal of legislation to protect human health. This is a factor of 10 different from the currently used one-in-one million risk level. To define the cost burden of a tenfold difference in cleanup for a contaminated site is difficult. For some cleanups, the factor of 10 could be fairly small in cost, while for others it could be an enormous difference. It depends on the nature of the contaminant, the media to be cleaned, and the extent of contamination. In the CIC's judgement, the cost difference, generally speaking, will be significant.

As an example, DuPont has a site in New Jersey where the contaminant of concern is a metal. The difference in cleaning the soil to a 100 parts per million level versus a 250 parts per million level -- a factor of only 2.5 -- would increase remediation cost by an estimated $100 million to $125 million, for an approximate threefold increase in total cost. In comparison, the EPA considers a 500 parts per million level to be protective of human health for this contaminant. This additional cost is not insignificant. As example, there are a number of businesses in DuPont where it would take years of earnings generation to pay such costs, and this is only one cleanup at one site. It has been estimated that there are over 8000 sites in New Jersey that will require remediation by the regulated community.

Clearly, overconservatism that dictates unnecessary action does not come free. This represents a significant, unnecessary financial penalty to society. I say society because industry must pass all its costs on to its customers or go out of business. So it is the public that pays the higher costs through higher taxes, higher prices, less competitive industry, and often, lost jobs.

There seems to be a growing awareness of the connection between economic well-being and physical health; that is, unemployment and poverty are clearly connected to higher disease and death rates. According to a paper published in the September 1991 issue of the journal "Health Physics", the most hazardous of all jobs is no job at all -- unemployment. It was estimated that a 1 percent increase in unemployment for the year represents 37,000 deaths.

In closing, if a bright line level must be defined for risk management decisions, the bright line, or lines, should reflect the weight of scientific evidence and distinguish among the categories of carcinogens. The CIC encourages you to

recommend a risk management level of Group A carcinogens at one-in-one hundred thousand, and for Groups B and C at one-in-ten thousand.

Also, the CIC recommends that the Commission make full use of the current body of scientific understanding, and steer the development and application of risk assessment technologies in a way that is both protective of human health and economically responsible.

DR. GALLO: Thank you.

Colin Sweeney is not here, is that correct?

UNIDENTIFIED SPEAKER: Mr. Sweeney is not testifying.

DR. GALLO: He's not testifying, okay.

Michael Draikiwicz. As they say in mathematics, the sum total is five minutes, so go ahead.

M I C H A E L J. D R A I K I W I C Z: That's right.

Good afternoon. My name is Michael Draikiwicz, Senior Staff Engineer from the Environmental Affairs Department of Public Service Electric and Gas, sitting in for James Shissias, the General Manager of the Environmental Affairs Department of PSE&G. At this time, I would like to hand over the presentation to Dr. Cristopher Williams, a toxicologist from TERRA, Inc. who is assisting PSE&G in developing these comments.

C R I S T O P H E R A. W I L L I A M S, Ph.D.: Our comments relate specifically to the DEPE's use of redundant conservative assumptions in the establishment of minimum remediation soil standards for carcinogens. The assumptions used by the DEPE represent reasonable maximum exposure assumptions which were developed to represent the 90 to 95 percentile exposure for a given population. The RME case, however, describes an exposure condition more conservative than this; a condition which rarely, if ever, occurs.

This was illustrated in a paper by Burmaster and Lehr. These authors demonstrated that when three conservative 95 percentile values are multiplied together, the outcome actually represents the 99.99 percentile of exposure, not the 95. In other words, only 0.01 percent of a given population would experience such an exposure.

In the following discussion we will demonstrate through a review of current scientific literature that many of the factors used by the DEPE to develop remediation standards for soil are indeed redundant and conservative assumptions. The factors which were specifically examined included: the one-in-a-million cancer risk, cancer slope factor, soil ingestion rates, and time correction factors. There are a number of precedents which argue against the use of the one-in-a-million cancer risk as the basis for establishing remediation soil standards for carcinogens.

California has adopted a one-in-one hundred thousand value as the no significant risk level for the implementation of Proposition 65. This risk level is also acceptable under the Massachusetts Contingency Plan. Maryland, Minnesota, Ohio, and Oregon use this one-in-one hundred thousand risk level for establishing ambient air quality standards, while the State of Mississippi has adopted a risk range of one-in-ten thousand to one-in-one million for this purpose. Louisiana uses a higher acceptable risk level, one-in-ten thousand, for establishing ambient air quality standards.

In addition, Travis et al., in '87, reported that carcinogenic substances were not regulated by Federal agencies if the risk to small populations was below one-in-ten thousand. Thus, given the examples of other states and the fact that a one-in-a-million risk would be undetectable in a small population potentially impacted by a site, the Commission should reconsider strict reliance on the one-in-a-million cancer risk by following the lead of various state and Federal

agencies. A recommended approach would be to apply a one-in-one hundred thousand risk level of chemicals which are known human carcinogens, and a one-in-ten thousand risk level to those chemicals which pose less of a carcinogenic threat.

The DEPE has developed cancer slope factors for a total of 43 chemicals, and uses these values to determine soil remediation standards for carcinogens. Of the 43 chemicals for which it has developed slope factors, the DEPE has proposed values greater than those of the EPA for a total of 12 -- some by as much as sixteenfold. Thus, the DEPE has introduced conservative bias in the development of soil remediation standards, in some instances by as much as sixteenfold, simply by incorporating slope factors which are more conservative than those developed by the EPA.

Recent studies of soil ingestion using proper mass balance approaches have been conducted in children and adults. These studies form the basis of our recommendation that ingestion rates in children under residential exposure conditions not exceed 50 milligrams a day; a value fourfold below the DEPE's value of 200. For adults, under residential conditions these studies suggest soil ingestion rates of 0 to 20 milligrams per day, rather than the 100 milligrams per day values of the DEPE. Finally, we recommend soil ingestion rates of 10 to 25 milligrams per day under occupational conditions based on worker soil ingestion studies, rather than the 100 milligram per day value of the DEPE.

The time correction factors proposed by the DEPE do not account for normal patterns of human behavior; such as, time spent away from home on vacation, the average length of time at a single residence, typical number of days spent away from a job due to illness or vacation, or the average number of years at a single job. Residence times for individuals living in a single location have been reported in recent studies, as have data from the U.S. Bureau of the Census records concerning the average length of employment at a single workplace.

These studies demonstrate the DEPE's assumptions of residence time and length of employment have been overestimated by as much as six and a half-fold. In addition, the DEPE has not adjusted the exposure duration portion of the TCF to account for climatic conditions, which reduce the potential for exposure to soil; for example, the average yearly number of rainy days, the number of days in which the ground is frozen or snowcovered.

As an alternative to the proposed risk assessment approach which derives single point estimate of acceptable levels of chemicals in soil, the Commission should recommend probabilistic -- i.e., Monte Carlo -- techniques to develop distributions or ranges of acceptable soil remediation standards. We conducted a Monte Carlo analysis of the proposed soil remediation standard for benzene-- (timer beeps)

DR. GALLO: One minute.

DR. WILLIAMS: --which is 13 milligrams. Our analysis demonstrated that the range was from 150 to 15,000, and the most likely was 750. So we propose Monte Carlo as way to get away from the redundant conservative stance.

PSE&G would also like to discuss the fact that the Commission is not addressing subsurface soil cleanup criteria. As of February 3, 1994, the latest revision to the soil cleanup guidance criteria indicated that 60 percent of subsurface soil levels were more stringent than surface soil levels under both industrial and residential conditions. Thus, the fact that the subsurface soil levels are more stringent than the surface soil levels for a large proportion of chemicals would tend to negate what the Commission has set out to do. Therefore, it is strongly recommended that either the Commission examine subsurface soil cleanup criteria concurrently, or at a minimum, propose that another commission be assembled to look at subsurface soil criteria.

Thank you.

DR. GALLO: You're welcome. Thank you very much.

Our last witness-- Is there another? (affirmative response) Not our last witness, our next witness is Arnold Gray.

I have to apologize to Mr. Gray. I cut him off the other night when he drove all the way down to South Jersey. I felt very badly all the way home, as I drove home in the rain.

A R N O L D L. G R A Y, Ph.D.: Not to worry, not to worry. (distributes statement)

DR. GALLO: Thank you.

DR. GRAY: You provided a nice day for me to travel up here.

DR. GALLO: That's right. You can see lovely-- As I said to you, you can come up to lovely downtown Newark, and it's a gorgeous day. Right?

DR. GRAY: Well, it's my first time in downtown Newark, and I hope my car is not going to be towed away.

DR. GALLO: Oh, no. Dr. Magee will handle all of those issues.

DR. GRAY: Very good. Thank you, Doctor.

DR. MAGEE: Just see me afterwards. (laughter)

DR. GRAY: Okay. I was wondering if I have-- You can see the nature of my outline. Considering that no one has represented the environmental side at this particular hearing, and considering I'm attacking three groups -- the environmentalists, the industrialists, and this Commission -- I was hoping I might get just a tad more than the five minutes, especially in view of the fact that I have appeared twice.

DR. GALLO: No, now wait a minute now. (laughter) We've got to be fair -- six minutes.

DR. GRAY: My name is Arnold L. Gray. I'm Assistant Professor of Natural Resource Management at Richard Stockton College.

My first attack goes against environmentalists. Basically, there is no such thing as a zero risk, which is what I heard environmentalists calling for at the last public meeting. Household toxins abound. A mercury thermometer, for example, if it were dropped on the floor, would require an extensive remediation of a household property. If the same standards that we're trying to apply with the 10 to the minus 6 (10^{-6}) factor were applied to private households, the public would be up in arms in a way that is very, very difficult not to appreciate. A simple broken thermometer could make it so a house would have to have as much as $100,000 in cleanup remediation, in as much as a single pin drop of mercury can create enough mercury vapor so that it could not pass the former 10 to the minus 6 (10^{-6}) health risk, or air emissions within building interiors.

My second attack is against the general nature of the 10 to the minus 6 (10^{-6}) level, in that it had -- as was mentioned before -- a repetitive, conservative bias. Basically, this is a violation of the Central Limits Theorem. It violates the General Rule of the Second Best, which says if you make consistent mistakes in either direction, you'll probably wind up on course, but as long as you keep making mistakes in a particular direction, you're going to be way off course. The methodology used by the DEPE does, in fact, do this. I would guess that you might very well be winding up with a level -- although I haven't done a study -- closer to 10 to the minus 12 (10^{-12}). It's really quite unreasonable for many of the compounds listed, we agree.

Against industry: The problems listed above can be cured with the Monte Carlo method, but the methods were never the problem with risk assessment, rather it is the assumptions that go into creating the risk assessment. As a former public servant in the field of environmental remediation, we rarely

found RAs that had a serious problem; that indicated that anything at all would have to be done. When the assumptions were considered for many of these reports, the results would have, in fact, been laughable had the impact -- or the potential impact -- of not taking any action at all been so serious.

Regardless of the method, you put bad data in and you're going to get bad data out. The statistics I needed to learn for this came from my very first class as an undergraduate in a statistics course. The one says that a statistician is a person who, with his head in a block of ice and his feet in an oven, says, "On an average, I feel fine." (laughter) A little more cynical approach is -- and one that I have had the chance to observe personally in my own professional life -- "Figures don't lie, but liars can't figure."

When you put millions of dollars at stake in a decision that a company can make as to whether or not there should be a cleanup, I'm not sure that the company is always in the best, unbiased position to make that particular decision. I think it becomes important that we have a group like the NJDEPE to moderate between the extreme views expressed to help us through those decisions. A comment that I heard in the meeting the other night was that carcinogenic studies are based mostly on rat studies. Well, Class A carcinogenic studies are also based on human epidemiology, so that particular statement mentioned earlier was not true.

Cumulative and synergistic effects are not investigated and remain unknown for mixed contaminants. The best example that we know of is tobacco and asbestos. Either one produces a particular risk, but when you put them together the result is much greater than either one of the two would give you in an additive fashion.

When you look at the way the risks or the health assessments are put together, they look at, for example, the risk of benzoapyrene, and then they look at the risk of this other thing, and then the risk of this other thing. They don't consider not only the additive effects, but also the possible synergistic effects. This is a very serious flaw in the entire methodology. Because of this, it is not unreasonable to take the overly simplistic and overly conservative numbers generated by the DEPE, since they also don't look into cumulative and synergistic effects. If we're going to make the mistake, I would ask the Commission to consider very seriously where we're going to make our mistakes.

Most serious of all, however, is that risk assessment is a layered or staged process. Right now there are conversations going on about reducing the confidence level from a 90 percent to an 80 percent level for these particular types of studies. Well, if you lower the overall toxicity factor, and then you lower the confidence level, and then you do this, and then you do that, and then you do that, ultimately, what you wind up with is a step-by-step production -- public protection process -- being dismantled. This is not correct.

For the Commission: The public notice-- (timer beeps)

DR. GALLO: You've got one minute. Go ahead.

DR. GRAY: The public notice was unacceptable for this particular exercise. I cannot call this a public meeting. The press was notified, but no legal notice was issued. It was not in the register, and only a very narrow list of people are here today. I haven't seen any environmentalists, for that matter, or anybody who represents what we would call the general public. Up to this point, at this particular meeting I have only seen representatives of industry.

Observations: I'll leave this, of course, to be viewed. I brought extra copies for anybody in the room. But environmentalists, you're being unreasonable. You're asking

for more than is possible. Industrialists, your credibility is not there. You are unreliable. What I would strongly recommend is a composition of another committee that brings together representatives of both the environmental community, public citizenry, and the industrial community to work out reasonable alternatives, which have to include a case-by-case--

DR. GALLO: Five seconds. (timer beeps) That's it.

DR. GRAY: Okay.

DR. GALLO: Thank you. We've got it all written down. Thank you.

DR. GRAY: There are extra copies for anybody who wants them, and my number is there if you want to talk.

DR. GALLO: Okay. Do we have anybody else? (affirmative response) Thank you.

David Aronson.

D A V I D A R O N S O N, P.E.: David Aronson, I'm the Coordinator to the State Legislature for the American Society of Mechanical Engineers. However, I came here primarily to be informed as to what was going on. I did bring with me two references that put some light on it and may be of help to the Commission.

One is the winter issue of "Resources", put out by the Resources For the Future, a nonprofit, Ford Foundation supported organization. It has made a tremendous number of studies in these areas and is not a biased group. So I think this-- I will leave this with you.

By the way, all their publications are free. They contain a considerable amount of data, so you should take advantage of it.

The other is a book. It was put out by a professor at Rutgers University, Leonard Cole, who gives some insight to the way some of these decisions get made. He refers to radon in a particular case, analyzes different participants in arriving at risks from that source, and shows how personality enters into a

wide variety of effects. This is one of the difficulties of the situation. You cannot be completely unbiased. So that is why a hearing like this can contribute in the sense of giving different viewpoints.

I can refer just to a recent case I'm taking a little interest in that shows how decisions are made. It has to do with the question of heating electric cars. California regulations, which will come here into New Jersey, require that if you use fuel, it can only be used when the temperature is below 40 degrees Fahrenheit, and the fuel has to be either compressed natural gas or liquefied petroleum gas. There is no relationship to anything connected with space heaters, since everybody who uses oil heating in a home would be polluting enormously.

Yet the people have not -- some how or another missed calling on appropriate standards. Such heaters were in use at one time in cars, and contribute to reducing pollution by heating up the catalyst ahead of time, so when you start your engine you're not having an ineffective catalyst. I mean, this just indicates the way these things some how or another sneak in, and it requires eternal vigilance to see that they don't take place.

So I'm glad you gave me the opportunity to greet you and leave this material with you.

DR. GALLO: Thank you. Are you going to leave us that reference from Dr. Cole's book?

MR. ARONSON: I can leave a reference to it.

DR. GALLO: Thank you.

Has Delores Phillips arrived? (no response) She's the only other speaker.

Thank you very much. I appreciate it. We'll review the comments and the literature that you have given to us.

The meeting is closed.

(HEARING CONCLUDED)

APPENDIX

Friday, March 11, 1994

Environmental Risk Assessment and Risk Management Study Commission

Gentlemen:

Nature is not benign!

Plants and animals have spent billions of years trying to protect themselves from one another. Powerful, toxic chemicals have evolved, quite naturally, in the process!

All life has evolved in a toxic environment. The background is normal. Small doses of some toxins are beneficial, ie Vitamin A, aspirin (acetylsalicylic acid), curare...large doses will kill you! It's a matter of degree and life style. Some people can take more than others.

When the magic number, 10^{-6} drifted into the bureaucratic awareness, the results were predictable.

I have attached the cover sheets from a number of papers published by Bruce Ames showing the level of toxins in common foods. Most of the vegetables that are known to be good for you, contain high levels of a vast array of chemical toxins and carcinogens.

Nobody wants a toxic environment. However, the definition of what and how much is toxic cannot be defined arbitrarily.

I'll read you the parts-per-million and the names of the chemicals found in a variety of foods...

Please keep this in mind when passing on advice to legislators.

Thank you!

Franklin G. Reick

Concerned Citizen

for "Commerce & Industry Association of New Jersey"

IX

Table 2. Concentrations of natural pesticide carcinogens

Plant	Carcinogen	Concentration (ppm)
Parsley	5- and 8-methoxypsoralen	14
Parsnip, cooked	—	32
Celery	—	0.8
Celery, new cultivar	—	6.2
Celery, stressed	—	25
Mushroom, commercial	*p*-hydrazinobenzoate	11
Mushroom, commercial	glutamyl-*p*-hydrazinobenzoate	42
Cabbage	sinigrin* (allyl isothiocyanate)	35–590
Cauliflower	—	12–66
Brussels sprouts	—	110–1560
Mustard (black)	—	16,000–72,000
Horseradish	—	4500
Basil	estragole	3800
Fennel	—	3000
Nutmeg	safrole	3000
Mace	—	10,000
Pepper, black	—	100
Apple, Pear, Plum, Cherry, Carrot, Celery, Lettuce, Potato, Endive, Grapes, Eggplant	caffeic acid	50–200
Thyme, Basil, Anise, Sage, Dill, Caraway, Rosemary, Tarragon, Coffee (roasted beans)	caffeic acid	>1000
Apricot, Cherry, Plum, Peach	chlorogenic acid** (caffeic acid)	50–500
Coffee (roasted beans)	—	>21,600
Apple, Pear, Peach, Apricot, Plum, Cherry, Brussels sprouts, Kale, Cabbage, Broccoli, Coffee (roasted beans)	neochlorogenic acid** (caffeic acid)	50–500 11,600

*Sinigrin is a co-carcinogen[47] and is metabolized to the carcinogen allyl isothiocyanate, although no adequate test has been done on sinigrin itself. The proportion converted to allyl isothiocyanate or to allyl cyanide depends on food preparation.[53,54] **Chlorogenic and neochlorogenic acid are metabolized to the carcinogen caffeic acid but have not been tested for carcinogenicity themselves. The clastogenicity and mutagenicity of the above compounds are referenced in Table 1. *Carcinogen refs* (refs 32–35 and the following): 5-methoxypsoralen (light activated),[57] 8-methoxypsoralen,[58] *p*-hydrazinobenzoate and glutamyl-*p*-hydrazinobenzoate,[59,60] allyl isothiocyanate,[45,46] D-limonene,[61] estragole and safrole,[56,62] ethyl acrylate,[63] benzyl acetate,[64] caffeic acid.[50–52] *Concentration refs*: 5-, 8-methoxypsoralen,[37,65–69] *p*-hydrazinobenzoates,[59,60] sinigrin,[53,54,70] D-limonene,[71–73] estragole and safrole,[74–77] ethyl acrylate,[78] benzyl acetate,[79–81] caffeic acid, chlorogenic acid, neochlorogenic acid.[82–90] D-limonene is found in citrus oil, ethyl acrylate in pineapples, and benzyl acetate in basil and jasmine tea.

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EDITORIAL

Pesticides and Food

A court ruling mandating that the Delaney Clause be strictly applied has ensured major attention to this legislation. Rigid enforcement would result in banning many herbicides, fungicides, and insecticides (collectively called pesticides). As a result, costs of food would increase, growers and processors would be impacted, and enhanced soil erosion would result (no-till agriculture would decrease). Increased costs of vegetables and fruit would deleteriously affect the health of low-income people. Benefits to public health would be negligible.

The maximum levels of pesticides in unprocessed plant products are established by the Environmental Protection Agency (EPA). The agency relies on tests performed on laboratory rodents using huge doses followed by questionable extrapolation to tiny doses in humans. The regulatory level is then usually set with the objective that individuals consuming the food for 70 years would have, as an upper limit, one extra chance in a million of incurring cancer. (The true risks may be zero according to the EPA.) In contrast, the probability of suffering a cancer-caused death from a bad diet (e.g., excessive fat) is about 70,000 chances in a million.

The Food and Drug Administration (FDA) monitors adherence to the pesticide levels established by the EPA.* Domestic samples of food are collected as closely as possible to the point of production. Fresh produce is analyzed as the unwashed whole raw commodity, with peel or skin intact. If residues above the EPA standards are found, the FDA can seize the produce. Imports may be stopped at the point of entry when illegal residues are found. Residues present at 10 to 100 parts per billion are usually quantitatively measurable. Trace amounts can be detected at lower levels. In 1991, 19,082 samples of food were analyzed by the FDA. No violative residues were found in 99% of all 8281 domestic surveillance samples. Indeed, 64% of these had no detectable residues. No violative residues were found in all 155 baby-food samples tested. When violative residues were found in other samples, few of them exceeded standards by more than a factor of about 4.

In addition to the FDA activities, many states carry out effective monitoring, and there is a "Foodcontam" database which is a compilation of state-collected residue data. The FDA also utilizes the Battelle World Agrochemical Data Bank or the Landell Mills Data Bank, which contain pesticide usage data for about 20 to 25 countries that export food to the United States.

Synthetic pesticides in marketed foods constitute no appreciable threat to human health. What is the problem about the Delaney Clause? Under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), the EPA determines appropriate tolerance levels in or on agricultural commodities by considering both potential health effects and the value of pesticide uses. For example, pesticides are beneficial to health by controlling disease and damage to foods caused by bacteria, fungi, and insects. However, section 409 of the FFDCA, which applies only to processed foods, includes the Delaney Clause that prohibits food additives, including pesticides found to induce cancer in humans or animals. The Delaney Clause requires the EPA to consider only a pesticides risk, however insignificant, and not to consider any offsetting benefits. In some instances a ban on a pesticide found in processed foods has been arbitrarily extended by the EPA to revoke its use on the crop in question.

The Delaney Clause was enacted in 1958 at a time of insensitive instrumentation, lack of knowledge about levels of pesticides, and ignorance about causes of human cancer. For instance, it was not recognized how much cancer is caused by smoking, excessive fat in diets, and the production of carcinogens by cooking. It was also a time of ignorance about natural pesticides in food. Ames and Gold† have reminded us that the defense mechanisms of plants create an enormous number of endogenous pesticides. Many of these chemicals, when tested by the procedures used on synthetic substances by the EPA, produce cancer in rodents. The natural pesticides are abundant in plants. Ames and Gold have estimated that humans ingest about 10,000 times as much of the natural pesticides as of the synthetic varieties. If the Delaney Clause is sound legislation, why isn't it applied to natural carcinogens?

The long-lasting flap about the Delaney Clause and synthetic pesticides probably had the side effect of increasing cancer by diverting attention from the real factors causing the dreaded disease. Citizens deserve a more judicious source of information affecting their health than has been provided by the federal government.

Philip H. Abelson

*Food and Drug Administration Pesticide Program, *J. Assoc. Off. Anal. Chem.* **75** (1992). †B. N. Ames and L. S. Gold, *Science* **249**, 970 (1990); B. N. Ames *et al.*, *Proc. Natl. Acad. Sci. U.S.A.* **87**, 7777 (1990); L. S. Gold *et al.*, *Science* **258**, 261 (1992).

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DIETARY CARCINOGENS, ENVIRONMENTAL POLLUTION, AND CANCER: SOME MISCONCEPTIONS

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(*Received* 10 *October* 1989; *accepted* 25 *October* 1989)

Various misconceptions about dietary carcinogens, pesticide residues, and cancer causation are discussed. The pesticides in our diet are 99.99% natural, since plants make an enormous variety of toxins against fungi, insects, and animal predators. Although only 50 of these natural pesticides have been tested in animal cancer tests, about half of them are carcinogens. About half of all chemicals tested in animal cancer tests are positive. The proportion of natural pesticides positive in animal tests of clastogenicity is also the same as for synthetic chemicals. It is argued that testing chemicals in animals at the maximum tolerated dose primarily messures chronic cell proliferation, a threshold process. Cell proliferation is mutagenic in several ways, including inducing mitotic recombination, and therefore chronic induction of cell proliferation is a risk factor for cancer.

Key words: **Pesticides, Animal cancer tests, Cancer causation.**

MISCONCEPTION No. 1: CANCER RATES ARE SOARING

Overall cancer death rates in the United States are staying steady or coming down, the major exception being smoking-related cancer. The latest update[1] from the National Cancer Institute (February 1988) indicates that 'the age adjusted mortality rate for all cancers combined except lung cancer has been declining since 1950 for all individual age groups except 85 and above.' (That represents a 13% decrease overall, 44,000 deaths below expected, and a 0.1% increase in the over-85 group.)

The types of cancer deaths that have been decreasing during this period are primarily stomach (by 75%, 37,000 deaths below expected), cervical (by 73%, 11,000 deaths below expected), uterine (by 60%, 9000 deaths below expected), and rectal (by 65%, 13,000 deaths below expected). The types of cancer deaths that are increasing are primarily lung cancer (by 247%, 91,000 deaths above expected), which is due to smoking (as is 30% of all U.S. cancer), and non-Hodgkin's lymphoma (by 100%, 8000 deaths above expected).

Clearly, changes in survival rates and incidence rates are also relevant in interpreting those changes.[1,2] Incidence rates have been increasing for some types of cancer.[1] Sir Richard Doll and Richard Peto of Oxford University, two of the world's leading epidemiologists, in their definitive study on cancer trends,[2] point out that though incidence rates are of interest, they should not be taken in isolation because of the substantial extent to which trends in the recorded incidence rates are biased by improvements in the level of registration and diagnosis, as appears to be the case, for instance, with breast cancer. Even if particular types of cancer can be shown to be increasing or decreasing, establishing a causal relation among the many changing aspects of our lives remains difficult.[3–15] There is no persuasive evidence that there is a general increase in cancer that can be attributed generally to life in the modern industrial world.[2,10,13]

Life expectancy is steadily increasing in the United States and other industrial countries. Infant mortality is decreasing. And, although the statistics are not good on birth defects, there is no evidence that they are increasing. Conclusion: Americans are the healthiest they have been in their history.

MISCONCEPTION No. 2: CHEMICALS CARCINOGENIC TO RODENTS ARE FEW IN NUMBER AND EASILY ELIMINATED

More than half of the chemicals tested to date in both rats and mice have been found to be carcinogens at the high doses administered,[3,16] the maximum tolerated dose (MTD). Synthetic industrial

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Ranking Possible Carcinogenic Hazards

BRUCE N. AMES,* RENAE MAGAW, LOIS SWIRSKY GOLD

This review discusses reasons why animal cancer tests cannot be used to predict absolute human risks. Such tests, however, may be used to indicate that some chemicals might be of greater concern than others. Possible hazards to humans from a variety of rodent carcinogens are ranked by an index that relates the potency of each carcinogen in rodents to the exposure in humans. This ranking suggests that carcinogenic hazards from current levels of pesticide residues or water pollution are likely to be of minimal concern relative to the background levels of natural substances, though one cannot say whether these natural exposures are likely to be of major or minor importance.

EPIDEMIOLOGISTS ESTIMATE THAT AT LEAST 70% OF HUMAN cancer would, in principle, be preventable if the main risk and antirisk factors could be identified (*1*). This is because the incidence of specific types of cancer differs markedly in different parts of the world where people have different life-styles. For example, colon and breast cancer, which are among the major types of cancer in the United States, are quite rare among Japanese in Japan, but not among Japanese-Americans. Epidemiologists are providing important clues about the specific causes of human cancer, despite inherent methodological difficulties. They have identified tobacco as an avoidable cause of about 30% of all U.S. cancer deaths and of an even larger number of deaths from other causes (*1, 2*). Less specifically, dietary factors, or their absence, have been suggested in many studies to contribute to a substantial proportion of cancer deaths, though the intertwined risk and antirisk factors are being identified only slowly (*1, 3, 4*). High fat intake may be a major contributor to colon cancer, though the evidence is not as definitive as that for the role of saturated fat in heart disease or of tobacco in lung cancer. Alcoholic beverage consumption, particularly by smokers, has been estimated to contribute to about 3% of U.S. cancer deaths (*1*) and to an even larger number of deaths from other causes. Progress in prevention has been made for some occupational factors, such as asbestos, to which workers used to be heavily exposed, with delayed effects that still contribute to about 2% of U.S. cancer deaths (*1, 5*). Prevention may also become possible for hormone-related cancers such as breast cancer (*1, 6*), or virus-related cancers such as liver cancer (hepatitis B) and cancer of the cervix (papilloma virus HPV16) (*1, 7*).

Animal bioassays and in vitro studies are also providing clues as to which carcinogens and mutagens might be contributing to human cancer. However, the evaluation of carcinogenicity in rodents is expensive and the extrapolation to humans is difficult (*8–11*). We will use the term "possible hazard" for estimates based on rodent cancer tests and "risk" for those based on human cancer data (*10*).

Extrapolation from the results of rodent cancer tests done at high doses to effects on humans exposed to low doses is routinely attempted by regulatory agencies when formulating policies attempting to prevent future cancer. There is little sound scientific basis for this type of extrapolation, in part due to our lack of knowledge about mechanisms of cancer induction, and it is viewed with great unease by many epidemiologists and toxicologists (*5, 9–11*). Nevertheless, to be prudent in regulatory policy, and in the absence of good human data (almost always the case), some reliance on animal cancer tests is unavoidable. The best use of them should be made even though few, if any, of the main avoidable causes of human cancer have typically been the types of man-made chemicals that are being tested in animals (*10*). Human cancer may, in part, involve agents such as hepatitis B virus, which causes chronic inflammation; changes in hormonal status; deficiencies in normal protective factors (such as selenium or β-carotene) against endogenous carcinogens (*12*); lack of other anticarcinogens (such as dietary fiber or calcium) (*4*); or dietary imbalances such as excess consumption of fat (*3, 4, 12*) or salt (*13*).

There is a need for more balance in animal cancer testing to emphasize the foregoing factors and natural chemicals as well as synthetic chemicals (*12*). There is increasing evidence that our normal diet contains many rodent carcinogens, all perfectly natural or traditional (for example, from the cooking of food) (*12*), and that no human diet can be entirely free of mutagens or agents that can be carcinogenic in rodent systems. We need to identify the important causes of human cancer among the vast number of minimal risks. This requires knowledge of both the amounts of a substance to which humans are exposed and its carcinogenic potency.

Animal cancer tests can be analyzed quantitatively to give an estimate of the relative carcinogenic potencies of the chemicals tested. We have previously published our Carcinogenic Potency Database, which showed that rodent carcinogens vary in potency by more than 10 millionfold (*14*).

This article attempts to achieve some perspective on the plethora of possible hazards to humans from exposure to known rodent carcinogens by establishing a scale of the possible hazards for the amounts of various common carcinogens to which humans might be chronically exposed. We view the value of our calculations not as providing a basis for absolute human risk assessment, but as a guide to priority setting. One problem with this type of analysis is that few of the many natural chemicals we are exposed to in very large amounts (relative to synthetic chemicals) have been tested in animals for carcinogenicity. Thus, our knowledge of the background levels of human exposure to animal carcinogens is fragmentary, biased in favor of synthetic chemicals, and limited by our lack of knowledge of human exposures.

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Medical Sciences

Nature's chemicals and synthetic chemicals: Comparative toxicology*

(carcinogens/mutagens/teratogens/clastogens/dioxin)

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Contributed by Bruce N. Ames, July 19, 1990

ABSTRACT **The toxicology of synthetic chemicals is compared to that of natural chemicals, which represent the vast bulk of the chemicals to which humans are exposed. It is argued that animals have a broad array of inducible general defenses to combat the changing array of toxic chemicals in plant food (nature's pesticides) and that these defenses are effective against both natural and synthetic toxins. Synthetic toxins such as dioxin are compared to natural chemicals, such as indole carbinol (in broccoli) and ethanol. Trade-offs between synthetic and natural pesticides are discussed. The finding that in high-dose tests, a high proportion of both natural and synthetic chemicals are carcinogens, mutagens, teratogens, and clastogens (30–50% for each group) undermines current regulatory efforts to protect public health from synthetic chemicals based on these tests.**

The Toxicology of Synthetic and Natural Toxins Is Similar

It is often assumed that, because plants are part of human evolutionary history whereas synthetic chemicals are recent, the mechanisms that animals have evolved to cope with the toxicity of natural chemicals will fail to protect us against synthetic chemicals (1, 64).¶ We find this assumption flawed for several reasons.

(*i*) Defenses that animals have evolved are mostly of a general type, as might be expected, since the number of natural chemicals that might have toxic effects is so large. General defenses offer protection not only against natural but also against synthetic chemicals, making humans well buffered against toxins (2–6). These defenses include the following. (*a*) The continuous shedding of cells exposed to toxins: the surface layers of the mouth, esophagus, stomach, intestine, colon, skin, and lungs are discarded every few days. (*b*) The induction of a wide variety of general detoxifying mechanisms, such as antioxidant defenses (7, 8) or the glutathione transferases for detoxifying alkylating agents (9): human cells that are exposed to small doses of an oxidant, such as radiation or hydrogen peroxide, induce antioxidant defenses and become more resistant to higher doses (10–14). These defenses can be induced both by synthetic oxidants (e.g., the herbicide paraquat) and by natural oxidants and are effective against both. (*c*) The active excretion of planar hydrophobic molecules (natural or synthetic) out of liver and intestinal cells (15). (*d*) DNA repair: this is effective against DNA adducts formed from both synthetic and natural chemicals and is inducible in response to DNA damage (16). (*e*) Animals' olfactory and gustatory perception of bitter, acrid, astringent, and pungent chemicals: these defenses warn against a wide range of toxins and could possibly be more effective in warning against some natural toxins that have been important in food toxicity during evolution, than against some synthetic toxins. However, it seems likely that these stimuli are also general defenses and are monitoring particular structures correlated with toxicity; some synthetic toxic compounds are also pungent, acrid, or astringent. Even though mustard, pepper, garlic, onions, etc. have some of these attributes, humans often ignore the warnings.

That defenses are usually general, rather than specific for each chemical, makes good evolutionary sense. The reason that predators of plants evolved general defenses against toxins is presumably to be prepared to counter a diverse and ever-changing array of plant toxins in an evolving world; if a herbivore had defenses against only a set of specific toxins, it would be at a great disadvantage in obtaining new foods when favored foods became scarce or evolved new toxins.

(*ii*) Various natural toxins, some of which have been present throughout vertebrate evolutionary history, nevertheless cause cancer in vertebrates. Mold aflatoxins, for example, have been shown to cause cancer in trout, rats, mice, monkeys, and possibly in humans (2, 17). Eleven mold toxins have been reported to be carcinogenic (6), and 19 mold toxins have been shown to be clastogenic (18). Many of the common elements are carcinogenic (e.g., salts of lead, cadmium, beryllium, nickel, chromium, selenium, and arsenic), or clastogenic (18) at high doses, despite their presence throughout evolution. Selenium and chromium are essential trace elements in animal nutrition.

Furthermore, epidemiological studies from various parts of the world show that certain natural chemicals in food may be carcinogenic risks to humans: the chewing of betel nuts with tobacco around the world has been correlated with oral cancer (17, 19). The phorbol esters present in the Euphorbiaceae, some of which are used as folk remedies or herb teas, are potent mitogens and are thought to be a cause of nasopharyngeal cancer in China and esophageal cancer in Curacao (20, 21). Pyrrolizidine toxins are mutagens that are found in comfrey tea, various herbal medicines, and some foods; they are hepatocarcinogens in rats and may cause liver cirrhosis and other pathological states in humans (19).

Plants have been evolving and refining their chemical weapons for at least 500 million years and incur large fitness costs in producing these chemicals. If these chemicals were not effective in deterring predators, plants would not have been naturally selected to produce them.

(*iii*) Humans have not had time to evolve into a "toxic harmony" with all of the plants in their diet. Indeed, very few of the plants that humans eat would have been present in an African hunter–gatherer's diet. The human diet has changed

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Abbreviations: DDT, 1,1,1,-trichloro-2,2-bis(*p*-chlorophenyl)ethane ("dichlorodiphenyltrichloroethane"); TCDD, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin; IC, indole-3-carbinol; Ah receptor, aromatic hydrocarbon receptor.

*This is paper no. 3 of a series. Paper no. 2 is ref. 6.

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¶"For the first time in the history of the world, every human being is now subjected to contact with dangerous chemicals, from the moment of conception until death." Rachel Carson (1962) *Silent Spring* (Houghton Mifflin, Boston), p. 15.

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Medical Sciences

ALL THREE PAPERS ATTACHED

Chemical carcinogenesis: Too many rodent carcinogens*

(tumor promotion/mutagenesis/mitogenesis/animal cancer tests)

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Contributed by Bruce N. Ames, July 19, 1990

ABSTRACT **The administration of chemicals at the maximum tolerated dose (MTD) in standard animal cancer tests is postulated to increase cell division (mitogenesis), which in turn increases rates of mutagenesis and thus carcinogenesis. The animal data are consistent with this mechanism, because a high proportion—about half—of all chemicals tested (whether natural or synthetic) are indeed rodent carcinogens. We conclude that at the low doses of most human exposures, where cell killing does not occur, the hazards to humans of rodent carcinogens may be much lower than is commonly assumed.**

In current strategies to prevent human cancer, chronic rodent bioassays are the major source of information used to predict the risk to humans from chemical exposures. This paper addresses the issue of the role of cell division (mitogenesis) in animal cancer tests and the implications of an improved theory of mechanisms of carcinogenesis for the assessment of cancer hazards to the general population. In animal tests done at the maximum tolerated dose (MTD), about half of the chemicals tested are rodent carcinogens (1–7). We argue that the explanation for a high percentage of chemicals being carcinogens at the MTD is that these high doses stimulate mitogenesis, which increases rates of mutagenesis and carcinogenesis. While chemicals selected for testing are primarily synthetic industrial compounds, the high positivity rate does not imply that synthetic chemicals are more likely to induce tumors in rodents than naturally occurring chemicals. [The chemicals in the human diet are nearly all natural (8).] To the extent that increases in tumor incidence in rodent studies are due to the secondary effects of administering high doses, then *any* chemical that increases mitogenesis (e.g., by cell killing) is a likely rodent carcinogen. The correct analysis to determine the proportion of rodent carcinogens among chemicals would require a comparison of a random group of synthetic chemicals with a random group of natural chemicals. This analysis has not been done. We have examined the available results from the limited number of natural chemicals tested and have found that about half are rodent carcinogens, just as for the synthetic chemicals (8).

The high proportion of carcinogens among chemicals tested at the MTD emphasizes the importance of understanding cancer mechanisms in order to determine the relevance of rodent cancer test results for humans. A list of rodent carcinogens is not enough. The main rule in toxicology is that "the dose makes the poison": at some level, every chemical becomes toxic, but there are safe levels below that. However, the precedent of radiation, which is both a mutagen and a carcinogen, gave credence to the idea that there could be effects of chemicals even at low doses. A scientific consensus evolved in the 1970s that we should treat carcinogens differently, that we should assume that even low doses might cause cancer, even though we lacked the methods for measuring carcinogenic effects at low levels. This idea evolved because it was expected that (*i*) only a small proportion of chemicals would have carcinogenic potential, (*ii*) testing at a high dose would not produce a carcinogenic effect unique to the high dose, and (*iii*) chemical carcinogenesis would be explained by the mutagenic potential of chemicals. However, it seems time to take account of new information suggesting that all three assumptions are wrong.

Carcinogens Are Common in Rodent Tests

More than half of the chemicals tested to date in both rats and mice have been found to be carcinogens in chronic rodent bioassays at the high doses administered, the MTD (1–7). Synthetic industrial chemicals account for 350 (82%) of the 427 chemicals tested in both species; about half (212/350) were classified as rodent carcinogens (1–7). Even though the overwhelming weight and number of the chemicals humans eat are natural, only 77 natural chemicals have been tested in both rats and mice; again about half (37/77) are rodent carcinogens (1–6). The high proportion of positives is not due simply to selection of suspicious chemical structures. While some synthetic or natural chemicals were selected for testing precisely because of structure or mutagenicity, most were selected because they were widely used industrially—e.g., they were high-volume chemicals, pesticides, food additives, dyes, or drugs (2). The natural world of chemicals has never been looked at systematically. We explain below why the developing understanding of the mechanisms of carcinogenesis justifies the prediction that a high proportion of all chemicals, natural and synthetic, will prove to be carcinogenic to rodents if tested at the MTD. How to select the MTD is a process that has been changing (9–11).

A chemical is classified as to carcinogenicity in our analysis based on the author's positive evaluation in at least one adequate experiment (3–6) using the criteria given in ref. 8. Rodent carcinogens clearly are not all the same: some have been tested many times in several strains and species and others in only one experiment; some (e.g., safrole) are positive in two species and they or their metabolites are genotoxic in animals; some (e.g., D-limonene) are only positive at one site in one species and are not genotoxic.

Mechanism of Carcinogenesis

It is prudent to assume that if a chemical is a carcinogen in rats and mice at the MTD, it may well be a carcinogen in humans at doses close to the MTD. However, understanding the mechanism of carcinogenesis is critical to the attempt to predict risk to humans at low doses that are often hundreds of thousands of times below the dose at which an effect is observed in rodents. There are two major problems. (*i*) Within rodents, how can measurable carcinogenic effects at

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Abbreviation: MTD, maximum tolerated dose.
*This is paper no. 1 of a series.
‡To whom reprint requests should be addressed.

TESTIMONY OF JOHN WHYSNER, M.D., Ph.D., D.A.B.T.

ONE IN ONE MILLION RISK

A Reasonable Basis For Policy?

March 11, 1994

My name is John Whysner. I am a physician, a scientist, and a board certified toxicologist, speaking on behalf of the Chemical Industry Council of New Jersey. I thank the members of the Commission for this opportunity to address you this afternoon on this important issue.

My manuscript on the one in one million risk-based standard has been submitted to the Commission as an attachment to this testimony. In the interest of the Commission's time constraints, my testimony will provide a distilled and excerpted version of this paper. However, I hope that you will have an opportunity to scrutinize the manuscript that contains the detailed rationale for my testimony.

In order to put different risk levels into perspective, government agencies often derive estimates of the annual risk reduction for a proposed law or regulation. Using such a calculation for S1070, the adoption of a 10^{-6}, 10^{-5} or 10^{-4} risk level results in risk reductions of only 0.0001, 0.001, or 0.01 of a hypothetical cancer case per year for the population of the State of New Jersey. This calculation is presented in detail in my attached paper. These hypothetical fractions can be compared to the actual annual incidence of 42,000 new cancer cases in the State of New Jersey as reported by the American Cancer Society. Clearly, the choice of any of these different risk levels would not appreciably affect the public health of the citizens of New Jersey.

The 10^{-6} risk level has been chosen historically in an arbitrary manner as a basis for regulation. Also, there is an apparent historical trend for the use of greater acceptable risks levels as the conservative nature of risk assessment calculations has been recognized. One

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review of these policies by Travis et al. has indicated that EPA does not consider individual risks of less than 10^{-4} in small geographic areas to require regulation.

The choice of any risk-based standard should include health protective assumptions; however, the methods of risk assessment as developed by the EPA overestimate the risks in several ways. Consequently, there is plenty of room to correct assumptions and risk assessment methodology without jeopardizing the public's health, and allow for other possible concerns such as the presence of several different chemicals at a site.

In order to illustrate the inflation of these risks, the naturally occurring levels of beryllium are present in soils at average levels that result in calculated risks above 10^{-6}, using NJDEPE soil ingestion calculation methods. For 10% of both urban and rural soil samples, the naturally occurring levels of beryllium gives between 10^{-4} and 10^{-5} cancer risk. Consequently, using these criteria, New Jersey soil is inherently carcinogenic. An alternative and more plausible conclusion is that the methodology used, and the choice of a 10^{-6} risk level, greatly overstates the public health concern.

EPA classifies agents according to weight of evidence of carcinogenicity. This classification system reflects important differences in the demonstrated abilities of chemicals to cause cancer in humans, and S1070 has recognized this distinction. The wording "human carcinogens as categorized by the United States Environmental Protection Agency" was a deliberate designation on the part of the legislature since earlier versions of S1070 did not include this language. Consequently, S1070 leaves open the question of how to determine remediation levels for Groups B and C and implies that these chemicals may be regulated according to another standard. The designation of higher acceptable risk levels for Groups B and C is one method of taking weight of scientific evidence into account in the risk assessment process. There are many precedents for the establishment of distinct levels of risk for different groups of carcinogens that use a 10-fold difference, and it is proposed that the most important risk-based distinction should be between known human carcinogens and animal carcinogens.

Many past risk management decisions have chosen the most conservative risk

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numbers because there were no perceived negative consequences for this decision. However, there has been an increasing awareness, that these overly conservative decisions result in needless expenditure of hundred of millions of dollars for little or no incremental reduction in real risk.

In conclusion, 10^{-5} is the lowest lifetime cancer risk level that should determine any soil remediation standard. Furthermore, a higher risk level, such as 10^{-4}, should determine the standards for Groups B and C. Alternatively, remediation levels for Group C chemicals can be developed using NOELs. The adoption 10^{-4} or 10^{-5} risk levels will protect the health of the citizens of New Jersey. I am concerned that the adoption of a 10^{-6} risk level will make an insignificant difference on public health, and will create remediation gridlock and huge, unnecessary costs.

Biography

John Whysner, M.D., Ph.D. is testifying as Vice President of Washington Occupational Health Associates, Inc., a Washington, D.C. based consulting firm specializing in occupational and environmental medicine. Dr. Whysner is also Executive Secretary of the Environmental Health and Safety Council, American Health Foundation, a non-profit research foundation, dedicated to disease prevention. He also serves as a member of the Environmental Medicine Committee of the American College of Occupational and Environmental Medicine (ACOEM) and recently developed the risk assessment module for this organizations's course in environmental medicine.

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ONE IN ONE MILLION RISK

A Reasonable Basis For Policy?

by John Whysner, M.D., Ph.D., D.A.B.T.

March 11, 1994

INTRODUCTION

The Industrial Site Recovery Act (ISRA), also known as S1070[1], policy is "to protect the public health, safety, and the environment, to promote efficient and timely cleanups, and to eliminate any unnecessary financial burden of remediating contaminated sites;....." Paragraph 35.d. states that the department shall set minimum soil remediation standards for both residential and nonresidential uses that "(1) for human carcinogens, as categorized by the United States Environmental Protection Agency, will result in an additional cancer risk of one in one million;...." Paragraph 47.b. established the Environmental Risk Assessment and Risk Management Study Commission, and one duty of the commission is "(1) to examine and assess the scientific basis for selecting the risk management standard of one in one million of [this law] and to consider and assess alternative scientific standards and criteria for that purpose;..." Consequently, although the legislation appears to establish one in one million (10^{-6}) risk as the standard for human carcinogens, the legislation has clearly empowered the Commission with the responsibility of determining whether the 10^{-6} risk criterion can be scientifically justified.

Review of the scientific literature and other data collected through the members of the Chemical Industry Council of New Jersey finds that a 10^{-5} risk level is the lowest risk

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[1]S1070 was the New Jersey Senate bill creating ISRA, or P.L.1993, c.139, and "reformed" the Environmental Cleanup Responsibility Act (ECRA), or P.L.1983, c.330. Because of the ramifications for all soil clean-up level requirements, S1070 will be used to designate this law.

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required to accomplish the policy of the S1070 to protect the public health and safety and will provide equitable individual risk levels in comparison with other established standards. Additionally, animal carcinogens that have not be proven to be human carcinogens (EPA's Groups B and C).can be handled by a higher risk level such as 10^{-4}.

In order to put these risk levels into perspective, government agencies often derive estimates of the annual risk reduction for a proposed law or regulation. Using such a calculation, the adoption of a 10^{-6}, 10^{-5} or 10^{-4} risk level results in risk reductions of only 0.0001, 0.001, or 0.01 of a hypothetical cancer case per year for the population of the State of New Jersey. This calculation is shown in Appendix A and assume that 1) the aggregate risk reflects the average rather than maximally exposed individuals and 2) 1% of the State population is potentially exposed to remediations sites[2]. As noted in Appendix A, only 0.2% of the US population have been found to be impacted by contaminated sites studied by the Agency for Toxic Substances and Disease Registry (ATSDR), most of which are Superfund sites. Most of hazardous waste sites do not impact large numbers of people and 1% of New Jersey residents is a reasonable estimate. Even if one assumes that 10% of the state-wide population, or 700,000 citizens, would be potentially exposed, the differences between 10^{-6}, 10^{-5}, and 10^{-4} risk levels are 0.001, 0.01, and 0.1 of a hypothetical cancer case per year. These hypothetical fractions can be compared to the actual annual incidence of 42,000 new cancer cases in the State of New Jersey as reported by the American Cancer Society (ACS, 1994). Clearly, the adoption of any of these different risk levels would not substantially affect the public health of the citizens of New Jersey.

It is our conclusion that soil remediation levels based on 10^{-4} or 10^{-5} lifetime risk levels are health protective and will promote remediations that are timely and without undue financial burdens, even though these remediations will still be costly to the regulated community. The detailed justification for these findings is the subject of this paper.

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[2]Both of these assumptions are explained in Appendix A.

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SOIL REMEDIATION AND FEDERAL RISK-BASED REGULATIONS

In order to understand whether a 10^{-6} risk level is appropriate for soil remediation standards, it is important to recognize that the 10^{-6} risk level has been chosen historically in an arbitrary manner as a basis for regulation (FSC, 1980). Also, there is an apparent historical trend for the use of greater acceptable risks levels as the conservative nature of risk assessment calculations has been recognized. A risk-based recommended standard of 10^{-8} was first proposed by Mantel and Bryan in 1961. In 1977, the FDA instead used 10^{-6} as a risk-based standard for food residues of animal drugs after originally proposing the 10^{-8} risk level in 1973. The EPA has regulated chemicals on risk-based policies, and for decisions where the total predicted impact is a fraction of a cancer case per year for the entire population, as is the case being considered here, "10^{-5} seems to be in the range of what EPA might consider to be an insignificant average lifetime risk" (Rodricks et al., 1987). Another review of these policies by Travis et al. (1987) has indicated that EPA does not consider individual risks of less than 10^{-4} in small geographic areas to require regulation.

Both the EPA Superfund Program and the NJDEPE have been using site-specific risk assessment studies to determine soil remediation levels. In site-specific risk assessments, a calculated baseline risk determines whether any remediation is necessary. For Superfund sites, remediation is required if this assessment shows risks in excess of 10^{-4} and may not be required at lessor risks (EPA, 1991). Once this risk level has triggered an action, Federal Superfund legislation has established site-specific remediation goals based upon a range of risks from 10^{-4} to 10^{-6}.

THE ASSUMPTIONS USED IN RISK CALCULATIONS

The choice of any risk-based standard should include health protective assumptions; however, the methods of risk assessment as developed by the EPA overestimate the risks in several ways. Consequently, any chosen risk level will surely not be exceeded and some calculations will likely overestimate risks by several orders of magnitude. This has two important implications. First, there is plenty of room to correct assumptions and risk

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assessment methodology without jeopardizing the public's health. Second, even with such corrections, the excess margins of safety will account for other possible concerns such as the presence of several different chemicals at a site or for the possibility of additive or even synergistic effects by these chemicals.

The use of several assumptions in the low dose extrapolation methods alone for some carcinogens may create overstated risks by several orders of magnitude. These overestimates are due to the choice of the linearized multistage model, the use of a 95% upper confidence limit on the bioassay data, the choice of a "maximally tolerated dose," and the assumption of no sublinear or threshold response at very low doses. Just the choice of the mathematical model for low dose extrapolation impacts risks by several orders of magnitude (FSC, 1980; Park and Snee, 1983). In recognition of this reality, EPA (1986) has stated the following in its policy on the use of risk assessment:

> "It should be emphasized that the linearized multistage procedure leads to a plausible upper limit to the risk that is consistent with some proposed mechanisms of carcinogenesis. Such an estimate, however, does not necessarily give a realistic prediction of the risk. The true value of the risk is unknown, and may be as low as zero."

The use of this linearized extrapolation is only one part of risk assessment that tends to overestimate the risks. Exposure assessment calculations, even those using EPA methods, have several assumptions such as exposure time and contact rate that will overestimate the risk, especially when combined together in the calculation. The assumption of 100% oral bioavailability and drinking water consumption of two liters per day are two examples of other sources of overestimated assumptions.

In order to illustrate the inflation of these risks resulting from such assumptions, the naturally occurring levels of beryllium are present in soils at levels that result in calculated risks of greater than 10^{-6}, using NJDEPE methods. Applying the soil ingestion calculation from the 1992 NJDEPE proposed rules (NJDEPE, 1992a), as shown in Appendix B, the soil level associated with a 10^{-6} risk for naturally occurring beryllium is 0.16 ppm. The ATSDR has reported that typical beryllium concentrations in soil range from 0.6 to 6.0 ppm

(ATSDR, 1989a). Shacklette et al. (1971) reported a beryllium geometric mean of 0.6 ppm for 847 samples of soil taken throughout the US. A study by the NJDEPE of soils that had not been contaminated from any identifiable source found average beryllium levels were 1.07 ppm for urban and 1.04 ppm for rural soils with 90th percent levels of 2.55 and 1.63 ppm and maximum levels of 4.09 and 10.3 ppm (NJDEPE, 1993). Therefore, for 10% of urban and rural soil samples, the naturally occurring levels of beryllium corresponds to between 10^{-4} and 10^{-5} risk levels. Consequently, using the NJDEPE-endorsed risk assessment methods and assigning a level of acceptable risk of 10^{-6}, New Jersey soils and soils elsewhere in the US are inherently carcinogenic. A reasonable alternative conclusion is that the methodology used and the choice of a 10^{-6} risk level greatly overstates the public health concern.

PRACTICAL DIFFICULTIES FOR THE ONE PER MILLION RISK CRITERION

Other scientific and practical issues will continue to present difficulties at 10^{-6} risk levels, which would not occur at 10^{-5} or 10^{-4}. Major deviations from the 10^{-6} risk level standard will have to be developed due to naturally occurring elements, ubiquitous contaminations, and the lack of sensitivity for the analytical methods. Despite provisions in the legislation in paragraphs 35 g. (4) and (5), clean-up levels should be calculated in a uniform manner, and the improvement of risk assessment methodology and the adoption of a 10^{-5} or 10^{-4} risk levels would allow this consistency.

Certain elements whose naturally occurring levels are above a 10^{-6} risk level are particularly vexing since they are also involved in soil remediations due to site contamination. Two of these elements are beryllium and arsenic and the risks associated with naturally occurring levels beryllium have been described. For arsenic, using the calculation shown in Appendix B, the soil standard would be 0.39 ppm. The amount of naturally occurring arsenic in soils varies between 0.1 and 80 ppm with an average of around 5 to 6 ppm (ATSDR, 1989b). The study by the NJDEPE of soils that had not been contaminated from any identifiable source found average arsenic levels were 8.26 ppm for urban and 2.40 ppm for rural soils with 90th percent levels of 10.9 and 3.83 ppm and

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maximum values of 48.9 and 17.1 ppm (NJDEPE, 1993). Therefore, for 10% of urban and rural soils, the naturally occurring level of arsenic corresponds to greater than a 10^{-5} risk level and range to 10^{-4} risk levels. Based upon these examples of arsenic and beryllium, more than 10% of soils in New Jersey cannot be remediated to less than a 10^{-5} risk level and most soils are above a 10^{-6} risk level according to the methods used by New Jersey.

Also of practical concern are levels associated with some chemical soil contaminants that would be regulated to below the limit of reliable detection. For example, a 10^{-6} risk level for the benzo[a]pyrene results in a soil level of more than 10-fold below the limit of reliable detection (NJDEPE, 1992b). There are no specific legislative provisions in S1070 for these problems with analytical sensitivity limits. Several other such examples of the problems with ubiquitous contamination can be derived from the background levels detected New Jersey soils at the 10^{-6} risk level (NJDEPE, 1993).

WEIGHT OF EVIDENCE AND RISK LEVELS

The EPA classifies agents according to weight of evidence of carcinogenicity. Agents with any evidence of carcinogenicity are divided into three groups as follows:

> "*Group A -- Human Carcinogen*: This group is used only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer.
>
> *Group B -- Probable Human Carcinogen*: This group includes agents for which the weight of evidence of human carcinogenicity based on epidemiologic studies is 'limited' and also includes agents for which the weight of evidence of carcinogenicity based on animal studies is 'sufficient.'
>
> *Group C -- Possible Human Carcinogen*: This group is used for agents with limited evidence of carcinogenicity in animals in the absence of human data."

Whereas EPA currently lists approximately 150 chemicals in all three groups, only 12 have been identified as Group A or human carcinogens (Appendix C).

This classification system reflects important differences in the demonstrated abilities of chemicals to cause cancer in humans, and S1070 has recognized this distinction.

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Chemicals in Groups B and C have sufficient or limited evidence of carcinogenicity in animals, but no conclusive evidence of causing cancer in humans. Often for chemicals in Group B, there are numerous negative or contradictory epidemiology studies, which taken as a whole constitute no evidence of carcinogenicity in humans. Paragraph 35.d. of S1070 states that the Department shall set minimum soil remediation standards for both residential and nonresidential uses that "(1) for human carcinogens, as categorized by the United States Environmental Protection Agency, will result in an additional cancer risk of one in one million;...." The wording "human carcinogens as categorized by the United States Environmental Protection Agency" was a deliberate designation on the part of the legislature since earlier versions of S1070 did not include this language. Consequently, S1070 leaves open the question of how to determine remediation levels for Groups B and C and implies that these chemicals may be regulated according to another standard.

Several grounds exist for designating different acceptable risk levels according to weight of evidence. The basic premise of weight of evidence is the scientific certainty regarding the conviction that an agent is a human carcinogen. Given the large number of agents that produce some degree of carcinogenic response in test animals (approximately 50% for all agents) wnen given at very high doses, the animals experiments appear to have a high false positive rate for predicting human carcinogenicity at reasonable exposure levels. The designation of higher acceptable risk levels for Groups B and C is one method of taking weight of scientific evidence into account in the risk assessment process. Many of the chemicals in Groups B and C, are not DNA-reactive carcinogens and may not have any risk at subtoxic doses. Due to this observation and very limited evidence of carcinogenicity in test animals, it is not surprising that some programs Federal programs regulate Group C chemicals based upon no-observed-adverse-effect-levels (NOAELs) and upon noncancer endpoints.

There are many precedents for the establishment of distinct levels of risk for different groups of carcinogens that use a 10-fold difference. For example, the proposed NJDEPE soil remediation regulations (NJDEPE, 1992a) used a 10-fold greater risk for Group C

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carcinogens. Also, certain programs within the EPA and other states have made risk level distinctions that differentiate Group A from Groups B and C or that differentiate Groups A and B from Group C on a 10-fold basis. It is proposed that the most important risk-based distinction is between known human carcinogens and animal carcinogens (Group A versus Groups B and C) and that Group C chemicals be evaluated by NOAELs rather than by risk levels.

NON-SCIENTIFIC FACTORS THAT IMPACT RISK-BASED DECISIONS

Although this Commission is charged with the mission of examining the scientific merits of risk-based remediation goals and methods, a careful analysis of the benefits of these goals would not be necessary if there were no consequences associated with any of the choices. In fact, many past risk management decisions have chosen the most conservative risk numbers because there were no perceived negative consequences for this decision. However, there has been an increasing awareness, that these overly conservative decisions result in needless expenditure of hundred of millions of dollars for little or no incremental reduction in real risk. Consequently, the analysis of the scientific merit of these decisions requires more careful consideration. While the development of generic soil remediation levels will streamline the process of remediation and reduce the NJDEPE review time, if the risk criteria are too low the expenditure of resources will merely be shifted (and greatly enlarged) from the NJDEPE to the private sector involving excessive and needless cleanup activities.

The total cleanup costs for the ISRA program alone have been reported by the NJDEPE to be over 128 million dollars in fiscal year 1993. The risk-based remediation standard being reviewed by this Commission impacts the ISRA program and other soil remediation programs such as spill cleanup. These other programs combined may cost the regulated community an amount similar to ISRA. Although no studies have been done by the NJDEPE on the cost impact of different risk-based remediation goals, the members of the Risk Assessment Task Force of the Chemical Industry Council of New Jersey estimate that

the difference between a 10^{-6} and a 10^{-5} risk level will impact approximately 50% to 75% of the sites involved in ongoing remediation efforts and could potentially increase the remediation costs by 2-3-fold, depending upon the site. Even more importantly, the impact on the number of sites covered by the choice between these two remediation goals is believed to have even greater cost significance.

Another important difference between the establishment of a 10^{-6} versus 10^{-5} or 10^{-4} risk levels is that the later will more likely "promote efficient and timely cleanups." There will be an impact on the number of sites by adoption of a 10^{-6} criterion that the Department will have to administer. In contrast, the adoption of 10^{-5} or 10^{-4} risk levels would focus regulatory resources on the most important risks. Additionally, the regulated community will be much more likely to expeditiously perform remediations rather than invoking costly and time consuming site-specific risk assessments in accordance with paragraph 35 f. (1) of the S1070. Such problems could eliminate any benefits that are the intent of this legislation.

CONCLUSIONS

It is concluded that 10^{-5} is the lowest lifetime cancer risk level that should determine any soil remediation standard. Furthermore, a higher risk level, such as 10^{-4}, should determine the standards for Groups B and C. Alternatively, remediation levels for Group C chemicals should be developed using NOELs. The adoption 10^{-4} or 10^{-5} risk levels will protect the health of the citizens of New Jersey. The adoption of a 10^{-6} risk level for determining soil remediation criteria will make an insignificant incremental difference in public health, and may create remediation gridlock and huge, unnecessary costs.

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APPENDIX A

It is generally understood that risk assessment calculations intentionally include many conservative (health protective) assumptions. However, the use of such assumptions to protect the individual may not be appropriate when applied to understanding the impacts of policy decisions involving populations. In this Appendix, the calculation shows that the difference between 10^{-6}, 10^{-5}, and 10^{-4} risk levels amounted to the difference between a 0.0001, 0.001, and 0.01 hypothetical cancer case per year for the population of the state of New Jersey. One assumption made in this calculation was that the average risk would actually be one-tenth of that obtained from standard risk assessment calculations. Methods used by the State of New Jersey (NJDEPE, 1992) and in the Risk Assessment Guidance for Superfund (EPA, 1989) contain assumptions that lead to the calculation of risks for the "reasonable maximum exposure." This involves the use of 90% or 95% upper limit values for contact rate, exposure frequency, and exposure duration variables. These are not statistical confidence limits, but numerical assumptions aimed at risk estimates for individuals with the highest exposures. Although it may be necessary to utilize 90% or 95% estimates for individual risk assessment purposes, the calculation of hypothetical cancer cases in a population are appropriately based upon the average individual risks.

The impact of the use of average versus maximal exposures for populations is shown in this Appendix. The exposure duration assumption used in all cancer risk calculations is 30 years at one residence, which is the 90th percentile estimate, rather than 9 years, which is the 50th percentile estimate. Assumptions used for the other factors contact rate and exposure frequency are pathway specific. Soil ingestion is the major pathway used by the NJDEPE for determining proposed soil clean-up levels (NJDEPE, 1992). The daily ingestion rate for soil is assumed to be 200 mg for children and 100 mg for adults with an exposure frequency 350 days per year. The most reliable studies on soil ingestion indicate that the average rates are less than 50 mg/day for both adults and children (Calabrese et al., 1989, 1990, 1991). In order to incorporate these average values into the estimate of expected hypothetical cancer cases, the following calculation is presented:

Residence Duration		*Daily Soil Ingestion*		*Factor*
9 years (average) / 30 years (upper limit)	X	50 mg/day (average) / 150 mg/day (upper limit)*	=	0.1

*represents average of upper limit of adult and child rate.

Consequently, for the soil ingestion pathway, the risk assessment calculations are 10 times greater than those for the average individual. Therefore, the calculation shown in this Appendix concerning the difference between 10^{-6}, 10^{-5}, and 10^{-4} risk levels, which resulted in 0.0001, 0.001, or 0.01 hypothetical cancer cases per year for the population of New Jersey, is a reasonable and valid calculation.

There are no estimates of the number of persons impacted by soil remediations in New Jersey that were available for this report. However, the ATSDR has reported that there are 500,000 persons (0.2% of the US population) impacted by the approximately 1,300 sites that have been investigated in the entire United States, which mostly involve Superfund sites (ATSDR, 1993). It is unlikely that the State of New Jersey would have more persons impacted by soil remediation standards than those covered by the entire Superfund program. Therefore, for the purposes of the calculations in this appendix, the number of persons impacted by soil remediation standards is estimated to be between 70,000 to 700,000 persons or 1-10% of the New Jersey population.

APPENDIX A

CALCULATION OF NEW JERSEY STATE-WIDE RISK

Factor	Explanation
$\frac{10^{-4}, 10^{-5}, \text{ or } 10^{-6}, \text{ Risk}}{\text{RMEI}}$	Initial assumption of risk per "Reasonably Maximally Exposed Individual" (RMEI).
$\frac{\text{RMEI Lifetime}}{70 \text{ Years}}$	Average life expectancy used to derive yearly rates from lifetime risks.
$\frac{0.1 \text{ RMEI}}{\text{AEI}}$	Risk for "Average Exposed Individual" (AEI) are 10% those of the RMEI due to residence duration and contact rate as explained in text.
$\frac{0.01 \text{ AEI}}{\text{N.J. Persons}}$	Assumption that 1% of the N.J. population is affected by remediation sites.
7×10^{6} N.J. Persons	Population of New Jersey.
0.0001, 0.001, or 0.01, Risk/Yr.	Total state-wide risk obtained from the product of all factors.

APPENDIX B

Calculation of
Residential Soil Criteria (ppm)

$$\frac{RSD \times 1 \times 10^6}{\frac{(SIC \times 5.5 \text{ years})}{(BWC_c \times LL)} + \frac{(SIA \times 24 \text{ years})}{(BWA \times LL)}} = \frac{RSD \times 1 \times 10^6}{1.47}$$

$$RSD \text{ (mg/kg/day)} = \frac{1 \times 10^{-6} \text{ risk}}{PF \text{ (mg/kg/day)}^{-1}}$$

Where: 5.5 years = length of time for child soil ingestion
24 years = length of time for adult soil ingestion
1×10^6 = factor to convert from mg to kg
LL = length of a lifetime = 70 years
SIC = soil ingestion rate for a child = 200 mg/day
SIA = soil ingestion rate for an adult = 100 mg/day
BWC_c = body weight of a child = 16 kg.
BWA = body weight of an adult = 70 kg.
RSD = risk specific dose.
PF = potency factor

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Chemical	PF $(mg/kg/day)^{-1}$	RSD mg/kg/day	Residential Soil Criterion (ppm)
Beryllium	4.3	2.3×10^{-7}	0.16
Arsenic	1.75	5.7×10^{-7}	0.39

APPENDIX C

AGENTS THAT EPA PROGRAMS REPORT AS HUMAN CARCINOGENS

(Not all have been given a Group A designation in IRIS)

CHEMICALS

Arsenic

Asbestos

Benzene

Benzidine

Bis(chloromethyl)ether

Chloromethyl methyl ether

Chromium (VI)

Direct Black 38

Direct Blue 6

Direct Brown 95

Nickel subsulfide

Vinyl chloride

RADIOACTIVE AND OTHER AGENTS

Coke oven emissions

Environmental tobacco smoke

Nickel refinery dust

Radionuclides

Radon

THE APPROPRIATENESS OF ONE-IN-ONE MILLION RISK FOR REMEDIATION OF CONTAMINATED SITES

ANDREW DWIGHT BEDSOLE
E. I. DUPONT DE NEMOURS & CO., INC.

PREPARED ON BEHALF OF:
CHEMICAL INDUSTRY COUNCIL OF NEW JERSEY

MARCH 11, 1994

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TESTIMONY PROVIDED TO THE ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION ON 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

MARCH 11, 1994
ANDREW DWIGHT BEDSOLE
E. I. DUPONT DE NEMOURS & CO., INC.

Mr. Chairman:

My name is Dwight Bedsole. I am Business Director of Remediation for DuPont's facilities in New Jersey. I am pleased to have the opportunity to come before this committee to provide testimony on behalf of the Chemical Industry Council of New Jersey, on these extremely important issues.

We commend the commission for their efforts to deal with the question of what appropriate risk management standard should be used in the remediation of contaminated sites and then to recommend risk assessment methodologies that should be used in defining, as accurately as possible, the nature and magnitude of potential risks presented by contaminated sites. The CIC/NJ and it's member companies are committed to protection of human health and the environment and believes that such assessments by the commission are in the best interest of the state's citizens and businesses. In several respects, the CIC/NJ believes that the currently used "one-in-one million" risk level along with the overly conservative risk assumptions and

methodologies used by the NJDEPE go beyond that needed for protection of human health and the environment and thus have the potential for misuse of society's limited resources.

The CIC/NJ believes that many of the risk assumptions and methodologies currently used by the NJDEPE to set cleanup levels for contaminated sites are not justified to protect human health. The risk and exposure assumptions that have been built into the NJDEPE proposed "generic" cleanup standards are unnecessarily conservative, and in many instances do not reflect realistic exposure conditions. Rather these assumptions attempt to compensate for the uncertainty inherent in such analysis by using worst-case, inflated estimates of potential exposure. Also, the assumptions are in several instances, inconsistent with approaches currently used by other established federal and state programs. Mr. Tim Bingman, of DuPont, speaking on behalf of the CIC/NJ outlined areas of concern and proposed risk assessment methodologies in testimony presented to your committee on March 9.

The CIC/NJ also believes that there is no sound social, scientific, economic, or other basis for selecting a rigid one-in-one million risk level for human carcinogens in remediation of contaminated sites. A one-in-one million risk level is needlessly stringent, does not match up with other societal risks and has been chosen historically in an arbitrary manner as a basis for regulation. At a recent lecture (1/94) at Stanford University, William K. Reilly, former administrator of the Environmental

Protection Agency, stated that "Huge sums of money are being spent on hypothetical risks experienced by a few individuals" -- he went on to comment about the lifetime cancer risk of one-in-one million by saying "The hazard of death by lightning is 35 times as great; by accidental falls, 4000 times as great; and in motor vehicles 16,000 times as great". He emphasized that "one-in-one million is a very remote risk". An answer to the question "Just how remote is a one-in-one million risks"? I believe, has been answered very effectively in a paper co-authored by committee member Dr. Bernard Goldstein that looked at the risk of death to people on the ground due to airplane accidents. Results of the study show the lifetime risk of dying from being hit by an airplane is four times greater than a one-in-one million risk.

The risk to those on the ground from an airplane crash is an involuntary risk similar to how the public views an environmental risk from a contaminated site. It is concluded that the public will not make any significant change in personal behavior to reduce the risks of falling airplanes, such as living in their basements, since in their minds the risk is clearly too small to warrant such a lifestyle change. With the imposition of a one-in-one million risk management standard, the regulated community is being asked to spend enormous sums to reduce calculated risks from contaminated sites to a level that the private individual would rightly judge to be inconsequential. Dr. John Whysner, speaking on behalf of the CIC/NJ, presented

testimony this afternoon on the issue of one-in-one million and recommends the use of one-in-one hundred thousand risk level for Group A -- Human Carcinogens and a risk level of one-in-ten thousand for Group B -- Probable Human Carcinogen and Group C -- Possible Human Carcinogens.

Whether orders of magnitude of conservatism find their way into the methodologies used to calculate risks or into the risk management decision of what constitutes an acceptable risk level, the result is the same---scarce societal resources could be spent on issues of de minimus risk.

The CIC/NJ is concerned with the economic impact of over-conservatism. The CIC/NJ finds that a one-in-one hundred thousand risk level is the lowest risk level required to accomplish the goal of the legislation to protect public health. This is a factor of 10 different from the currently used one-in-one million risk level. To define the cost burden of a 10-fold difference in cleanup level for a contaminated site is difficult. For some cleanups, the factor of 10 difference could be fairly small in cost while for others it could be an enormous difference. It depends on the nature of contaminant, media to be cleaned, and extent of contamination. In CIC/NJ's judgment, the cost difference, generally speaking will be "significant".

As an example, DuPont has a site in New Jersey where the contaminant of concern is a metal. The difference in cleaning the soil to a 100 ppm level versus a 250 ppm level, a factor of only 2-1/2, would increase the remediation cost by an estimated

$100 million to $125 million for an approximate three-fold increase in total cost. In comparison, the EPA considers a 500 ppm level to be protective of human health for this contaminant. This additional cost is not insignificant, as example, there are a number of businesses in DuPont where it would take years of earnings generation to pay such costs, and this is only one cleanup at one site. It has been estimated that there are over 8,000 sites in New Jersey that will require remediation by the regulated community.

Clearly, over-conservatism that dictates unnecessary action does not come free. This represents a significant, unnecessary financial penalty to society. I say society because industry must pass all its costs on to its customers, or go out of business. So it is the public that pays the higher costs through higher taxes, higher prices, less competitive industry, and often, lost jobs.

To remediate contaminated sites to a risk management standard that is overly protective and that does not match up to other societal risks, and/or to remediate to a level set by over-conservative risk assessment methodologies will drive the cost of remediation far beyond the value that the remediated site could have to a prospective business. Investment and jobs will go elsewhere.

There seems to be a growing awareness of the connection between economic well being and physical health. That is, unemployment and poverty are clearly connected to

higher disease and death rates. According to a paper published in the September 1991 issue of the Journal Health Physics, the most hazardous of all jobs is no job at all-- unemployment. It was estimated that a 1% increase in U.S. unemployment for one year results in 37,000 deaths (plus 4,200 admissions to mental hospitals and 3,300 admissions to prisons).

We believe that the adoption of costly standards such as one-in-one million diverts valuable resources needed to address other pressing issues on the social agenda such as education, crime, health care and unemployment.

In closing, if a "bright line" level must be defined for risk management decisions, the bright line or lines should reflect the weight of scientific evidence and distinguish among the categories of carcinogens. The CIC/NJ encourages you to recommend a risk management level for Group A carcinogens at one-in-one hundred thousand and for Groups B & C a risk management level of one-in-ten thousand.

Also, the CIC/NJ asks that the commission make full use of the current body of scientific understanding and steer the development and application of risk assessment technologies in a way that is both protective of human health and economically responsible.

ADB/m

PUBLIC HEARING

Scientific Basis for the Selection of the One in One Million Cancer Risk: Alternative Standards and Methodologies

March 11, 1994

Newark, New Jersey

James A. Shissias - General Manager, Environmental Affairs Dept.

Public Service Electric and Gas

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Good afternoon. My name is Michael Draikiwicz, Senior Staff Engineer from the Environmental Affairs Department of Public Service Electric and Gas (PSE&G). On behalf of James A. Shissias, the General Manager of the Environmental Affairs Department of PSE&G, I would like to say that PSE&G is pleased to have the opportunity to speak before the Environmental Risk Assessment and Risk Management Study Commission to comment and share our views on issues concerning the proper application of risk management standards. The following comments are based on the assumptions and methodologies as they were proposed by the New Jersey Department of Environmental Protection and Energy in their February, 1992 Technical Basis and Background Document Concerning Cleanup Standards for Contaminated Sites. At this time, I would like to hand over the presentation to Dr. Cristopher Williams. Dr. Williams is a toxicologist from TERRA, Inc., and is assisting PSE&G in developing these comments.

Our comments relate specifically to NJDEPE's use of "redundant conservative" assumptions in the establishment of minimum remediation soil standards for carcinogens. The assumptions used by the NJDEPE represent "reasonable maximum exposure" (RME) assumptions originally developed by the USEPA and described in *Risk Assessment Guidance for Superfund*. Although RME assumptions define the "maximum exposure that is reasonably expected to occur at a site" (USEPA, 1989, p. 6-19) and were developed to define exposures which represent the 90th to 95th percentile for a given population, the RME case in fact describes an exposure condition much more conservative than this, a condition which rarely, if ever, actually occurs. This was illustrated in a paper by Burmaster and Lehr (1991, p. 8), in which the authors provide a simple relationship from probability theory which describes the likelihood of occurrence

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of an outcome based on a series of conservative assumptions. If, for example, three conservative (95th percentile) values are multiplied together, the outcome actually represents the 99.99th percentile of exposure (not the 95th percentile), based on the following equation:

$$1-(1-0.95)^3 = 99.99$$

In other words, only 0.01% of a given population would experience exposure greater than the resulting "four nines" condition.

To further illustrate the conservatism of NJDEPE's exposure assumptions, let's examine the effect that a number of conservative assumptions have on the appropriate speed needed to negotiate a turn on the highway. Lets assume that the posted speed limit around the turn is 50 mph (Figure 1). We know from our driving experience that posted speed limits are safe for the vast majority of highway travelers. But let's assume that, in order to protect a small segment of the driving population which suffers from impaired night vision, we reduce the "safe" speed to 20 mph. Let us further assume that, in order to assure that individuals on medication (who possess reduced reaction times) will safely negotiate the turn, the speed be reduced to 10 mph, which is equivalent to someone running around the curve. Further reductions in speed (to 3 mph, or normal walking speed) may be necessary to accommodate individuals driving older, perhaps less safe automobiles (e.g., cars with faulty brakes). Finally, to assure that older individuals (with impaired night vision and reduced reaction times) driving unsafe automobiles on perhaps an unfamiliar stretch of road, we may find it necessary to further reduce the posted speed limit to 0.5 mph. Thus, in

order to be absolutely certain that all possible individuals will safely make the turn, we have reduced the speed limit 100-fold; i.e., to the pace of a turtle.

This example illustrates that "redundant conservative" assumptions can transform a plausible limit into one which is highly implausible. The same can be said for risk assessment assumptions. In the following discussion, we demonstrate through a review of current scientific literature that many of the factors used by the New Jersey Department of Environmental Protection and Energy (NJDEPE) to develop remediation standards for soil are indeed "redundant conservative" assumptions. The factors which were specifically examined included the one in one million cancer risk, the cancer slope factor, soil ingestion rates, and time correction factors.

The one in one million risk of developing cancer was initially established by the Food and Drug Administration (FDA) as a screening tool to determine what carcinogenic animal drug residues merited further regulatory consideration (Kelly and Cardon, 1991; Mantel and Bryan, 1961). Since then, the original premise has been expanded to almost all areas of chemical regulation. Although the FDA intended to establish a lower regulatory limit of zero risk below which no further consideration would be given, many federal and state agencies have chosen to ignore the screening level intent of the one in one million risk and have adopted this value to represent a target level of acceptable risk. The NJDEPE is no different in this regard, since it has adopted the one in one million risk as the basis for determining acceptable soil standards for carcinogenic chemicals.

The one in one million cancer risk is an inherently conservative assumption. This is because carcinogenic risk assessment involves: 1) the use of

a conservative model, the linearized multistage (LMS) model, to extrapolate high dose animal cancer data to low-level chemical exposures in humans; 2) the use of the maximum tolerated dose (MTD) in animal experiments which causes overt toxicity in animals, but which is necessary to produce an observable number of tumors in the limited number of animals typically used in such experiments; 3) the use of animals which display a high background incidence of certain tumor types; 4) the use of the "no-threshold" assumption which dictates that any dose, no matter how small, is associated with a finite incidence of cancer; and 5) the use of a conservative animal-to-human scaling factor which attempts to convert the high doses given to animals which cause tumors to the appropriate low doses that humans are most likely to experience.

There are a number of precedents which argue against the use of the one in one million cancer risk as the basis for establishing remediation soil standards for carcinogenic chemicals. For example, California has adopted a one in one hundred thousand value as the "no significant risk level" for the implementation of Proposition 65 (Kizer et al., 1988, p. 954). The one in one hundred thousand risk level is also acceptable under the Massachusetts Contingency Plan (310 CMR 40.545). Maryland (MDE, 1991, p. 15-14), Minnesota (MPCA, 1991, p. 34), Ohio (OEPA, 1991), and Oregon (ODEQ, 1991) use this one in one hundred thousand risk level for establishing ambient air quality standards, while the State of Mississippi (MOPC, 1991) has adopted a risk range of one in ten thousand to one in one million for this purpose. Louisiana uses this higher acceptable risk level (one in ten thousand) for establishing ambient air quality standards (LDEQ, 1992, p. 949).

In addition, Travis et al. (1987, p. 418) reported that carcinogenic substances were not regulated by federal agencies if the risk to small populations was below

one in ten thousand. Thus, given the examples of other states and the fact that such a risk would be undetectable in a small population impacted by site that is either undergoing remediation or has been remediated, the Commission should reconsider strict reliance on the one in one million cancer risk by following the lead of various state and federal agencies. A recommended approach would be to apply a one in one hundred thousand risk level to chemicals which are known human carcinogens (USEPA Group A carcinogens) and a one in ten thousand risk level to those chemicals which pose less of a carcinogenic threat (i.e., probable and possible carcinogens, or USEPA Group B and C carcinogens, respectively).

The NJDEPE has developed cancer slope factors for a total of 43 chemicals and uses these values to determine soil remediation standards for carcinogens. Of the 43 chemicals for which it has developed slope factors, NJDEPE and USEPA values (the latter are published in USEPA's IRIS database and Health Effects Assessment Summary Tables; USEPA, 1994 and USEPA, 1993) differ for 19 chemicals. Of these 19 chemicals, the NJDEPE has <u>overestimated</u> slope factor values for a total of 12, some by as much as 16-fold. This is demonstrated in Table 1. Thus, the NJDEPE has introduced conservative bias in its development of soil remediation standards, in some instances by as much as 16-fold, simply by incorporating slope factors which are more conservative than those developed by the USEPA.

Recent studies of soil ingestion in young children (Calabrese et al., 1989; Barnes, 1990; Davis et al., 1990; Sedman, 1989; van Wijnen et al., 1990) indicate a soil ingestion rate range of < 9 to 104 mg/day, with a range midpoint of approximately 50 mg/day. In particular, Calabrese et al. (1989) reported that the median soil ingestion rate for children ranged from 0 to 20 mg/day, with a 95%

confidence interval of 8 to 24 mg/day. These values are considerably less than the default USEPA soil ingestion rate for children proposed by NJDEPE for residential conditions (200 mg/day). The Commission should reevaluate the soil ingestion rates for children in light of this more recent data and adopt a value no greater than 50 mg/day when determining remediation standards for chemicals in soil under residential exposure conditions.

Soil ingestion studies in adults (Calabrese et al., 1990; Paustenbach, 1989) indicate that less than 50 mg/day is appropriate for residential exposure conditions. Calabrese et al. (1990) suggested a soil ingestion rate in adults of 0-20 mg/day. This value too is considerably less than the default USEPA soil ingestion rate proposed by NJDEPE for adults under residential conditions (100 mg/day). As a result, it is suggested that the Commission recommend an adult soil ingestion rate of no greater than 50 mg/day under residential exposure conditions.

Although the NJDEPE proposed 100 mg/day to represent the amount of soil ingested under nonresidential (i.e., occupational) conditions, recent studies (Thompson and Burmaster, 1991; Binder et al., 1986; LaGoy, 1987; Paustenbach et al., 1991) suggest that soil intakes for workers are likely much lower, perhaps on the order of 10 to 25 mg/day. Given these data, the Commission should recommend soil ingestion values of between 10 and 25 mg/day for workers.

The time correction factors (TCFs) proposed by the NJDEPE are "redundant conservative" assumptions and do not account for normal patterns of human behavior, such as time spent away from home on vacation, the average length of time at a single residence, the typical number of days spent away from a job due to illness or vacation, or the average number of years at a single job. Residence

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times (i.e., the number of years per lifetime) for individuals living in a single location (i.e., near one particular site) have been reported in recent studies (Israeli and Nelson, 1992, p. 70), as have data from U.S. Bureau of the Census (1993, p. 412) records concerning the average length of employment at a single workplace. These studies demonstrate that NJDEPE's assumptions of residence time and length of employment have been overestimated by as much as 6.5-fold. In addition, the NJDEPE has not adjusted the exposure duration portion of the TCF (i.e., the number of weeks of exposure per year) to account for climatic conditions which reduce the potential for exposure to soil, e.g., the average yearly number of rainy days, or the number of days in which the ground is frozen or snow-covered.

As an alternative to the proposed risk assessment approach which derives single "point" estimates of acceptable levels of chemicals in soil, the Commission should recommend probabilistic (i.e., Monte Carlo) techniques to develop distributions of acceptable soil remediation standards. Monte Carlo simulation addresses many of the weaknesses of current risk assessment methods and has been embraced by the USEPA for use in risk assessments submitted to the Agency. We conducted a Monte Carlo analysis of the proposed soil remediation standard for benzene under occupational conditions and present the results in Figure 2. This figure illustrates the frequency associated with a particular benzene soil standard, as well as the probability of a particular standard's occurrence in the distribution. Values presented in the figure indicate that the distribution ranges from a minimum of approximately 150 mg/kg to a maximum of 15,000 mg/kg. The most likely value, based on frequency of occurrence, is 750 mg/kg. Also of note is the fact that more than 90% of the values in the distribution are greater than the NJDEPE benzene standard of 13 mg/kg. Thus, given this analysis, it is suggested that Monte Carlo analysis be used to eliminate

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"redundant conservative" assumptions from NJDEPE's remediation soil standards approach.

PSE&G would also like to comment briefly on two physiochemical characteristics which the NJDEPE did not consider when developing remediation standards: bioavailability of chemicals in soil and soil chemical half-lives. The NJDEPE made the assumption that 100% of a chemical is bioavailable from soil when in fact this is true for only a relatively small proportion of chemicals. The NJDEPE also did not consider the fact that chemicals disappear from soil over time due to factors such as biodegradation, photodegradation and volatilization. Bioavailability and chemical half-life, as well as additional chemical characteristics such as soil binding affinity, should be incorporated into the NJDEPE's approach for developing remediation standards for soil, not only to reflect "real world" conditions, but also to assist the Commission in eliminating "redundant conservative" assumptions.

Furthermore, PSE&G recommends that the Commission develop the numerical remediation standards. Although this is not currently the Commission's task, the benefits of this would be two-fold. First, since the Commission is providing the in-depth scientific analysis of the risk criteria, they would be most familiar with how the science applies to the remediation standards. Second, because the Commission is an uncompensated panel that will have no further charge after this task is complete, they would be unbiased as to the political ramifications of their actions.

One final point PSE&G would like to address is the fact that the Commission is not addressing "impact to groundwater soil cleanup criteria,"

previously referred to as the "subsurface soil cleanup criteria" in the now withdrawn proposal on Cleanup Standards for Contaminated Sites. This would be a serious omission. The Cleanup Standards for Contaminated Sites required the remedial party to remediate the surface soils to the subsurface soil levels if the subsurface soil levels were more stringent than the surface criteria. As of February 3, 1994, the date of NJDEPE's latest revision to their Soil Cleanup Guidance Criteria, more than 62% of the subsurface soil cleanup levels were more stringent than the surface soil cleanup criteria under residential conditions, while more than 67% of the subsurface soil cleanup levels were more stringent than the surface soil cleanup criteria for nonresidential conditions. This means that currently, the Commission's recommendations will affect less than 38% of the chemicals under residential and less than 33% of the chemicals under nonresidential conditions.

Thus, based on this fact that subsurface soil cleanup levels are more stringent than surface soil criteria for such a large percentage of chemicals, it is apparent that the Commission's recommendations for revisions to the surface soil cleanup standards would be greatly minimized. It is therefore strongly recommended that either the Commission examine subsurface soil cleanup criteria concurrently with the surface soil criteria, or at a minimum, propose that another commission immediately be assembled to look at the subsurface soil criteria.

In closing, let me state that the Commission's task, if performed in a reasonable scientific manner, will again demonstrate New Jersey to be a leader in environmental issues. Let's use the best and most recent scientific data to develop remediation standards that are not only reasonable but protective of human

health and the environment. To do otherwise would cause unnecessary expenditures of limited resources, an outcome surely inconsistent with the intended goal. Thank you.

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Table 1

Comparison of Slope Factors Used by the NJDEPE and the USEPA

Chemical	NJDEPE Slope Factor* $(mg/kg/day)^{-1}$	USEPA Slope Factor† $(mg/kg/day)^{-1}$	Ratio of NJDEPE Value to USEPA Value
Benzene	0.23	0.029	7.9
Benzo(a)anthracene	1.15	0.73	1.6
Benzo(a)pyrene	11.5	7.3	1.6
Benzo(b)fluoranthene	1.15	0.73	1.6
Benzo(k)fluoranthene	1.15	0.73	1.6
Bromodichloromethane	0.13	0.06	2.2
Chrysene	1.15	0.073	16
Dibenz(a,h)anthracene	11.5	7.3	1.6
1,2-Dichloroethane	0.12	0.091	1.3
Isophorone	0.0039	0.00095	4.1
Methylene chloride	0.014	0.0075	1.9
Tetrachloroethene	0.082	0.052	1.6

*Source: (Technical Basis and Background Document for Cleanup Standards for Contaminated Sites, 1992, p. 21-23).

†Source: USEPA's IRIS database (USEPA, 1994) and Health Effects Assessment Summary Tables (USEPA, 1993b).

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Figure 1:
Understanding Conservative Assumptions

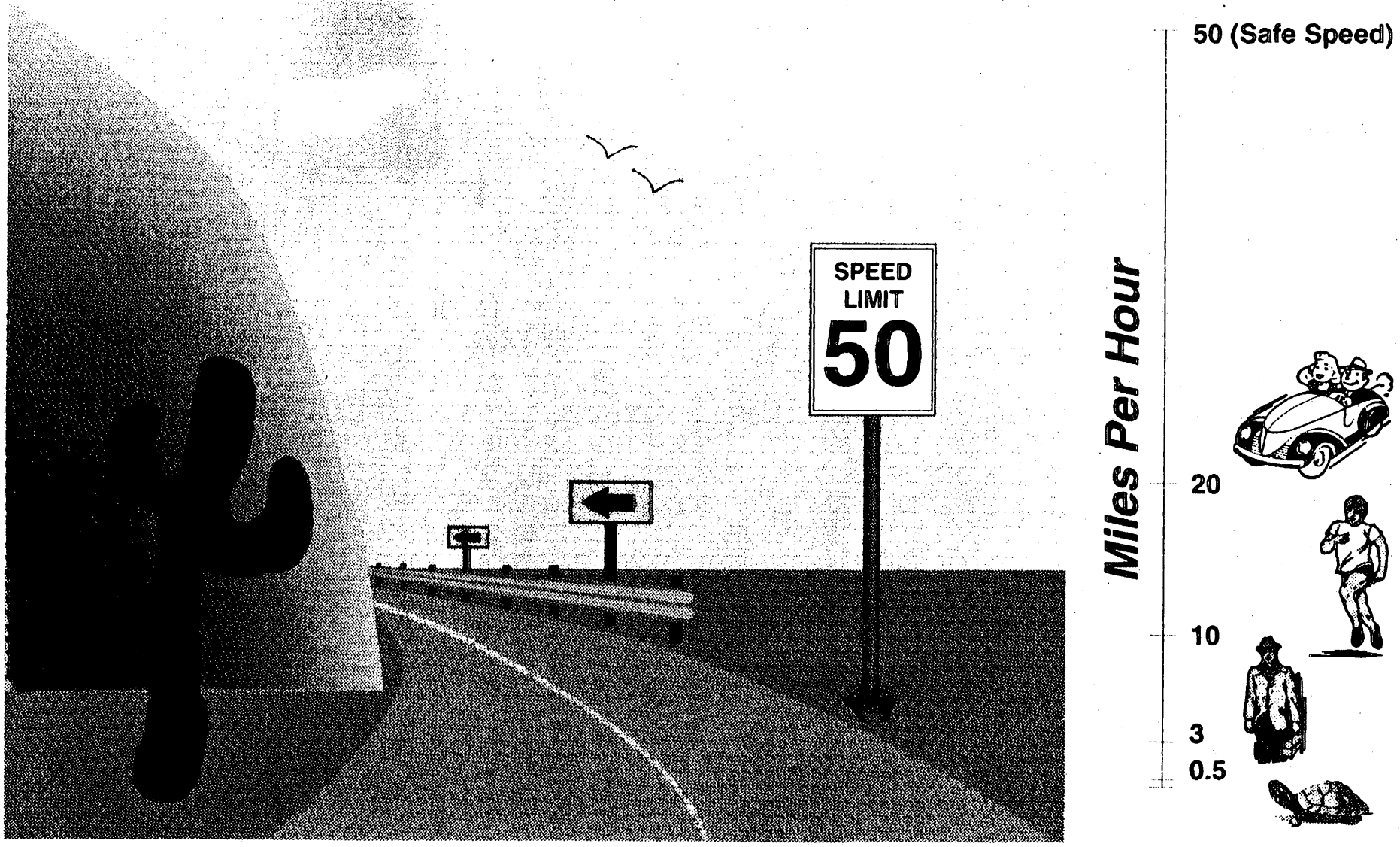
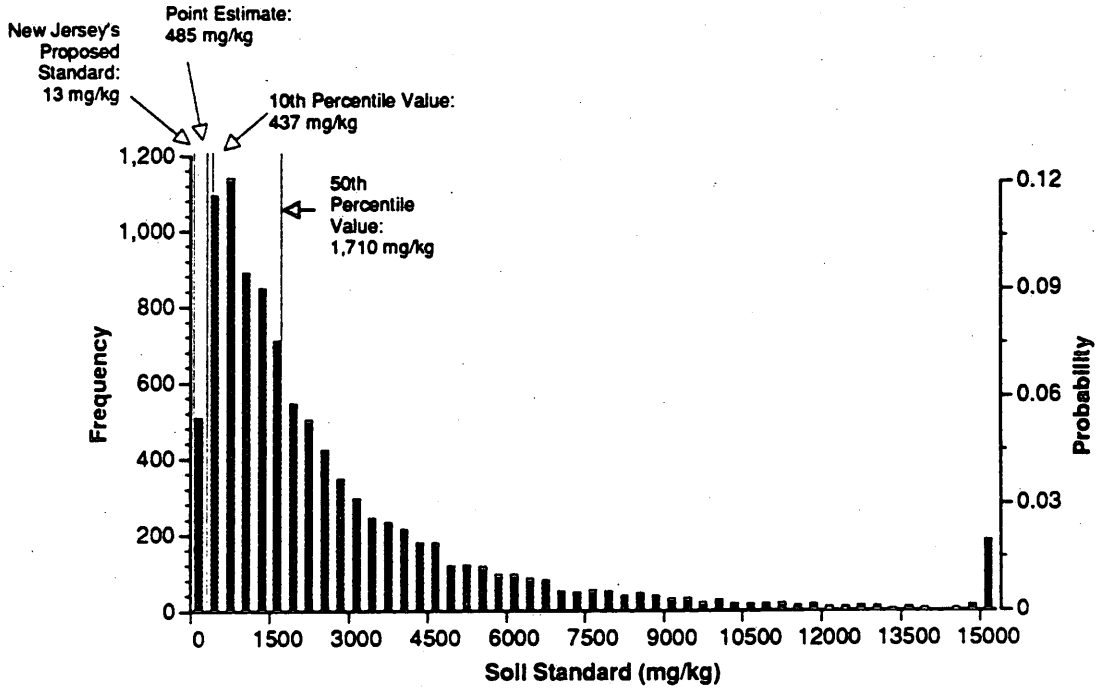


Figure 2

Frequency Distribution of the Benzene Soil Standard Based on Incidental Soil Ingestion Under Non-Residential Conditions



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Dr. Arnold L. Gray
Division of Natural Science and Mathematics
Richard Stockton College of New Jersey
(609) 652-4276

1. Environmentalists -- No such thing as a zero risk, e.g., Household toxics
Mercury thermometer Public would not tolerate business standards

2. Former Proposed Standards -- 10^{-6} Conservative Bias
General Rule of the 2nd Best violation , leads closer to 10^{-12}

3. Industries -- (a) The above problem cured with Monte Carlo methods ***BUT***,
(b) Method were never the problem, rather, it is the assumptions
As a former public servant in the field of environmental remediation ,
RAs rarely found a serious problem. When
assumptions considered, many reports would be laughable if not so serious.
Regardless of method, bad data in, bad data out. Statistics analogies.
(c) Class A carcinogen studies based on human epidemiology, not just animal studies.
(d) Cumulative and synergistic effects not investigated and remain unknown for mixed contamination, e.g., asbestos & tobacco, also effects of regulated substances mixed with unregulated substances, anthropogenic or natural sources.
(e) Most serious, Risk assessment a layered or staged process.
Reduced confidence levels also being discussed, leading to less certainty.
First reduce risk level, then reduce confidence level, and so forth until step-by-step, public protection process has been dismantled.

4. Committee -- Public notice inadequate and unacceptable for this exercise.
A press release was issued, but no legal notice, not in Register, OLS list sent to a narrow list, but public was not informed. This challenges the legitimacy of these procedures.
The actions of this committee are critically important to the general public
In the future, when discussion again rises, "we agreed to this 5 years ago in a process that included public comment." Not so.
At that time will we be able to re-open the discussion.
Challenge for a commitment.
We should not allow either political or economic pressures force a decision that is not in the public interest.

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5. Observations -- Despite pressure to produce a workable result, it is better to make no decision than to make the wrong decision.
EPA is developing guidance independently to use in the interim.
Entire RA process represents a Gestalt--the whole is greater than the sums.
All sides argue in the extremes. Public is tired of both sides. NJ wants both a healthy economy and environment, and this is not impossible to achieve.

It is not necessary to remediate in every instance of contamination.
1. the days of shipping waste to Ohio are mostly over.
2. some substances break down and go away by themselves, money wasted.
3. exposure elimination has to be part of the solution.
4. Neither can we regulate away waste by simply defining it not a problem.
5. Department--and it is a good Department--has a share of the responsibility to provide responsible oversight.
6. Environmentalist--you are unreasonable
7. Industry--you are unreliable
8. Bridge of communication and trust must be developed.

6. Recommendations -- (a) Proceed case by case until a rational and balanced policy can be developed that examines the entire RA process and cleanup criteria.
(b) Formulate long-term environmental task force comprised of representatives of the regulated community and environmental groups as well as moderators to search out common ground.
(c) Do not let your investment in your expertise lead you to make decisions or offer testimony that expands beyond the borders of your wisdom or abilities.
(d) Make no decision before its time.

When Is a Life Too Costly To Save? The Evidence from Environmental Regulations

George L. Van Houtven and Maureen L. Cropper

Some environmental statutes require the U.S. Environmental Protection Agency (EPA) to balance benefits and costs when issuing regulations, while other statutes prohibit such balancing. But do these requirements or prohibitions make a big difference in the regulations that are written? According to a recent study conducted at Resources for the Future, the answer is "no." The study reveals that both benefits and costs appear to have influenced the regulations issued by EPA, regardless of the statutory mandate under which the agency was operating. The study also suggests that the value that EPA implicitly attaches to the prevention of one case of cancer is very high—from $15 million to $45 million. This is much more than individuals appear to be willing to spend to reduce their own risks of death.

Under the various environmental statutes the U.S. Environmental Protection Agency (EPA) administers, the agency is responsible for issuing regulations to protect the public from exposure to pollution. These regulations can include outright bans of certain products—for instance, pesticides and products containing asbestos. They more commonly include limitations on the amount of pollution a factory or vehicle can emit.

Most economists would argue that these regulations should be made, at least in part, on the basis of benefit-cost analyses. That is, they believe that an environmental standard should be set just at that point where the marginal cost of setting a slightly more stringent standard would begin to outweigh the marginal benefit of increased stringency. Congress, however, sometimes limits EPA's ability to engage in such balancing when the agency issues regulations.

For example, under the provisions of the Clean Air Act that pertain to the establishment of maximum permissible air pollution concentrations, EPA cannot take costs into account. When establishing effluent standards under the Clean Water Act, the agency is allowed to consider costs but not benefits. Only two environmental statutes—the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA)—actually require that EPA balance the benefits and costs of regulation in setting environmental standards.

Recently, we conducted an after-the-fact analysis of regulatory decisions that EPA has made over the last two decades. Our purpose was to see whether EPA *appears* to have balanced costs and benefits in issuing its regulations, regardless of whether the law under which the agency is operating directs or prohibits this balancing. In our study, "balancing" is determined by the following question: If we look back at a class of regulations EPA has put in place—for example, emissions standards for toxic air pollutants—do variations in the costs and benefits of all the regulatory options the agency considered at the time help explain the standards selected? If the answer is "yes," we argue that balancing has taken place.

We conclude that EPA *has* acted as if both costs and benefits influence its selection of regulatory standards; specifically, other factors being equal, a more costly standard is less likely to have been selected than a less costly one, and a standard that saves a greater number of lives is more likely to have been selected than one that saves a smaller number of lives.

Intuitively, however, balancing requires more than just paying some attention to costs and benefits. It also requires that the cost EPA is willing to impose on society to save an additional life be regarded as "reasonable." One way to determine what EPA considers reasonable is to see if there is some threshold value for the cost-per-life-saved above which the agency has been reluctant to issue regulations. (For lack of a better term, we call this threshold value the "value of a life" implied by the regulations.) For each class of regulations that we examined, we calculated the value of a life that was implicit in the regulations.

We conclude that EPA has acted as if both costs and benefits influence its selection of regulatory standards.

We were especially interested in two issues. The first and most important of these is how the value of a life implicit in environmental regulations compares with society's apparent willingness to pay to save lives: Is this value acceptable to American society? The second issue concerns the way in which the implicit value of a life seems to vary across EPA programs and across population groups: for instance, do environmental regulations pertaining to pesticides place a higher value on a life saved than regula-

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tions pertaining to hazardous air pollutants? Also, does EPA implicitly attach more weight to saving the life of a worker exposed to pesticides or asbestos on the job than to the life of a consumer exposed to these pollutants?

To answer these questions, we gathered data on EPA-estimated costs and benefits associated with three categories of pollutants that EPA regulates:

1. asbestos, sources of which are regulated under the Toxic Substances Control Act;

2. all cancer-causing pesticides used on food crops that underwent EPA's Special Review process between 1975 and 1989; and

3. all carcinogenic air pollutants for which EPA set National Emissions Standards for Hazardous Air Pollutants between 1975 and 1990.

When we gathered data for each source of these pollutants (each crop in the case of pesticides), we arrived at a total of 39 asbestos regulations, 245 pesticide regulations, and 40 regulations pertaining to four hazardous air pollutants—benzene, inorganic arsenic, radionuclides, and vinyl chloride.

We limited our study to the regulation of carcinogens because quantitative risk data—that is, estimates of the number of lives at risk as a result of exposure to a particular pollutant or product—are available more often for carcinogens than for other substances. The availability of such data for carcinogens implies that the number of lives saved by each of the regulations we examined can be quantified. We also purposely selected some regulations issued under the two statutes (TSCA and FIFRA) that require EPA to balance costs and benefits, as well as those regulations that set emissions standards for hazardous air pollutants under the Clean Air Act, which prohibits such balancing. We included these regulations in our study in order to determine whether the directives given EPA in the enabling legislation made any difference in the way in which the agency appeared to weigh benefits and costs.

It is important to be clear about one thing. We were not privy to EPA's decision-making process for any of the regulations discussed here. What we have done is to look back at the information on benefits and costs that the agency had when it formulated the regulations, to examine the pattern of regulatory decisions, and then—using statistical analysis—to ascertain whether these decisions were consistent with the hypothesis that benefits and costs influence the regulatory outcome, regardless of the statutory mandate.

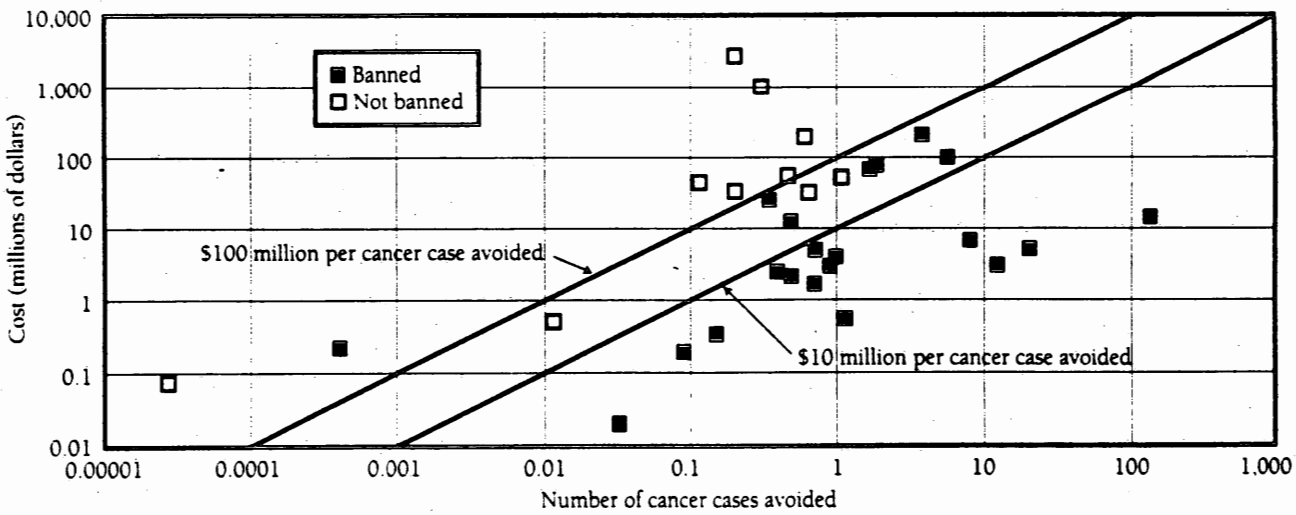
We turn now to a discussion of the specific regulations.

Asbestos regulations under TSCA

In 1985 EPA announced its intent, under the authority of the Toxic Substances Control Act, to ban the use of asbestos in 39 products. Because TSCA requires EPA to balance benefits and costs, the agency's Notice of Intent to Regulate was followed by a detailed assessment of the health risks associated with exposure to asbestos fibers, as well as the costs that would result from the proposed bans.

Well-documented epidemiological evidence indicates that some forms of

Cost-effectiveness of asbestos ban



Note: Each of the 31 squares represents a decision by EPA to ban or not to ban the use of asbestos in one particular product. The lower diagonal line illustrates the rule "ban only those products for which the cost-per-life-saved is less than $10 million." The higher diagonal line illustrates the rule "ban only those products for which the cost-per-life-saved is less than $100 million."

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asbestos are human carcinogens. This evidence is particularly strong for lung cancer, gastrointestinal cancer, and mesothelioma, a cancer of the lung or abdominal lining. Estimating the number of cancer cases associated with a particular asbestos-containing product (for example, brakes lined with asbestos) requires estimates of the potency of asbestos—that is, of the likelihood that an individual will develop cancer as a function of exposure—as well as of the number of people who are exposed to various levels of asbestos.

In the analysis accompanying its final rule, EPA presented estimates of consumers' and various groups of workers' exposure to each product to be regulated, as well as an estimate of the number of cancer cases then-currently associated with each of these sources of asbestos. It also calculated the number of cancer cases that would be avoided if each product were banned. EPA was able to estimate this number, as well as the cost of the ban, for 31 of the 39 products considered for regulation.

EPA's asbestos regulations imply that the value of a cancer case avoided is $49 million; this value seems high considering that the value of life implicit in workers' occupational choices is about $5 million.

A plotting of the regulatory costs and the number of cancer cases avoided for each of the 31 products for which complete data are available (see figure, p. 7) is consistent with the hypothesis that EPA considered benefits and costs in issuing its asbestos decision. Products for which the cost of the ban was low and the number of lives saved was high (tending toward the lower right-hand corner of figure) were almost always banned, while products for which the cost of the ban was high and the number of lives saved was low (tending toward the upper left-hand corner of figure) were for the most part not banned.

Since avoiding cancer cases is the only benefit of the asbestos ban mentioned by EPA (ecological risks, for example, not being mentioned), it is tempting to infer from the plot that there is a threshold value for a cancer case avoided below which all products were banned. For instance, the rule "ban only those products for which the cost-per-life-saved is less than $10 million" (a rule illustrated by the lower of the two diagonal lines in the figure) would explain many of the bans, but it would yield incorrect predictions for some products. Similarly, the rule "do not ban any product for which the cost-per-life-saved is greater than $100 million" (a rule illustrated by the higher of the two diagonal lines in the figure) would be correct almost all the time, but it would yield incorrect predictions for some asbestos-containing products.

To compute the threshold value of a cancer case avoided that is implied by the asbestos regulations, we estimated statistically the line that maximized the number of regulations correctly predicted by the above-noted rule. We found that the implied threshold value of a cancer case avoided is $49 million (measured in 1989 dollars). (This value would have fallen between the two diagonal lines in the figure.) This value seems high—especially in contrast to estimates of the value of life that are based on individuals' willingness to pay for risk reductions.

Consider, for example, the added compensation that workers require to accept jobs that pose increasingly greater health risks, compensation that provides useful information about individuals' risk-reward trade-offs. Based on dozens of studies, the value of life that seems to be implicit in workers' occupational choices is about $5 million, an amount much lower than the value of life implicit in EPA's regulation of asbestos. While labor market compensation is for risks that are voluntarily borne, it is hard to imagine that the additional premium associated with involuntary risks is $44 million. Not coincidentally, perhaps, EPA's failure to give sufficient weight to the costs of regulation in issuing its asbestos bans was cited by the Fifth Circuit Court of Appeals in the *Corrosion Proof Fittings* case, which overturned the ban.

Pesticide regulations under FIFRA

Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA is responsible for ensuring that all pesticides used in the United States have no unreasonable adverse effects on the environment. If EPA suspects that a pesticide poses risks to human health or to ecosystems, the pesticide—or, more accurately, the active ingredients used in the pesticide—is subject to what is known as a Special Review.

A Special Review entails a formal risk-benefit analysis of the pesticide, after which EPA can either ban the pesticide for use on specific crops, restrict the manner in which the pesticide is applied, or allow its continued use without modification. Between 1975, when EPA initiated its first Special Review, and December 1989, Special Reviews of 37 active ingredients were completed. We restricted our analysis to those active ingredients that are suspected human carcinogens.

In considering whether or not to ban a pesticide, EPA examines risks of cancer to consumers of food containing pesticide residues and to persons exposed to the pesticide in the workplace—these are the people who mix the pesticides (mixers) and load them into the dispensing equipment (loaders), as well as those who apply the pesticides (applicators). The agency also examines noncancer health risks, such

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as risks of miscarriages or of fetal damage. In addition, it considers the adverse effects of the exposure of fish, birds, and mammals to pesticides.

The implicit value of a cancer case avoided among pesticide applicators was $52 million. Risks to mixers and loaders of pesticides and to consumers seemed not to influence EPA's decisions to ban uses of active pesticide ingredients.

Against these risks, EPA balances the benefits of pesticide use—that is, the gains to both farmers and consumers as a result of the increase in agricultural output brought about by pest control. Depending on the relative weight given to these and other factors, EPA might decide that a particular ingredient can no longer be used on a particular crop.

It is tempting to plot the cost of bans against the number of cancer cases avoided for pesticide regulations, as we did for asbestos regulations; however, the resulting diagram would be misleading. Because the avoidance of cancer cases is only one of the benefits of banning a particular use of a pesticide, our inferred threshold value of a cancer case avoided would overstate the value that EPA implicitly attaches to reducing cancer risks. Instead, we estimated a statistical model designed to predict EPA's decisions to cancel (or not cancel) the use of each of the active ingredients in pesticides on each of the food crops for which the ingredients were registered.

Our model, which correctly predicted 87 percent of the 245 decisions EPA made between 1975 and 1989, suggests that EPA considered both the risks and benefits of pesticide use in issuing its pesticide regulations. The benefits of pesticide use were statistically significant and of the expected sign: the higher the benefits of pesticide use, the less likely it was that a pesticide was banned for use on a particular crop. The risks associated with the pesticide were also important in explaining which uses of a pesticide were banned and which were not. Other factors being equal, the higher the risks of cancer to applicators (the group with the highest average exposure to pesticides), the greater the probability that a pesticide was banned. The implicit value of a cancer case avoided among applicators was about $52 million (1989 dollars)—a value remarkably close to the value we found to be implicit in asbestos regulations.

Our analysis was quite surprising in one respect: neither risks to mixers or loaders of pesticides nor dietary risks to consumers seemed to influence EPA's decisions to ban uses of active ingredients in pesticides. One possible explanation for this is that risks to both mixers and loaders and to consumers are lower than risks to applicators, and therefore seen to be a less pressing problem. The median lifetime cancer risk associated with exposures to the pesticide ingredients we examined was 1 in 1,000 for applicators but only 1 in 100 million for consumers of food with pesticide residues.

National emissions standards for hazardous air pollutants

In contrast to regulations issued under TSCA and FIFRA, the National Emissions Standards for Hazardous Air Pollutants were, according to the Clean Air Act of 1970, to be set to protect human health without consideration of costs. As we shall see, however, during the mid-1980s EPA did attempt to consider costs in setting emissions standards for sources of hazardous air pollution. In 1987, the Natural Resources Defense Council successfully sued the agency for making costs a factor in the determination of those standards. As discussed below, the ruling in that case had a pronounced effect on EPA's subsequent setting of standards for air pollution.

Section 112 of the Clean Air Act requires EPA to regulate the so-called toxic air pollutants, substances such as benzene, arsenic, asbestos, and mercury. These pollutants are not as ubiquitous as particulates, sulfur oxides, carbon monoxide, and other pollutants for which EPA is to set ambient air quality standards, but they are nonetheless harmful to human health. According to the Clean Air Act, EPA was required to establish a list of toxic air pollutants and then to set emissions limits for various sources of each pollutant. Between 1970 and 1990, only seven such substances were regulated. Five of these air pollutants are carcinogens, but quantitative risk data are available for only four—vinyl chloride, benzene, inorganic arsenic, and radionuclides. We examined the regulation of these substances.

After 1987, EPA always elected to regulate the source of a hazardous air pollutant if it posed a greater than 1 in 10,000 cancer risk to the maximally exposed individual. If this risk was less than 1 in 10,000, however, then the threshold value of a life saved was the same before and after 1987: $15 million.

In seeking to regulate the various sources of these four pollutants, EPA considered at least one regulatory option that would reduce emissions of each pollutant, as well as the option of no regulation. For each option, it computed cost, the number of associated cancer cases, and the post-regulation risk to the "maximally exposed individual," the individual who receives the

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greatest dose of a pollutant from a particular source. For most sources of hazardous air pollution, this individual is not exposed to the pollutant in the workplace, but rather lives near the source of the pollutant (for example, the person whose house is nearest to a copper or lead smelter).

To examine the possible trade-off between benefits and costs in the regulation of hazardous air pollution, we estimated a statistical model to explain which regulatory option was chosen for each of the 40 sources of vinyl chloride, benzene, inorganic arsenic, and radionuclides. Our results suggest that EPA's regulatory choices were consistent with the hypothesis that the agency was balancing the cancer risk reductions due to more stringent regulation against the costs this regulation would entail. In technical parlance, when we used all 40 sources of the four air toxics in our study to estimate our model, the coefficients of both the reduced cancer incidence and the regulatory cost were significant. The implicit value of a cancer case avoided—that is, the value that best enabled us to predict EPA's regulatory decisions—was very high—$153 million, to be exact.

These results look somewhat different, however, if we distinguish regulations issued before 1987 from those issued after 1987, when the U.S. Court of Appeals for the District of Columbia ruled that EPA had improperly considered costs in setting emissions standards for toxic air pollutants. In the so-called *Vinyl Chloride* decision, EPA was directed to consider the costs as well as the technological feasibility of regulatory options only after an "acceptable risk" level had been achieved.

When we modified our analysis to take this decision into account, our results came out quite differently: they implied that a cancer case avoided was valued at approximately $15 million before the 1987 court ruling and at the same amount after that ruling, so long as maximum individual risk was less than 1 in 10,000. After 1987, however, EPA always elected to regulate the source of a hazardous air pollutant if it posed a greater than 1 in 10,000 cancer risk to the maximally exposed individual; in other words, the threshold value of a life was infinite. If this risk was less than 1 in 10,000, however, then the threshold value was the same for the post-1987 regulations as for the pre-1987 regulations: $15 million (1989 dollars).

Surprises and questions

One of the striking findings of our analysis is that, in issuing the asbestos, pesticide, and toxic air pollutant regulations we examined, EPA has been willing to impose substantial costs on consumers and firms in order to save a life. Under each of the two statutes that allow the balancing of benefits and costs, the agency's implicit valuation of a cancer case avoided was in excess of $45 million. Whether members of society would agree with this valuation, which is about ten times greater than individuals implicitly value the risk of death due to occupational hazards, is an important question.

Our findings suggest that EPA has, in the past, put in place more stringent regulations under statutes that require *it to balance benefits and costs than it does under a statute that directs it to ignore costs and consider health risks only.*

Nevertheless, compensation for risks faced in the workplace is generally for voluntary exposure to immediate risk of death. Exposure to asbestos and pesticides may not be voluntary (even for workers) if people are unaware of the risks they face; this fact may account for the very high implicit value assigned to risk reductions in EPA regulations pertaining to these substances.

It is interesting to note that the value per cancer case avoided that is implicit in regulations pertaining to hazardous air pollutants was about one-third the value implicit in pesticide or asbestos regulations. In a sense, this is quite surprising. Our findings suggest that EPA has, in the past, put in place more stringent regulations under statutes that require it to balance benefits and costs than it does under a statute that directs it to ignore costs and consider health risks only. This does *not* "prove" that EPA balanced costs and benefits under the Clean Air Act, only that it made decisions that were consistent with the hypothesis that the agency behaved this way.

This in turn raises the question of whether statutes that prohibit consideration of costs in standard setting really make a difference in the regulations that are issued. Our analysis of the setting of the National Emission Standards for Hazardous Air Pollutants suggests that, short of recourse to the courts, prohibitions against consideration of costs may be difficult to enforce. Likewise, Congress may require that the costs of a regulation be balanced against its benefits; but as long as EPA has discretion in the weights it assigns to costs and benefits, the regulations it issues under statutes that allow balancing of benefits and costs may still be very costly.

George L. Van Houtven is a member of the Department of Economics at East Carolina University. Maureen L. Cropper, a senior fellow in the Center for Risk Management at Resources for the Future and a professor of economics at the University of Maryland, is currently on leave as a principal economist at the World Bank. *A detailed discussion of the issues in this article can be found in discussion paper CRM93-02, "When Is a Life Too Costly to Save? The Evidence from Environmental Regulations," by Van Houtven and Cropper.*

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AMERICAN
INDUSTRIAL
HEALTH
COUNCIL

AIHC

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April 11, 1994

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

Dear Dr. Gallo:

The American Industrial Health Council (AIHC) appreciates the opportunity to submit comments to the Environmental Risk Assessment and Risk Management Study Commission (the Commission) as established under the New Jersey Industrial Site Recovery Act (ISRA) on the scientific basis for the use of 10^{-6} as a management standard for site remediation. AIHC applauds and fully supports the state of New Jersey for its efforts in establishing the Commission. Further, AIHC commends the Commission for soliciting and evaluating information and opinions from the scientific community and general public on this issue.

As a policy position, AIHC does not support the use of bright-line risk standards because AIHC believes that such standards do not permit sufficient flexibility to address various issues (e.g., land use) encountered by a regulatory agency. The attached AIHC comments, therefore, discuss the need for the use of a range of risk (10^{-4} to 10^{-6}) applied on a site/situation specific basis, as exemplified by other risk-based regulations and programs. The AIHC comments also provides the rationale why the 10^{-6} risk level, specifically, is inappropriate for a risk management standard for site remediation.

The mission of AIHC is to promote the use of sound scientific principles and procedures in the assessment and regulation of risks of chronic human health effects and directly related public policy issues. AIHC addresses only the generic science or science policy issues that serve as the foundation for major human health and regulatory policies. AIHC does not act as an advocate for any product or substance although its generic positions directly affect the scope and impact of individual regulatory decisions.

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The Council's membership is a diverse coalition of companies and trade organizations, including producers of consumer products, chemicals, foods and beverages, high technology, pharmaceuticals, petroleum products, paper products, motor vehicles, aerospace and metals.

The AIHC would be happy to work with New Jersey to design a risk management policy consistent with the use of sound scientific principles.

Sincerely,

A. Guiseppi-Elie, Ph. D.
Chair, Environmental Health Risk
Assessment Subcommittee

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Comments of the American Industrial Health Council

To

New Jersey's

Environmental Risk Assessment and Risk Management Study Commission

On The Scientific Basis for Using The Risk Level of 10^{-6}

As a Risk Management Standard for Site Remediation Purposes

April 8, 1994

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Comments of the American Industrial Health Council

on the Scientific Basis for Use of 10^{-6}

as a Risk Management Standard for Site Remediation

Introduction

The American Industrial Health Council (AIHC) appreciates the opportunity to submit comments to the Environmental Risk Assessment and Risk Management Study Commission (the Commission) as established under New Jersey's Industrial Site Recovery Act (ISRA) on the scientific basis for the use of 10^{-6} as a risk management standard for site remediation.

AIHC would like to express its support to the Commission, and applauds the State of New Jersey, for its efforts in soliciting and evaluating information and opinions from the scientific community and the general public on this issue. AIHC believes that open discussion and review of issues such as this by the general public and scientific community will yield improved public policy decisions.

AIHC has a significant interest in the discussion, evaluation, and selection of an appropriate risk management standard for site remediation. AIHC recognizes that the New Jersey Department of Environmental Protection and Energy (NJDEPE) has been in the forefront of environmental policy development and that efforts by the Commission to discuss, evaluate and recommend an appropriate risk management standard for site remediation may be precedent setting in the development of health-based cleanup criteria both in New Jersey and around the country. AIHC believes that ISRA, the Commission and the report of the Commission's findings and recommendations may potentially serve as a model for discussion, review and establishment of risk management standards by other states and localities.

AIHC is concerned that bright-line risk standards do not permit sufficient flexibility to address the various issues likely to be encountered by a regulatory agency. Consistent with past and present federal regulatory decisions, AIHC believes that utilization of an appropriate range of acceptable risks produces an improved framework for regulatory activities. The Environmental Protection Agency (EPA) has codified the risk range of 10^{-4} to 10^{-6} for site remediation under its Superfund program. As discussed in the comments which follow, AIHC believes this risk range is appropriate for site remediation activities. Consistent with EPA guidance, AIHC further believes that 10^{-4} should serve as the preliminary site remediation risk standard and that selection of a lower risk level should require specific justification based on site-specific conditions, such as the size of the affected

population, technical feasibility and other pertinent factors. To ensure consistent program implementation, specific guidelines would need to be developed.

The mission of AIHC is to promote the use of sound scientific principles and procedures in the assessment and regulation of risks of chronic human health effects and directly related public policy issues. AIHC addresses only the generic science or science policy issues that serve as the foundation for major chronic human health and regulatory policies. AIHC does not act as an advocate for any product or substance although its generic positions directly affect the scope and impact of individual regulatory decisions.

The Council's membership is a diverse coalition of companies and trade associations, including producers of consumer products, chemicals, foods and beverages, high technology, pharmaceuticals, petroleum products, paper products, motor vehicles, aerospace and metals. Many of the Council's members have facilities and operations in New Jersey.

Summary of Comments

As an initial matter, AIHC supports the Commission's efforts and appreciates the opportunity to submit comments on the scientific basis for selecting an appropriate risk management standard for site remediation. AIHC believes that open discussion and review of this issue by the general public and scientific community will yield improved public policy decisions regarding site remediation.

AIHC believes a bright-line 10^{-6} risk standard is inappropriate for site remediation and that a range of acceptable risks is needed to permit sufficient flexibility to address the various issues likely to be encountered by the NJDEPE. AIHC's major comments are as follows:

1) *Historically, the Food and Drug Administration (FDA) first developed and used a risk level of 10^{-6} as a de minimis screening level for exposure of large populations to carcinogenic drug residues in meat products. The intent was to define an "essentially zero" level of risk for purposes of compliance with the Delaney Clause. FDA specifically indicated that 10^{-6} should not be interpreted as the maximum level of acceptable risk.*

2) *Consistent with FDA's approach and intent, several federal agencies have adopted and consistently used individual upper-bound lifetime cancer risk levels in the range of 10^{-4} to 10^{-6} as de minimis risk levels for a variety of programs.*

3) *Remediation standards have been codified for Superfund sites by the Environmental Protection Agency (EPA) under its National Contingency Plan. The Agency specified a range of acceptable risks, i.e., 10^{-4} to 10^{-6} and, in subsequent guidance, EPA reaffirmed its decision to use this range. The National Council on Radiation Protection and Measurements (NCRP) has adopted remedial action levels for naturally occurring radiation based on analysis of risks to background radiation and potential societal costs of remediation. The adopted risk levels exceed 10^{-4}.*

4) *Apart from selection of risk levels, it is important to note that current environmental site risk assessment methodology greatly exaggerates risks to potentially exposed populations, often by several orders of magnitude.*

5) *Bright-line risk standards do not permit sufficient flexibility to address the various issues likely to be encountered by regulatory agencies. The adoption of a bright-line site remediation standard of 10^{-6} would not likely permit sufficient flexibility to address (1) compliance and implementation issues, (2) risks associated with site-remediation activities, and (3) balancing costs and benefits of various remedial projects or options.*

Specific Comments

1. ***Originally, 10^{-6} was developed and used by FDA as a risk screening level.***

Originally, a risk level of 10^{-6} was selected by the U.S. Food and Drug Administration (FDA) as a screening level for determining the safety of carcinogenic residues in meat products to which the entire U.S. population could be potentially exposed. It was not intended to be used as a compliance level. Moreover, the risk level of 10^{-6} was not subjected to extensive scientific or public review and comment.

In a rather extensive review on the subject, Kelly and Cardon (1991) present the historical development of a 10^{-6} risk level as the basis for regulatory action. According to these authors, the risk level of 10^{-6} was originally an "arbitrary number, finalized by the U.S. Food and Drug Administration 14 years ago as a screening level of "essentially zero" or de minimis risk.

A de minimis level requiring no further action was first presented in 1973 by the USFDA in its proposed rule 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". (July 19, 1973 Federal Register 19226-19230). Guidelines were proposed for assay methods involving carcinogenic animal drugs "which may be administered to food-producing animals, but for which no residue is permitted in human food" according to the 1958 Delaney Clause. The use of diethylstillbestrol (DES) as a growth promoter in cattle prompted the proposed rule.

The USFDA proposal refers to an earlier article by Mantel and Bryan regarding safety testing in animal studies. To define the parameters of safety testing, Mantel and Bryan indicated in their article that a definition of what was or was not safe was needed. Although defining "safe" as a scientific or public policy issue was not the focus of their efforts, they assumed for discussion purposes that "safe" was equal to a risk of 1 chance in 100,000,000 of developing cancer.

The risk level of 1 in 100,000,000 originally presented in the 1973 USFDA proposed rule was changed to 1 in 1,000,000 when the rule was finalized in 1977. A risk of 1 in 1,000,000 was thereby established as the "maximum lifetime risk that is essentially zero" or the level below which no further

regulatory consideration would be required regarding the safety of carcinogenic animal drug residues. The regulations specifically indicate that the "essentially zero" risk level was not to be interpreted as the maximum acceptable level of risk, i.e., the level of 1 in 1,000,000 was only intended as (1) a basis to establish levels of carcinogenic animal drug residues in meats below which no further regulatory consideration was warranted, and (2) a definition of zero risk for compliance with the Delaney Clause. Quite importantly, Kelly and Cardon (1991) point out in their article that "only 2 comments were received on the proposed rule, 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."

It is important to appreciate that the de minimis risk level of 10^{-6} developed by the USFDA for carcinogenic drug residues in meat products applied to foodstuffs which would be consumed by a large portion of the U.S. population of over 200 million. Thus, the 10^{-6} risk level was intended as a screening level for very large exposed populations.

From this review of the historical development of 10^{-6} risk level for use in regulatory programs, the following are evident: (1) the 10^{-6} risk level was originally developed by the USFDA as a screening level and was never intended to be a compliance level; (2) the 10^{-6} risk level was deemed an acceptable level of risk for screening purposes involving carcinogenic drug residues in meat products to which very large populations - potentially the entire U.S. population - could be exposed, and (3) there was very little public or scientific review and comment on the selection of 10^{-6} as an appropriate risk level.

2. ***Individual upper-bound lifetime cancer risk levels in the range of 10^{-4} to 10^{-6} are accepted as de minimis risk levels for a variety of federal programs.***

In reviewing 132 federal regulatory decisions from the late 1970's through the mid-1980's, Travis et al, (1987) found remarkable consistency in risk management decisions based on individual and population risk levels among various federal agencies, most notably the Environmental Protection Agency (EPA), Food and Drug Administration (FDA) and Occupational Safety and Health Administration (OSHA). These investigators found that while every situation involving a chemical yielding an individual upper-bound lifetime cancer risk above 4×10^{-3} triggered a regulation, action was never taken to reduce upper-bound lifetime cancer risks below 1×10^{-6}. Decisions to regulate chemical carcinogens at risk levels between 4×10^{-3} and 1×10^{-6}

were based on the size of the exposed population, technical feasibility and associated costs.

Travis et al, (1987) also report that regulatory action was never taken in exposure situations involving small populations if individual upper-bound lifetime risks were below 10^{-4} and in situations involving the entire US population of 250 million people if individual risks were below 10^{-6}. These data indicate that de minimis risk levels consistently used by various federal agencies range from 10^{-4} to 10^{-6} depending on the size of the exposed population.

In declining to regulate natural radionuclide emissions from elemental phosphorus plants with an upper-bound individual lifetime cancer risk of 1×10^{-3}, EPA states, "If risk to the most exposed individuals were the only criterion for judgment, this relatively high risk might well have led to a decision to regulate. However, this risk must be weighted against both the low aggregate risk [0.06 cancer deaths per year] and against other factors" (USEPA, 1983). These other factors included cost and technical feasibility (Travis et al., 1987).

More recent federal regulatory actions are consistent with the findings of Travis et al, (1987). In its final National Contingency Plan for Superfund site remediation (USEPA, 1990), the USEPA specifically designates 10^{-6} as a starting point for discussion of an acceptable target risk at a site or as a "point of departure" and not the ultimate clean-up goal. Indeed, EPA codified a range of acceptable risks, i.e., 10^{-4} to 10^{-6}, as a basis for remediation of Superfund sites. The decision to use a range of acceptable risk levels and not specify 10^{-6} as the ultimate cleanup goal was reaffirmed in subsequent Agency guidance (USEPA, 1991a).

In 1987, the National Council on Radiation Protection and Measurements (NCRP) introduced the concept of a Negligible Individual Risk Level (NIRL). The level was defined as "the level of average annual excess risk of fatal health effects attributable to radiation below which efforts to reduce radiation exposure to the individual is unwarranted" (NCRP, 1993). The NCRP adopted an NIRL of 10^{-7}/yr, which represents the annual fatality risk level that corresponds to an annual effective dose equivalent of 1 millirem (mrem). In 1993, the NCRP revised its risk radiation estimates (NCRP, 1993) yielding an annual risk of fatal cancer to the general public of 5.0×10^{-4}/rem-yr. Under these revised estimates, the 1 mrem recommendation

corresponds to 5.0 × 10^{-7}/mrem-yr and a 70-year lifetime excess cancer fatality risk of 3.5 × 10^{-5} [(5.0 × 10^{-7}/yr) × 70 yrs] (NCRP, 1993).

A particularly significant example of the shift away from the use of a 10^{-6} bright-line is the explicit decision of Congress not to adopt this approach for purposes of the Clean Air Act Amendments of 1990. Section 112(f) of the Act, as amended, 42 U.S.C. §7412(f), contains a provision which specifically references and endorses the basis on which EPA determined acceptable risk and margin of safety in the benzene NESHAPs regulations. As EPA explained, "Under this policy, the agency considers all relevant risk factors, including uncertainty in the risk estimates, with a presumptive risk of approximately one in 10,000 (1×10^{-4}) in making acceptable risk decisions under section 112 (hazardous air pollutants) of the Clean Air Act". (USEPA, 1989a)

3. ***Current site remediation recommendations and standards utilize risk ranges above 10^{-6}.***

Remediation standards have been developed by the USEPA for Superfund sites and as action levels by the NCRP for natural radiation sources. In neither case was a risk level of 10^{-6} selected as the remediation standard.

In its National Contingency Plan, the USEPA codified a range of acceptable risks, i.e. 10^{-4} to 10^{-6}, for Superfund sites. The Agency has reaffirmed its decision in subsequent guidance memos. In addition, in its most recent recommendations on radiation protection, the NCRP has adopted remedial action levels for naturally occurring radiation for members of the general public. Recognizing current radiation protection standards for background radiation and societal costs involved in remediation, the NCRP adopted remediation action levels exceeding 10^{-4} for radon and other natural radiation sources.

The USEPA in its final National Contingency Plan specifically codified a range of acceptable risks for Superfund sites (USEPA, 1990). That range was 10^{-4} to 10^{-6}, although even 10^{-4} could be exceeded in some circumstances. The National Contingency Plan specifically designates 10^{-6} as a starting point for discussion of an acceptable target risk at a site or as a "point of departure" and not the ultimate clean-up goal.

The USEPA reaffirmed its intent to use a range of risk values under Superfund when it forth its general policy on risk and its current focus on 10^{-4} as an acceptable risk standard under typical circumstances:

> *"For sites where the cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}, action generally is not warranted...Records of Decision for remedial actions taken at sites posing risks within the 10^{-4} to 10^{-6} risk range must explain why remedial action is warranted" (USEPA, 1991a).*

In its publication entitled "Limitation of Exposure to Ionizing Radiation" (NCRP, 1993), the NCRP adopted remedial action levels for naturally occurring radiation for members of the general public. In developing its recommendations, the NCRP states, "Remedial action levels involve a balance of risk and many other socio-economic factors....A remedial action level must, therefore, be chosen for which the greatest risks are avoided but the societal impacts are not excessive." (NCRP, 1993). To accomplish this objective, the NCRP chose remedial action levels which represent specific multiples of average exposure levels to the pertinent population in question.

For exposure to natural background radiation <u>excluding</u> radon, the NCRP states,

> *"Since the average exposure to individuals in the United States from natural radiation sources, excluding radon, is approximately 1mSv annually, it is recommended that remedial action be undertaken when continuous exposures from natural sources, excluding radon, are expected to exceed five times the average, or 5 mSv annually".*

Five milliSievert (mSv) is equivalent to 500 mrems. Thus, the remediation action level adopted by the NCRP for continuous exposure of the general public to natural sources of radiation, excluding radon, is equivalent to a lifetime cancer fatality risk level of 1.75×10^{-2} ($[5.0 \times 10^{-4}$/ rem-yr] $\times$ 0.5 rem $\times$ 70 yr).

For radon, a higher risk level was recommended. The NCRP noted that imposition of similar risk estimates for radon as for all other radiation sources "would involve a very large number of homes and great societal cost" and selected "a value ten times the average level found in United States' homes" (NCRP, 1993). The choice by NCRP therefore balanced risk

and feasibility. For radon, the NCRP assumed the annual risk of fatal lung cancer associated with its remedial action level is 4×10^{-4}, which correlates to a risk of 2.8×10^{-2} for a 70-year lifetime.

4. *Current risk assessment methodology greatly exaggerates risks to exposed populations.*

Current environmental site risk assessment methodology generally ignores calculation of population risks. Individual risk estimates are assumed to be representative of population risks. However, assessments of individual risks typically use only upper-bound exposure factors which are not applicable to all members of the potentially exposed population. Therefore, use of individual risk estimates as surrogates for population risks greatly exaggerates risks to potentially exposed populations, often by several orders of magnitude.

An example is the typical exposure scenario used to develop Maximum Contaminant Levels (MCLs) under the Clean Water Act, namely 2 liters of contaminated water ingested daily for 70 years. This exposure scenario is used to ensure that MCLs, which in part reflect technology considerations, are within the acceptable risk range of 10^{-4} to 10^{-6}.

Recently reported scientific studies summarized below demonstrate that this exposure scenario yields an exposure estimate at the 99.9999+ percentile or that only one in one million exposed individuals fits the specified scenario. Therefore, only 1 in 10^6 exposed individuals would be exposed at or above the levels prescribed in EPA's standard drinking water exposure scenario. As such, only one individual in a population of one million people would have an individual cancer risk within the specified range. All other individuals would have <u>lower</u> individual risks, most of which would be considerably lower, even zero.

There are four specific exposure assumptions embedded in EPA's MCL exposure scenario. These are (1) daily water intake, (2 liters/day); (2) percentage of daily water intake from the contaminated source, (100%); (3) exposure frequency, (every day); and (4) exposure duration, (70 years).

(1) Daily Water Intake

Roseberry and Burmaster (1992) recently reported lognormal distributions for water intake by children and adults. Using statistical analyses of water

intake rates for children and adults in different age groups as published by Ershow and Cantor (1989), lognormal distributions for total water and tap water intake were developed. The statistical analyses developed by Ershow and Cantor were derived from water intakes measured and reported by the 1977-1978 Nationwide Food Consumption Survey (NFCS) of the U.S. Department of Agriculture on all foods and beverages consumed during a 3-day period. Roseberry and Burmaster (1992) also fitted the composite NFCS data to the age group distribution defined for the US population by the 1988 U.S. Census. Regression analyses of total water and tap water intake for both the NFCS age-group distributions and the data fitted to 1988 U.S. Census exceed 0.95. For the fitted data, regression analyses for the balanced US population were 1.000 for total water intake and 0.995 for tap water intake. The authors state, "These distributions are suitable for use in public health risk assessment". From this data, the daily tap water intake was 0.957 liters/day at the 50th percentile, 1.411 liters/day at the 75th percentile; and 2 liters/day at approximately the 90th percentile.

In EPA's Exposure Factors Handbook (USEPA, 1989b), the average daily drinking water intake is reported to be 1.4 liters/day, and "a value of 2.0 liters/day is recommended as the reasonable worst-case drinking water consumption rate for adults". Based on the available data, the daily intake value of 2.0 liters/day used in EPA's drinking water exposure scenario appears to represent an approximate 90th percentile value.

(2) Percentage of Daily Water Intake from the Contaminated Source

As for the percentage of contaminated drinking water ingested on a daily basis, EPA states in its Exposure Factors Handbook (USEPA, 1989b),

> *"Based on survey data on time spent at home, the average individual would consume 75% of the total amount of water consumed per day at home and 25 percent would be consumed away from home. For the reasonable worst-case value, it was assumed that the individual would consume 100 percent of the total amount at home".*

In defining "high-end" exposure in its recently published "Guidelines for Exposure Assessment" (USEPA, 1992), the Agency states "The lower part of the high-end exposure range, e.g., conceptually above the 90th percentile but below about the 95th percentile, has generally been the target used by those employing the term 'reasonable worst case exposure'".

Therefore, the value of 100% daily water intake from a residential source would appear to represent a value in the 90-95th percentile range.

(3) Exposure Frequency

As for the number of exposure days/year, the drinking water exposure scenario used by EPA assumes that exposure frequency is 365 days/year. Although no specific guidance is provided in EPA's Exposure Factors Handbook (USEPA, 1989b), EPA states, "It is assumed that an individual is exposed every day at the same consumption rate". However, this exposure frequency assumption discounts overnight travel outside the area of residence for such purposes as vacation, business travel, visiting, etc.

In a recent Office of Solid Waste and Emergency Response (OSWER) Directive (USEPA, 1991b), EPA states,

> *"The exposure frequency (EF) of 365 days/year for the residential setting used in RAGS Part A has been argued both inside and outside of the Agency as being too conservative for RME estimates. National travel data were reviewed to determine if an accurate number of "days spent at home" could be calculated. Unfortunately, conclusions could not be drawn from the available literature; as it presents data on the duration of trips taken for pleasure, but not the frequency of such trips ... However, the Superfund program is committed to moving away from values that represent the "worst possible case". Thus, until better data become available, the common assumption that workers take two weeks of vacation per year can be used to support a value of 15 days per year spent away from home (i.e., 350 days/year spent at home)."*

Given the lack of incorporation of travel outside the area of residence, the exposure frequency of 365 days/year used by EPA in its drinking water exposure scenario represents an upper-bound "worst case" estimate probably in the 90th+ percentile range.

In the recent "Statistical Abstract of the United States 1991" as published by the Bureau of the Census, information is presented on travel patterns for the US populations. Based on a monthly telephone survey of 1500 US adults conducted by the US Travel Data Center, 664.3 million trips of 100 miles or more were taken domestically in 1989 involving one or more household members. Domestic travel in 1989 involved over 1.25 billion

person-trips or an average of 5 trips/person for the approximately 250 million US residents. Business travel averaged 3.2 nights/trip (169.7 million trips), while pleasure travel including visiting friends and relatives, averaged 4.4 nights/trip (457.3 million trips). For travel outside the US, 14.9 million US residents traveled overseas in 1989 excluding travel to Canada or Mexico and excluding cruise travelers, military and government employees and US citizens living abroad. Information on overseas travel was developed by the US Bureau of Economic Analysis. Although these data may be insufficient to appropriately model travel by US residents, they certainly reinforce the perspective that the EPA's exposure frequency assumption of 365 exposure days/year for 70 years represents a "worst possible case".

(4) Exposure Duration

Using a survey of all occupied housing units conducted in 1983 by the Bureau of the Census, EPA developed 50th and 90th percentile values for the number of years a typical person lives in a current residence (USEPA, 1989b). These values were reported as 9 and 30 years, respectively. EPA uses current residence time (time since moving into current residence) as a surrogate for total residence time (time between moving into and out of a residence) for risk assessment purposes. However, as noted by Israeli and Nelson (1992), the frequency distributions and average values for the two differ. Israeli and Nelson (1992) modeled the moving process and developed estimates of <u>total</u> residence time from <u>current</u> residence data. Using 1985 and 1987 U.S. housing survey data published by the Bureau of the Census and the Department of Housing and Urban Development, distributions and averages for both current and total residence time were calculated for several housing categories. In contrast to values presented in EPA's Exposure Factors Handbook (USEPA, 1989b), average and 90th percentile total residence times for all housing units were reported as 1.4 and 12.9 years, respectively. Both values are far less than EPA reported values.

More importantly, Israeli and Nelson (1992) report calculated fractions of the population with total residence times of longer duration. The authors estimate that approximately 0.7% of the population dwells in one residence for 50 years or more. Residence times longer than 50 years were not presented since the upper end of the range in housing surveys conducted by the two US Agencies was 46+ and 48+ years. These data demonstrate that 99.3% of the population will reside in one residence for <u>less</u> than 50

years. Based on these data, very likely over 99.9% of the population would reside in one residence for less than the 70 years prescribed in EPA's drinking water scenario. In other words, the 70-year value EPA uses in its exposure scenario likely represents a percentile value on the total residence time frequency distribution curve of over 99.9%.

The following table presents the standard exposure assumptions used in EPA's drinking water exposure scenario and the estimated percentile for each factor.

Exposure Factor	*EPA Value*	*Estimated Percentile*	*Probability of ≥ Exposure*
Daily Water Intake	*2 liters*	*90*	$< 10^{-1}$
% of Water Intake From Contaminated Source	*100%*	*>90*	$< 10^{-1}$
*Exposure Duration**	*70 years*	*>99.9*	$< 10^{-3}$
Exposure Frequency	*365 days/year*	*>90*	$< 10^{-1}$
Cumulative Estimate		***>99.9999***	$< 10^{-6}$

* *Time in one residence is usually used as a surrogate for exposure duration.*

Assuming that these four variables are independent, the cumulative nature of the assumptions suggest that ***only 1 in 10^6 exposed individuals would be exposed at or above the levels prescribed in EPA's standard drinking water exposure scenario.*** *As such, only one individual in a population of one million people would have an individual cancer risk of 10^{-6}. All other individuals would have lower individual risks, most of which would be considerably lower, even zero.*

Population risk estimates should reflect an accurate assessment of cancer risks to the exposed population. As such, direct application of an individual cancer risk level developed from very conservative upper-bound exposure assumptions is inappropriate and greatly exaggerates risks to the exposed population: an individual upper-bound cancer risk level of 10^{-6} does not translate to a population risk of one excess incidence of cancer in one million exposed individuals. The original FDA rule that adopted 10^{-6} as a screening level recognized this limitation in 1977 and states "This lifetime risk is the maximum, and therefore unlikely human risk level. Because of the series of conservative assumptions built into the modified Mantel-Bryan procedure....the most likely human risk level will be several orders of

magnitude less than this maximum." (47 Federal Register 10412, 10421 (Feb. 25, 1977))

However, even if population risks were only an order of magnitude lower than upper-bound individual risks, the effect is quite dramatic. For example, assuming a risk to the exposed population of one excess cancer in 10^7 individuals and a stable exposed population size of one million people/generation, it would take approximately 10 generations to yield one excess cancer. If population risks were two orders of magnitude below upper-bound individual risks, the result would be approximately one excess cancer in 100 generations. These are certainly very trivial risks. It is also worth noting that, in an unexposed population of 10^7 individuals, an estimated 3,000,000 cancer cases would be expected based on the current US cancer incidence rate of 30% (ACS, 1989). In an exposed population of similar size with a population risk of 10^{-7} from exposure to contaminants at a hazardous waste site, the cancer incidence would be 3,000,001 - essentially unchanged compared to the unexposed population.

5. ***Bright-line risk standards do not permit sufficient flexibility to address the various issues likely to be encountered by regulatory agencies.***

A bright-line risk standard is unlikely to provide the NJDEPE with the necessary flexibility to address program-specific and site-specific issues likely to be encountered, including advances in scientific methodology and remediation technology.

Regarding EPA's selection of a range of acceptable risks, i.e. 10^{-4} to 10^{-6}, for Superfund sites under its National Contingency Plan, an EPA attorney has stated,

> *"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." (Kelly and Cardon, 1991).*

The adoption of a bright-line site remediation standard of 10^{-6} would not likely permit sufficient flexibility to address (1) compliance and

implementation issues, (2) risks associated with site-remediation activities, and (3) balancing costs and benefits of various remedial projects or options.

(1) A bright-line site remediation standard of 10^{-6} could present problems in compliance and implementation.

Insistence on a bright-line site remediation standard of 10^{-6} could result in at least two anomalies: (1) Maximum Contaminant Levels may not meet this standard, and (2) soils remediated to background levels may still present an unacceptable risk.

Under the Safe Drinking Water Act (SDWA), the USEPA develops Maximum Contaminant Levels (MCLs) which are enforceable drinking water regulations. MCLs are often used as "applicable or relevant and appropriate requirements" (ARARs) for site remediation purposes and as such are the compliance standards for groundwater remediation. However, risk levels from which MCLs for carcinogenic constituents are derived can range from 10^{-4} to 10^{-6} depending on technical or analytical considerations. In discussing the US national drinking water regulations, Cotruvo (1988) states, "A target reference risk range of 10^{-4} to 10^{-6} was considered to be safe and protective of public health...". Cotruvo (1988) reports MCLs and associated risk levels for 5 compounds. These are as follows:

Constituent	*MCL (mg/L)*	*Risk Level*
Trichloroethylene	*0.005*	*1.67×10^{-6}*
Carbon Tetrachloride	*0.005*	*1.67×10^{-5}*
1,2-Dichloroethane	*0.005*	*1.25×10^{-5}*
Benzene	*0.005*	*5.00×10^{-6}*
Vinyl Chloride	*0.002*	*1.00×10^{-4}*

In each of these 5 cases, the associated risk level exceeds 10^{-6}. Therefore, use of MCLs as ARARs and a bright-line remediation standard of 10^{-6} may not be compatible.

In addition to potential compliance difficulties with the use of MCLs, remediation of contaminated soils could also pose a problem for compliance with a bright-line 10^{-6} remediation standard as the risks associated with exposure to naturally occurring carcinogenic metals in

soils using standard exposure scenarios, i.e., 100 mg of contaminated soil ingested daily for 70 years, exceed 10^{-6}. The table below illustrates this for arsenic and beryllium.

Metal	10^{-6} Risk-Based Soil Conc. (mg/kg)	Background Soil Conc.* (mg/kg)		
		Geo. Mean	Range	Arith. Mean
Arsenic**	0.40	4.8	<0.1-73	7.4
Beryllium	0.16	0.55	<1-7	0.85

* Background soil values are from the Eastern United States (east of the 96th meridian) (ATSDR, 1990).

** The carcinogenicity slope factor published in IRIS for arsenic is a unit risk value of 5×10^{-6} $(\mu g/L)^{-1}$. As noted previously, the following formula is used to convert unit risk values to carcinogenicity slope factors (USEPA, 1989c): Water unit risk (µg/L) = slope factor × (1/70 kg) × 2 L/day × 10^{-3}. Rearranging this formula yields the following: Slope factor = Water unit risk × 70 kg/(2 L/day × 10^{-3}). For arsenic, this yields a slope factor of 1.75 mg/kg/day and an acceptable soil concentration of 4.0×10^{-1} mg arsenic/kg soil.

These data would suggest that, following excavation of contaminated soils, replacement with "clean" fill containing background levels of carcinogenic metals would result in a risk exceeding the bright-line risk level of 10^{-6}. In short, contaminated soils could not be remediated to comply with a risk-based remediation standard of 10^{-6}.

(2) *The adoption of a bright-line site remediation standard of 10^{-6} could preclude consideration of other relevant, real risks associated with site remediation activities.*

In its latest publication, the NCRP presents fatal accident rates in various US industries as compiled by the National Safety Council (NCRP, 1993). The NCRP uses fatal accident rates as a basis for establishing its radiation protection guidelines for occupational settings. Data reported by NCRP include the following:

Industry	1991 Mean Fatal Accident Rate (10^{-4}/yr)
All Groups	0.90
Transport and Public Utilities	2.20
Construction	3.10
Mines and quarries	4.30
Agriculture (1973-80)	4.40

These data indicate that the mean annual industrial fatality risk based on compiled labor statistics for 1991 is approximately 1 × 10^{-4}. However, for site remediation workers, the risk of fatality is likely to be higher than the mean for all industry groups since remediation activities often involve the use of heavy construction and transport equipment.

In reviewing these data, it is important to note that disabilities and serious injuries are not included. The NCRP states, "Many nominally safe industries have annual fatal accident rates of 10^{-4} or less. However, these industries may have substantial morbidity from nonfatal injuries and work-related diseases". (NCRP, 1993). Therefore, the risk of death, disability or serious injury among all workers is very likely to be much higher than 10^{-4}.

These data are germane to discussion of the appropriate risk level for site remediation. Site risk assessments involve calculation of the risk of excess cancer incidence based on upper-bound or worst-case exposure assumptions and cancer slope factors. Such calculations yield a worst-case statistical estimate of cancer risk to a hypothetical individual. In sharp contrast, industrial fatality rates represent real risks to actual workers based on the latest incidence data collected in the population in question.

Implementation of a 10^{-6} bright-line site remediation standard would potentially subject "real" remediation workers to a risk of fatality or serious injury which may be orders of magnitude higher than the calculated cancer risk to the "hypothetically exposed" individual from exposure to contaminants at a site. In essence, "real" people would be exposed to a relatively high risk of death or disability based on actual accident records in order to protect a hypothetical individual from calculated upper-bound cancer risks that may not even exist.

(3) The adoption of a bright-line site remediation standard of 10^{-6} could preclude balancing costs and benefits of various state environmental programs.

AIHC believes that limitations on public and private financial resources require the evaluation of investments from various regulatory programs addressing public health issues to ensure the maximum benefit to human health and welfare.

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In discussing the impact of current risk assessment methodology on regulatory efforts to control risk, Nichols and Zeckhauser (1988) state, "....apart from creating a tendency toward over-control, biased estimates distort the pattern of regulation. Some low-level risks are regulated too stringently while more severe risks are tolerated. The price we pay for risk reduction is too high, and, if the discrepancies in stringency are great enough, we may even end up with more risk than we would with realistic assessments. Conservatism in risk assessment ....may well lead to a pattern of regulatory decisions that jeopardizes public health and safety".

In developing this theme, several investigators have attempted to quantify the potential number of lives saved for various federal regulatory programs and the associated costs involved (Cohen, 1980; Graham and Vaupel, 1981).

Graham and Vaupel (1981) analyzed 57 programs involving several federal agencies and found wide disparities in the cost effectiveness of the various programs in saving lives. Expressed as the number of lives saved per million dollars invested, the data presented by Graham and Vaupel (1981) are as follows

Agency Proposals	***Number Lives Saved/ Million Dollars Spent***
Consumer Product Safety Commission (CPSC)	*20*
National Highway Traffic Safety Admin. (NHTSA)	*16*
Department of Health and Human Services (DHH)	*10*
Environmental Protection Agency (EPA)	*0.38*
Occupational Safety and Health Admin. (OSHA)	*0.08*

Median costs/life saved for the various proposals in each agency were as follows: CPSC = $50,000; NHTSA = $64,000; DHH = $102,000; EPA = $2,100,000; and OSHA = $12,100,000.

Regarding site remediation programs, current cost estimates are quite staggering. In his recent book entitled "Breaking the Vicious Circle: Toward Effective Risk Regulation", Judge Stephen Breyer states

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> *"Consider such present-system cost estimates as a New York Times survey of experts predicting the total toxic waste cleanup costs will mushroom to $300-700 billion..., a university study suggesting various toxic site cleanup costs of $245-700 billion, a Mitre Corporation estimate of total Superfund cleanup costs of as much as $1 trillion, and a Department of Energy estimate of its (quite separate) nuclear site cleanup costs of $240 billion" (Breyer, 1993).*

These data demonstrate a wide variation in the cost effectiveness of various federal public health programs and the staggering cost estimates associated with federal remediation programs. AIHC anticipates increased public awareness of such information and increased public desire to allocate resources to programs yielding the maximum benefit to human health and the environment. AIHC believes that a bright-line remediation standard of 10^{-6} would not permit sufficient flexibility to balance the costs and associated benefits from the various regulatory programs administered by the NJDEPE. Therefore, AIHC believes that specifying a range of acceptable risks, i.e. 10^{-4} to 10^{-6} could provide, at least in part, the necessary flexibility to address this issue.

Conclusion

AIHC appreciates the opportunity to submit these comments to the Commission on the scientific basis for the use of 10^{-6} as a risk management standard for site remediation. AIHC would like to express its support to the Commission, and applauds the State of New Jersey, for its efforts in soliciting and evaluating information and opinions from the scientific community and the general public on this issue. AIHC believes that open discussion and review of issues such as this by the general public and scientific community will yield improved public policy decisions.

As presented in these comments, AIHC believes that bright-line risk standards do not permit sufficient flexibility to address the various issues likely to be encountered by a regulatory agency. Consistent with past and present federal regulatory decisions, AIHC believes that utilization of an appropriate range of acceptable risks produces an improved framework for regulatory activities. The USEPA has codified the risk range of 10^{-4} to 10^{-6} for site remediation under its Superfund program. AIHC believes this risk range is appropriate for site remediation activities. Consistent with EPA guidance, AIHC further believes that

10^{-4} should serve as the preliminary site remediation risk standard and that selection of a lower risk level should require specific justification based on site-specific conditions, such as the size of the affected population, technical feasibility and other pertinent factors. To ensure consistent program implementation, AIHC believes that specific guidelines would need to be developed.

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April 8, 1994

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

Dear Dr. Gallo:

Please find enclosed 15 copies of ChemRisk's written comments on 1×10^{-6} as an acceptable risk level for carcinogens. ChemRisk has conducted numerous risk assessments on behalf of many industrial clients in the State of New Jersey, and submit these comments to the Committee based on our intimate understanding of several hazardous waste sites in New Jersey. We suggest that there are multiple factors that should be incorporated into the determination of an acceptable risk level for deriving cleanup standards for a specific site, and encourage the Committee to work towards the development of a methodology that would integrate each of these factors. Most importantly, we encourage the Committee to consider the flexibility afforded by a range of risk levels from which to select site-specific risk levels rather than a single risk value as is currently prescribed under ISRA.

We appreciate the opportunity to provide comments on this important matter to the Committee.

Sincerely,

Steve Huntley
Senior Associate Health Scientist

cc: Russell E. Keenan
David Crawford

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TECHNICAL COMMENTS ON 1 X 10^{-6} AS AN ACCEPTABLE RISK LEVEL FOR CARCINOGENS

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prepared for submission to:

THE ENVIROMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

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April 8, 1994

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TECHNICAL COMMENTS ON 1 X 10^{-6} AS AN ACCEPTABLE RISK LEVEL FOR CARCINOGENS

Executive Summary

The Industrial Site Recovery Act (ISRA) prescribes a single cancer risk level of one in one million (1×10^{-6}) for the purpose of deriving site remediation standards. While the 1×10^{-6} risk level was used as a benchmark *de minimis* risk level for making regulatory decisions throughout the 1970s and early 1980s, many recent environmental policy decisions, including the National Contingency Plan and the Safe Drinking Water Act, have encompassed a range of risk levels for making site-specific or situation-specific risk management decisions. Under these regulatory programs, risk levels ranging from 1×10^{-4} to 1×10^{-6} are considered to be protective of human health.

A range of risk levels provides the flexibility for making scientifically based, health-protective risk management decisions, while allowing for the integration of site-specific factors that may have a significant impact on the selection of an acceptable risk for a given site. These key factors include the size and nature of the population at risk, uncertainties associated with the toxicologic database and carcinogen classification, and the comparative costs and benefits associated with the different risk management options under consideration.

ChemRisk suggests that the Committee give careful consideration to establishing a methodology that integrates each of the factors that are critical to evaluating site-specific acceptable risk levels. The most significant of these factors are summarized below.

1. *De minimis* Risk Level: The *de minimis* risk level should not be viewed as a finite value by which the Department would base all regulatory decisions, but rather a point of departure from which the site-specific factors listed below would be applied to define an acceptable risk level for a specific site.

2. Acceptable Range: Consistent with a number of federal regulations, including the NCP, ChemRisk encourages the use of an acceptable risk range of 1×10^{-4} to 1×10^{-6} for the general population.

   Use of the 1×10^{-6} risk level as the point of departure may be appropriate if it is recognized that, when appropriate, other factors such as population size, carcinogenic classification, and the comparative costs associated with different risk

levels would be integrated during further refinement of an acceptable risk level for a given hazardous waste site, as described below.

3. Population Size: While the *de minimis* risk level of 1×10^{-6} described above may be appropriate for large populations of 100,000 or more individuals, for small populations (less than 100,000 individuals), a ten-fold higher risk level is likely to be more appropriate. As such, an acceptable risk level for an exposed population of less than 100,000 individuals may be 1×10^{-5}.

4. Carcinogen Classification: The degree of confidence associated with the different classes of carcinogens indicates that known human carcinogens (Class A) should be given greatest weight when making remedial decisions at hazardous waste sites. However, for those chemicals for which carcinogenicity in humans is not confirmed, application of a lower risk level is not likely to compromise the protection of human health. As such, probable (Class B) carcinogens should be given lessor weight, and possible (Class C) carcinogens given even lessor weight in decision making.

5. Comparative Costs: Following the determination of an acceptable risk level as described above, the comparative costs of remedial action should be evaluated at incremental risk levels both above and below a proposed acceptable risk level. From this comparison, the most appropriate risk level on which to base remediation would be determined; a risk level higher than the "acceptable" risk level, but not higher than 1×10^{-4}, would be justified based on a finding of significant cost savings without increased public health threat. On the other hand, if remedial costs are not significantly greater, a more stringent risk level may be used for determining site remediation or restoration objectives.

In summary, there are a number of critical factors that should be evaluated when selecting the appropriate risk level for hazardous waste site remediation. The most important of these are: (1) population size, (2) carcinogen classification, and (3) comparative costs of remediation. Integration of these factors can be accomplished most effectively through a methodology that is based on a range of acceptable risks, such as 10^{-4} to 10^{-6}. Within this range, a point of departure

can then be identified based on population size (i.e., 10^{-5} or 10^{-6}) from which further refinement can be made according to carcinogen classification and comparative costs. ChemRisk believes that adopting such an approach in the State of New Jersey would facilitate the timely and cost effective remediation of hazardous waste sites to a condition that is protective of human health and the environment.

TECHNICAL COMMENTS ON 1 X 10-6 AS AN ACCEPTABLE RISK LEVEL FOR CARCINOGENS

Introduction

The current New Jersey Department of Environmental Protection and Energy (NJDEPE) guidance as described under the Industrial Site Recovery Act (ISRA) prescribes a single cancer risk benchmark value of one in one million (1×10^{-6}) for the purpose of deriving site remediation standards. As stated in P.L.1993, Chapter 139 (35):

> d. In developing minimum remediation standards intended to be protective of public health and safety, the department shall identify the hazards posed by a contaminant to determine whether exposure to that contaminant can cause an increase in the incidence of an adverse health effect and whether the adverse health effect may occur in humans. The department shall set minimum soil remediation standards for both residential and nonresidential uses that:
>
> (1) for human carcinogens, as categorized by the federal United States Environmental Protection Agency, will result in an additional cancer risk of one in one million.

Historically, the 1×10^{-6} risk level has been a *de facto* risk level, originally used by a number of regulatory agencies in the late 1970s and early 1980s to represent a *de minimis* risk when large populations are exposed (Paustenbach, 1989a). Over the years, the philosophy of applying a single "acceptable risk" value to all situations has evolved towards one that prescribes a range of acceptable risk levels from which the appropriate risk level might be selected for a specific situation. Acceptable risk may be determined on a case-by-case or site-specific basis following an evaluation of such factors as the size and nature of the population at risk, uncertainties associated with the toxicologic database and carcinogen classification, and the comparative costs and benefits associated with the different risk management options under consideration.

Incremental Risks

In the risk assessment and risk management fields, health risks are defined as an estimate of the probability that a given exposure to an agent in a particular environmental setting will result in an adverse health effect (NAS, 1983; Paustenbach, 1989b). Adverse health effects may include death

(mortality), illness (morbidity), or injury to individuals or a population as a whole (Graham, 1990). Historically, regulatory policy has been directed toward identifying and managing risks posed by carcinogens (EPA, 1986). A key justification for concerns over carcinogens likely stems from the fact that approximately one of every three individuals in the United States will be diagnosed with some form of cancer during their lives (i.e., a cancer incidence rate of 33%) (ACS, 1993). While noncancer effects (e.g., reproductive, immunological, etc.) are rapidly being thrust into a new category of heightened regulatory concern, carcinogens remain the highest priority.

An individual cancer risk value is an estimate of the probability that an individual member of a population will develop cancer as a result of a lifetime of exposure to a cancer-causing agent. Considering that the cumulative incidence of cancer in the U.S. population is about 33%, or 330,000 cases of cancer in 1,000,000 people (ACS, 1993), an individual exposed to a chemical over the course of his or her lifetime resulting in an estimated incremental cancer risk level of 1 in 1,000,000 is equivalent to stating that the lifetime total cancer risk for this person is not greater than 330,001 chances in 1,000,000 (33.0001%) rather than 330,000 in 1,000,000. Clearly, the significance of 330,001 in 1,000,000 as compared to 300,000 in 1,000,000 is not in itself compelling.

Population risk, on the other hand, is a measure of the upper-limit estimate of the number of additional incidences of cancer in the exposed population (Travis et al., 1987; EPA, 1992 [Guidelines for Exposure Assessment]). It is expressed as the product of the individual risk estimate and the size of the population that is potentially exposed.

Because risk management decisions involve a balancing of individual risks, population risks, and site-specific considerations (Travis et al., 1987), such decisions and remedies under the Superfund or RCRA programs of EPA are not based on a simple "budget-line" test at an individual risk level of 1×10^{-6}. In fact, these EPA programs allow for cancer risks associated with certain hazardous waste sites as high as 1×10^{-4} (EPA, 1990). As described below, other regulatory initiatives have dealt with the "range-of-risk" approach.

Acceptable Risk Defined Under Existing Regulatory Initiatives

The foundation for risk management decisions is the selection of a cancer risk criterion which is considered to be either acceptable or *de minimis* with respect to the protection of public health and the environment. The term *de minimis* risk is used by risk assessors and regulators to define insignificant risks, or those risks that are not of regulatory concern (Travis et al., 1987). In actuality, a *de minimis* risk should be characterized as one that is judged by society to be of negligible public health concern and too small to justify the expenditure of limited risk management resources (Whipple, 1989). Often times the terms acceptable risk or *de minimus* risk are used interchangeably.

A common misconception within the field of risk assessment is that all occupational and environmental regulations adopt a theoretical maximum cancer risk of 10^{-6} as the *de minimis* or acceptable level of risk. When this criterion is exceeded, the public and the media often view the situation as a serious public threat to public health. In 1987, Dr. Frank Young, then commissioner of the U.S. Food and Drug Administration (FDA), addressed this misconception as it related to setting tolerances for methylene chloride residues in decaffeinated coffee (Young, 1987):

> The risk level of one in one million is often misunderstood by the public and the media. It is not an actual risk; i.e., we do not expect one out of every million people to get cancer if they drink decaffeinated coffee. Rather, it is a mathematical risk based on scientific assumptions used in risk assessment. FDA uses a conservative estimate to ensure that the risk is not understated. We interpret animal test results conservatively and we are extremely careful when we extrapolate risks to humans. When FDA uses the risk level of one in one million, it is confident that the risk to humans is virtually nonexistent.

Implicit within the FDA's use of the 10^{-6} risk level for establishing a "safe level" of methylene chloride in decaffeinated coffee is the intent to protect the very large potentially exposed population of coffee drinkers. In the case of very small populations, such as pesticide applicators, *de minimis* risk levels as low as 10^{-3} for some pesticides have been deemed acceptable (Rodricks et al., 1987). In recent years, most regulatory decisions related to environmental exposure have been based on *de*

minimis risk levels ranging from 10^{-4} to 10^{-6}. On the other hand, the theoretical risks associated with occupational exposure limits are usually in the range of 10^{-2} to 10^{-4} (Paustenbach, 1990).

National Contingency Plan

,Final revisions to the National Contingency Plan (NCP) (EPA, 1990) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) establish a range of 1 x 10^{-4} to 1 x 10^{-6} for acceptable risks at Superfund sites [40 CFR 300.430(e)(2)(i)(A)(2)]. In establishing this risk range, the EPA rejected the argument that a risk range, rather than a single risk criterion, does not adequately protect health and the environment [55 FR 8716-17, March 8, 1990]. The EPA noted that "CERCLA does not require the complete elimination of risk"; rather, remedies comply with CERCLA "when the amount of exposure is reduced so that the risk posed by contaminants is very small, i.e., at an acceptable level. EPA's risk range of 10^{-4} to 10^{-6} represents EPA's opinion on what are generally acceptable levels" [55 FR 8716]. The EPA stated that, after starting at an incremental cancer risk of 10^{-6}, selection of appropriate risks within the range should be based on "consideration of a variety of site-specific or remedy-specific factors" [55 Fed. Reg. 8717]. According to the EPA [55 FR 8717], the appropriate factors include, but are not limited to, exposure factors, uncertainty factors, and technical factors:

> Included under exposure factors are: the cumulative effect of multiple contaminants, the potential for human exposure from other pathways at the site, population sensitivities, potential impacts on environmental receptors, and cross-media impacts of alternatives. Factors related to uncertainty may include: the reliability of alternatives, the weight of scientific evidence concerning exposures and individual and cumulative health effects, and the reliability of exposure data. Technical factors may include: detection/quantification limits for contaminants, technical limitations to remediation, the ability to monitor and control movement of contaminants, and background levels of contaminants.

Resource Conservation and Recovery Act

In proposing regulations to govern corrective action of solid waste management units under the Resource Conservation and Recovery Act (RCRA), the EPA stated that, for carcinogens, media cleanup standards should be established "within the protective risk range of 1 x 10^{-4} to 1 x 10^{-6}, based on site-specific factors" [55 FR 30826, July 27, 1990]. In addition, the Agency proposed

that specific risk levels be set based on carcinogen classification. Following this approach, Class A (known human) and Class B (probable human) carcinogens would be assessed at a 10^{-6} risk level and Class C (possible human) carcinogens at a 10^{-5} risk level [55 FR 30826].

Safe Drinking Water Act

In establishing Maximum Contaminant Levels (MCLs) for drinking water under the Safe Drinking Water Act (SDWA), the EPA utilized the same risk range 10^{-4} to 10^{-6} for carcinogens as promulgated under the NCP and proposed under RCRA. Under SDWA mandates, the EPA set Maximum Contaminant Level Goals (MCLGs) for known or suspected carcinogens at zero on the assumption that there is no known threshold for carcinogenic effects, an assumption that the EPA is open to reconsidering based on new data [56 FR 3533-35, January 30, 1991]. However, recognizing that MCLGs of zero are not attainable, and based on the SDWA directive that MCLs be set as close to the MCLGs as feasible, the EPA has derived MCLs as follows:

> Based on the statutory directive for setting the MCLs, EPA derives the MCLs based on an evaluation of (1) the availability and performance of various technologies for removing the contaminant, and (2) the costs of applying those technologies. Other technology factors that are considered in determining the MCL include the ability of laboratories to measure accurately and consistently the level of the contaminant with available analytical methods. For [carcinogens], the Agency also evaluates the health risks that are associated with various levels of the contaminants, with the goal of ensuring that the maximum risk at the MCL falls within the 10^{-4} to 10^{-6} risk range that the Agency considers protective of public health, therefore achieving the overall purpose of the SDWA [56 FR 3547, Jan. 30, 1991].

The EPA further explained this risk range as follows:

> For drinking water contaminants, EPA sets a maximum reference risk range [of] 10^{-4} to 10^{-6} excess individual risk for carcinogens at lifetime exposure. This policy is consistent with other EPA regulatory programs that generally target this range using conservative models that are not likely to underestimate the risk. Since the underlying goal of the [SDWA] is to protect the public from adverse effects due to

> drinking water contaminants, EPA seeks to ensure that the health risks associated with MCLs for carcinogenic contaminants are not significant [56 FR 3547].

Other Regulatory Initiatives

The EPA has departed from the use of 1 x 10^{-6} as the *de minimis* risk level in numerous other regulatory decisions. As of September 1993, the EPA had approved ambient water quality criteria (AWQC) for dioxin in 52 states, territories, and Indian tribal lands. Of these 52 AWQC approvals, 22 were based on an acceptable risk level of 1 x 10^{-5} (EPA, 1993).

In 1991, the EPA selected the risk level of 10^{-5} (1 in 100,000) when promulating the Hazardous Waste Management System Toxicity Characteristics (TC) Revisions (55 FR 11798-11863). In their justification, the EPA cited the following rationale:

> The chosen risk level of 10^{-5} is at the midpoint of the reference risk range for carcinogens (10^{-6} to 10^{-4}) targeted in setting MCLs. This risk level also lies within the reference risk range (10^{-6} to 10^{-4}) generally used to evaluate CERCLA actions. Furthermore, by setting the risk level at 10^{-5} for TC carcinogens, EPA believes that this is the highest risk level that is likely to be experienced, and most if not all risks will be below this level due to the generally conservative nature of the exposure scenario and the underlying health criteria. For these reasons, the Agency regards a 10^{-5} risk level for Group A, B, and C carcinogens as adequate to delineate, under the Toxicity Characteristics, wastes that clearly pose a hazard when mismanaged.

The Occupational Safety and Health Administration (OSHA) has often used a range of acceptable risk levels for determining whether chemical exposures are significant. For example, the American Public Health Association (APHA) found that exposure to the Threshold Limit Value (TLV) for 8 hrs/day, 40 hrs/wk, for 40 years results in estimated cancer risks greater than 1 x 10^{-3} for at least 12 chemicals including benzene, 1,3-butadiene, methylene chloride, and vinyl chloride (APHA, 1991). As a result of the Supreme Court's ruling in the 1980 benzene case, "OSHA has embraced quantitative risk assessment and used 1 in 1,000 has a threshold of significant risk" (Graham, 1993).

Overview of Regulatory Decisions

In a retrospective review of the use of cancer risk estimates in 132 federal decisions, Travis et al. (1987) examined the cancer risks that triggered regulatory action. The authors considered three risk issues: individual risk, the size of the population exposed, and the population risk. The results of the review showed that for exposures resulting in a small-population risk, regulatory action was never taken for individual risks below 1×10^{-4}, whereas regulatory agencies almost always took action when the cancer risk exceeded approximately 4×10^{-3}. For large-population risks (e.g., the entire U.S. population), agencies typically acted on risks of about 3×10^{-4}, and *de minimis* risk was typically defined as 1×10^{-6}. These decisions demonstrate that the size of a potentially impacted population does have bearing, as it should, on the selection of acceptable risk criteria within regulatory agencies. Based on the findings of Travis et al. (1987), and upon further examination of the database, Graham (1990) has suggested using a range of 1×10^{-4} to 1×10^{-6} for acceptable lifetime cancer risk for the average exposed individual and a less stringent risk range for smaller, more highly exposed sub-populations of the general population.

Rodricks et al. (1987) also evaluated regulatory decisions and reached similar conclusions. In decisions relating to promulgation of National Emission Standards for Hazardous Air Pollutants (NESHAPS), the EPA found that the maximum individual risks and total population risks from a number of radionuclide and benzene sources were too low to be judged significant. Maximum individual risks considered were in the range of 1.0×10^{-3} to 3.6×10^{-5} (Rodricks et al., 1987).

Comparison of Risks

Quantitative cancer risk estimates can be more readily understood when placed in perspective with health risks associated with familiar activities, occupations, or commodities. Most of the risk values cited below are annual risk estimates, reflecting mortality rates during any given year. The examples used in this section are summarized for the purpose of providing a conceptual yardstick for measuring the magnitude of a risk.

Commonplace Risks

Many common human activities entail risks greatly in excess of one in one million (Table 1). For example, although risks are inherent in various modes of transportation, people generally accept those risks. Driving a car not only subjects the driver and passengers to the risk of an accident, but also poses a risk to pedestrians. The total annual risk of dying in a car accident is about 2 in 10,000 (2.4×10^{-4}). The risk to a pedestrian dying in a motor vehicle accident is approximately 4 in 100,000 (4.2×10^{-5}). This equates to a lifetime risk of dying in a motor vehicle accident of approximately 7 in 1,000. An airline passenger that flies an average of four hours per week has an annual risk of 1 in 100,000 (1.0×10^{-5}) (Wilson and Crouch, 1987). An average bicyclist also has an annual risk of dying of 1 in 100,000 (Hutt, 1978; as cited in Rodricks and Taylor, 1983).

In general, accidents occurring in the home pose an annual risk of about 1 in 10,000 (1.1×10^{-4}). This overall risk is comprised of risks from falls, drowning, fires, inhalation and ingestion of objects, firearms, accidental poisoning, and electrocution (Crouch and Wilson, 1982). Living in an average stone or brick building for about 20 months is estimated to increase an individual's risk of cancer caused by natural radioactivity by 1 in 100,000 (1.0×10^{-5}) (Allman, 1985).

Exposures to radiation, either natural background radioactivity or radiation for medical purposes, may increase the chances of cancer. Average diagnostic medical chest x-rays have been reported to increase the risk of cancer by 2 in 100,000 (2.0×10^{-5}) annually. Exposure to natural radiation at sea level (excluding radon) is reported to pose a similar level of risk (2.0×10^{-5}). Exposure to air pollution in the eastern United States has been estimated to pose an even greater risk of 2 in 10,000 (2.0×10^{-4}) annually (Wilson and Crouch, 1987). Furthermore, Gough (1990) estimates that between 2 and 3 percent of all cancers are associated with environmental pollution, while between 3 and 6 percent of all cancers may be attributed to total radiation sources.

Similarly, numerous popular sporting activities pose an increased potential risk of dying due to accidents. Boating, hunting, swimming and football pose an annual risk level of between 3 and 5 in 100,000 (3.0 to 5.0×10^{-5}) (Crouch and Wilson, 1982). Other sports that were not included in Table 1 have even higher levels of risk such as flying amateur aircraft (3 in 1,000), mountaineering (6 in 10,000) and scuba diving (4 in 10,000) (Crouch and Wilson, 1982).

Table 1. Commonplace Risks [a]

Action	Annual Risk
Travel	
Motor vehicle accidents	2.4×10^{-4}
Collisions with pedestrians	4.2×10^{-5}
Frequent airline passenger (4 hrs per week)[b]	1.0×10^{-5}
Bicycling	1.0×10^{-5}
Housing	
Home accidents (all causes)	1.1×10^{-4}
Natural background radiation (sea level)	2.0×10^{-5}
Living in a natural stone or brick building	1.0×10^{-5}
Average diagnostic medical x-rays in U.S.	2.0×10^{-5}
Air pollution	2.4×10^{-4}
Sports	
Boating	5.0×10^{-5}
Hunting	3.0×10^{-5}
Swimming	3.0×10^{-5}
Football [b]	4.0×10^{-5}
Smoking	
Smoking, all effects (1 pack per day)	3.6×10^{-3}
Person sharing room with smoker	1.0×10^{-5}

a. Wilson and Crouch, 1987.
b. Hutt, 1978 as cited in Rodericks and Taylor, 1983.

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Cigarette smoking has been suggested to increase one's annual average risk of cancer and other health effects by more than 1 in 1,000. In addition, chronic exposure to secondary tobacco smoke has been estimated to increase individual's risks of health problems associated with tobacco smoke by 1 in 100,000 or 1.0×10^{-5} (Crouch and Wilson, 1982).

Dietary Risks

Dietary factors, such as alcohol consumption and a high fat diet, have been implicated in many studies as a major contributor to cancer deaths (Ames et al., 1987; Scheuplein, 1990). In addition, people are exposed to risks every day by ingesting natural carcinogens in food (Ames et al., 1987; Scheuplein, 1990). Dr. Robert Scheuplein, Director of the Office of Toxicological Sciences at the FDA, estimated the risk of dying from cancer from dietary exposure to natural and man-made carcinogens is about 7 in 100 (7.7×10^{-2}). Of this, about 98% of the cancer risk in the diet may be attributable to natural carcinogens in food (Scheuplein, 1990). Diet contributes approximately 35% of the total human cancer risk, and smoking, the other major risk factor for cancer, accounts for another 30% (Doll and Peto, 1981).

Ames (1983) estimated that the daily intake of natural carcinogens in traditional food may exceed several grams. Scheuplein (1990) more conservatively assumed that of 1,000 grams of solid food consumed per day, approximately 0.1% or one gram of food per day consists of carcinogens. Table 2 lists intake and risk estimates for various food categories containing carcinogenic substances. This analysis concludes that the risks associated with exposure to natural carcinogens are much greater than those posed by traces of pesticide residues or contaminants (Scheuplein, 1990). Methods of storing, preparing and consuming food, as well as dietary patterns (protein to fat ratios), also contribute to the high cancer risks.

Table 3 lists some of the naturally occurring carcinogens in food. Natural carcinogens in food and those produced during food preparation have been shown to occur in amounts that exceed environmental exposure levels. For example, certain molds in foods synthesize toxins that are mutagenic or carcinogenic; e.g., aflatoxin, is found in nuts (peanut butter), wheat, and corn, and through food chain exposure in cow's milk, (Ames et al., 1987). Furthermore, consumption of as little as 40 tablespoons of peanut butter has been reported to increase the chance of liver cancer caused by aflatoxin by 1 in a million (Covello, 1989).

Table 2. Risk Estimates of Various Food Categories Containing Carcinogenic Substances

Food Category	Amount of Food Consumed	(Estimated) Amount of Carcinogen Consumed	Risk
Traditional food	1,000 g	1,000 mg	7.61×10^{-2}
Spices and flavors	1.0 g	10 mg	7.61×10^{-4}
Indirects	20 mg	2 mg	1.52×10^{-4}
Pesticides and contaminants	200 µg	0.1 mg	7.61×10^{-6}
Animal drugs	1.0 mg	0.1 mg	7.61×10^{-6}
Food preparation (charred protein only)	1.0 g	0.1 mg	7.61×10^{-6}
Mycotoxins	10 µg	0.001 mg	7.61×10^{-8}
		Total Risk =	7.7×10^{-2}

Adapted from Scheuplein, 1990.

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Table 3. Naturally Occurring Carcinogens in Food [a]

Food	Carcinogen
Apples	Patulin
Mushrooms	Hydrazines
Parsnips, celery [b]	Psoralens
Cereals, corn, seeds, nuts	Aflatoxins
Plants (herbal teas)	Pyrrolizidine alkaloids
Spinach, beets, lettuce, radishes	Nitrates --> nitrosamines
Phytoplankton (fish and shellfish)	Polyaromatic hydrocarbons
Garlic[b]	Alkyl isothiocyanate
Chilies[b]	Capsaisin
Oranges[b]	d-limonene
Spices:[b]	
Mustard	Allylisothiocyanate
Pepper, nutmeg	Safrole
Cinnamon	Cinnamaldehyde
Smoke	Nitrosamines
Marjoram	Carvacrol
Tarragon	Estragole

a. Compiled from Scheuplein, 1990; Cheeke and Shull, 1985.
b. Foodstuffs or spices with known or suspected carcinogenic activity.

Similarly, large amounts of hydrazine, a known carcinogen and mutagen, have been found in most edible mushrooms. The most common commercial mushroom (*Agaricus bisporus*) contains about 300 mg of a hydrazine derivative per 100 grams of mushrooms.

Cooking of food generates a variety of carcinogenic substances. Carcinogens formed during food processing include: ethyl carbamate (fermentation), nitrosamines (curing, frying, salting, pickling), polynuclear aromatics (broiling meat, smoking), and heterocyclic amines and nitropyrenes (grilling and charring of fish or meat) (Scheuplein, 1990). Intake of nitropyrenes from grilled chicken has been estimated to be much higher than that from air pollution (Sugimura, 1986; Kinouchi et al., 1986). In fact, according to Ames (1983), the amount of burnt material eaten in a typical day is at least several hundred times more than that inhaled from severe air pollution.

Currently, safety information on direct food additives is more available than for most dietary categories because of consumer concern. Direct food additives are not approved by the FDA unless they are either non-carcinogenic or *de minimis* in animal tests; the *de minimis* risk in this context is 10^{-6}. However, saccharin is an exception to this rule because of a Congressional moratorium of an FDA regulation banning its use (Scheuplein, 1990). According to another study (Wilson, 1979), drinking a 12-ounce can of diet soda containing saccharin every day of the year results in an annual cancer risk of 1 in 100,000 (1.0×10^{-5}).

In summary, potential cancer risks are associated with intake of foods containing carcinogenic substances that are naturally occurring, or are formed during cooking and preparation. Comparison of these risk values for common, everyday exposures with proposed acceptable levels of risk, such as 10^{-5} and 10^{-6}, is an effective means of placing risks in perspective.

Comparative Costs

While risk assessment provides a quantitative estimate of the potential health threat associated with a given situation, risk management strives to balance the social, political, and economic facets of a given situation (CEQ, 1989). In selecting an acceptable risk level for setting site remediation goals, economic factors (i.e., the cost of remediation) become the most important of these additional considerations.

When choosing appropriate risk levels, regulators should weigh the economic costs and benefits that may be associated with risk reduction. Although some environmental laws attempt to restrict economic considerations, common sense and studies of regulatory behavior indicate that economic factors play a critical role in environmental decision making. The economic consequences of regulatory decisions must be heeded so that public health is not adversely affected. Public health professionals have recognized for decades that reducing family income impairs public health (Graham, 1990). The costs of environmental regulation may reduce real family income by increasing the prices of goods and services that all of us purchase, which ultimately causes a reduction in real family incomes. Subsequently, when families have less income, they have less money available for everything from preventive checkups to smoke detectors. If regulatory costs are excessive, the regulator may inadvertently cause more harm to the health status of families than will be prevented.

As a case in point, consider the chlorination of public drinking water supply by municipalities. As a direct result of chlorination, a number of potentially harmful compounds known as trihalomethanes are produced. Most notable of these is chloroform. Based on exposure calculations which assume that the average 70 kg adult ingests 2 liters of water per day (EPA, 1989d), the dose of individual trihalomethanes received in water is associated with risk levels ranging from 1.7×10^{-5} to 3.7×10^{-4}. In order to comply with a 10^{-6} risk level, treatment systems would have to be modified in order to reduce the levels of these compounds in finished water. Implementation of an activated charcoal filter system is one method which would reduce trihalomethane levels sufficiently to bring the risk associated with these compounds in drinking water into compliance. The life of a charcoal bed and, thus, the cost of system maintenance, is highly dependent upon the level of organic matter entering the treatment system. In a worst-case estimation in which the bed life is only 30 days, use of the charcoal filter water treatment system would raise the cost of municipal drinking water by $1.562 per 1,000 gallons (Adams and Clark, 1989). For a 1,000,000 gallon per day facility supplying water to 3,000 to 4,000 homes, this would result in an added water treatment plant operating cost of $1,562 daily or $570,130 yearly. Conversely, in an optimal situation in which the water entering the system is low in organic material, a bed life of 730 days would result in a daily system cost of $417 ($152,205 annually) for the same size plant (Adams and Clark, 1989). These costs, as well as costs in the range of $100,000 for the initial installation of the system, would have to be met by municipalities and passed on to the consumers. If an acceptable risk level of 10^{-6} were applied to this industry,

municipalities would be faced with a dilemma. Since shutting down the public water treatment facility is not an option, each town and city would need to make costly process changes or apply to the state for an exemption from this regulation.

As a second example of the significant costs of implementing an across-the-board limit of risk, consider the changes that will be required at every gasoline station in the state. In order to reduce occupational exposures to benzene fumes from gasoline to the proposed 10^{-6} risk level, retrofitting of all pump nozzles and underground storage tanks would be required to recover vapors. According to a study conducted by the American Petroleum Institute in 1988 (personal communication, H. Thompson, API, 1990), the cost of retrofitting the average 6 nozzle service station with a vapor collection system ranges from $2,582 to $2,795 per nozzle. These costs would be passed on to the consumer in the form of increased gasoline prices. Likewise, similar types of costly vapor recovery systems would most likely be required at dry cleaning facilities in order to comply with a 10^{-6} risk level.

The food industry provides a final example of the costs of compliance. Based on the discussion presented on risks associated with common activities and consumption of natural carcinogens in food and beverages, many areas could be affected by a universal acceptable risk level of 10^{-6}. The risks associated with exposure to naturally-occurring carcinogenic substances in a number of foods and spices exceed the 10^{-6} level (Table 2). The costs of bringing these products into compliance with a 10^{-6} risk level would be high. For example, the aflatoxin mold is a carcinogenic substance which is associated with high moisture crops like peanuts and corn. When crops are subjected to the warm, moist, dark environments which are created during storage and transport, the spore is released and the mold grows. Reduction of aflatoxin levels for the purpose of compliance with a 10^{-6} risk level would require major changes in the technologies involved in storage and transport of fresh crops. Crops would need to be quickly and carefully dried and stored in cool environments in order to prevent release of the spore. Methods of transport to other parts of the country would need to be modified in order to reduce the amount of time the crops are subjected to a moist, warm environment. Without major changes in the way the crops are handled, high percentages of these crops would not be permitted to be sold to consumers, and would need to be discarded. The cost to the consumer would be decreased availability and higher prices. The cost to the farmer or transporter would be significant financial loss.

The justification for integrating comparative remedial cost estimates into the establishment of a site-specific acceptable risk level is tied to the concept that, in most cases, there is little difference between a 10^{-6} risk level and a 10^{-5} risk level or between a 10^{-5} risk level and a 10^{-4} risk level, in terms of real human health risks. In fact, although there may be little difference in real health risk, there may be a significant difference in remedial costs associated with one risk level as compared to another. When it can be shown that significant cost savings would be realized at a less stringent risk level without increased public health threat, then it may be appropriate to establish a less stringent risk level.

Conclusions and Recommendations

A review of the most recent literature and federal regulatory initiatives addressing the issue of acceptable risk indicates that a range of acceptable risks is preferable for evaluating potential exposures to carcinogenic contaminants at hazardous waste sites. A range of risk values will allow the Department to consider a number of site-specific factors including the characteristics of the potentially exposed population (e.g., residential verses occupational exposures), the size of the potentially exposed population (e.g., large versus small), and the uncertainty associated with our current understanding of the potential carcinogenicity of specific chemicals (e.g., Class A versus Class B versus Class C).

A review of risk decisions implemented under various federal regulatory programs indicates that for large population risks, agencies typically acted on cancer risks of about 3×10^{-4}. For small population exposures, regulatory action was never taken for individual cancer risks below 1×10^{-4}. For occupational exposures, acceptable risks are often within the range of 10^{-2} to 10^{-4}. Therefore, the risk range of 1×10^{-4} to 1×10^{-6} used by the EPA and other federal agencies provides the necessary flexibility and is more than adequate to protect public health.

ChemRisk suggests that the Committee give careful consideration to establishing a methodology that integrates each of the factors that are critical to evaluating site-specific acceptable risk levels. The most significant of these factors are summarized below.

1. *De minimis* Risk Level: The *de minimis* risk level should not be viewed as a finite value by which the Department would base all regulatory decisions, but rather a

point of departure from which the site-specific factors listed below would be applied to define an acceptable risk level for a specific site.

2. Acceptable Range: Consistent with a number of federal regulations, including the NCP, ChemRisk encourages the use of an acceptable risk range of 1×10^{-4} to 1×10^{-6} for the general population.

   Use of the 1×10^{-6} risk level as the point of departure may be appropriate if it is recognized that, when appropriate, other factors such as population size, carcinogenic classification, and the comparative costs associated with different risk levels would be integrated during further refinement of an acceptable risk level for a given hazardous waste site, as described below.

3. Population Size: While the *de minimis* risk level of 1×10^{-6} described above may be appropriate for large populations of 100,000 or more individuals, for small populations (less than 100,000 individuals), a ten-fold higher risk level is likely to be more appropriate. As such, an acceptable risk level for an exposed population of less than 100,000 individuals may be 1×10^{-5}.

4. Carcinogen Classification: The degree of confidence associated with the different classes of carcinogens indicates that known human carcinogens (Class A) should be given greatest weight when making remedial decisions at hazardous waste sites. However, for those chemicals for which carcinogenicity in humans is not confirmed, application of a lower risk level is not likely to compromise the protection of human health. As such, probable (Class B) carcinogens should be given lessor weight, and possible (Class C) carcinogens given even lessor weight in decision making.

   The diminished likelihood that an actual risk exists for Class B and Class C carcinogens, may be integrated into the determination of an acceptable risk level by application of toxicity-adjustment factors to the population-based acceptable risk level. For example, factors of 10 and 100 may be appropriate for Class B and Class C carcinogens, respectively. These factors would be multiplied by the

population-based acceptable risk level, determined following an evaluation of population size, as described above.

Example: If population-based risk level is 1×10^{-5} and PCBs are the chemicals of concern, then:
Acceptable Risk Level = $1 \times 10^{-5} \times 10 = 1 \times 10^{-4}$

5. Comparative Costs: Following the determination of an acceptable risk level as described above, the comparative costs of remedial action should be evaluated at incremental risk levels both above and below the acceptable risk level. From this comparison, the most appropriate risk level on which to base remediation would be determined; a risk level higher than the "acceptable" risk level, but not higher than 1×10^{-4}, would be justified based on a finding of significant cost savings without increased public health threat. On the other hand, if remedial costs are not significantly greater, a more stringent risk level may be used for determining site remediation or restoration objectives.

The following examples illustrate the methodology proposed by ChemRisk:

Example A

If a city of 90,000 were exposed to benzene, a known human carcinogen, then the acceptable risk level would be 1×10^{-5}. Assuming that the cost differentials of remediation at 10^{-5} and 10^{-6} were insignificant, then remedial action based on the 1×10^{-6} risk level may be justified for benzene, in order to afford an extra measure of health protection.

Example B

If 500 people in the vicinity of a hazardous waste site are potentially exposed to arsenic, a known human carcinogen, then the acceptable risk level would be 1×10^{-5}. However, if remedial action at the 10^{-5} risk level is estimated to cost $25 million and remedial action at the 10^{-4} risk level is estimated to cost $2 million, then a finding of significant cost savings without a significantly increased public health threat may justify remedial action based on the 10^{-4} risk level. At either risk

level, one would not expect to see even one increased case of cancer based on the results of the risk assessment for this site.

In summary, there are a number of critical factors that should be evaluated when selecting the appropriate risk level for hazardous waste site remediation. The most important of these are: (1) population size, (2) carcinogen classification, and (3) comparative costs. Integration of these factors can be accomplished most effectively through a methodology that is based on a range of acceptable risks, such as 10^{-4} to 10^{-6}. Within this range, a point of departure can then be identified based on population size (i.e., 10^{-5} or 10^{-6}) from which further refinement can be made according to carcinogen classification and comparative costs. ChemRisk believes that adopting such an approach in the State of New Jersey would facilitate the timely and cost effective remediation of hazardous waste sites to a condition that is protective of human health and the environment.

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CONCERNED CITIZENS of MAYWOOD

FOR IMMEDIATE RELEASE

April 7, 1994

TO: Enviromental Risk Assessment & Risk Management Study Commission
c/o Michael Gallo, Chairman

RE: Commission report on alternative scientific standards, criteria and methods for the risk assessment

Please include the following comments and documentation in your deliberations:

(1) Newspaper reports of your hearings seem to indicate many of the speakers are, have been or may be involved with properties at which they would like to dictate what standards (scientific) would be used for remediation, or if remediation would take place at all! They cite a need for a realistic, scientific standard.

(2) Please therefore deliberate on the enclosed "one in a million risk" letter to The Editor, Starledger, June 25th 1993 from four scientists of NJDEPE that clearly establishes that the one in a million risk level or any other risk level- is not a scientific decision- it is a public policy decision- based on the level of risk with which the public is comfortable- science does not tell us how much risk the public is willing to accept. Read the last paragraph for the role of science.

(3) Refer also to enclosed page 4(2ndpp. from bottom) of Assistant Commissioner Lance Miller (NJDEPE) comments on S-1070: He corrects those who say New Jersey's clean up requirements are more stringent than any other state and points to the fact that <u>most</u> other states incorporate a one in a million risk management criteria in their regulations or as policy.

(4) A Wayne resident letter (2/22/94) cites the problem of citizens vs. those with money and power to influence the behavior of public agencies.

(5) Copy of Hazardous Waste News #371 (Jan. 6th 1994) deals with studies of populations living near a hazardous waste site. Note 3rd paragraph citing higher level of liver disease and birth defects among persons living near a thorium waste disposal site in Wayne, N.J.- A site in Maywood N.J. contains the same classification of wastes.
Note last paragraph about " move to divert attention from and to cut funding for the federal superfund program of waste clean up- a move that will result in increased health costs for American people." Proof of this is provided in #6.

(6) Nick Marton (NJDEPE) two letters both dated April 8th 1993 to Ms. Cange (DOE), Jeffery Gratz (USEPA) letter of May 21st 1993 to Ms Cange (DOE).

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CONCERNED CITIZENS of MAYWOOD

FOR IMMEDIATE RELEASE

continued

Pages (1) and (6) of USEPA Action Criteria for residential areas in West Chicago, Illinois including institutional, commercial and municipal properties. These documents clearly estabish a 5 pci/g criteria for clean up. That 15 pci/g is not a health based standard. These facts mean nothing to DOE, and Assistant Secretary Thomas P Grumbly sets out on a "scientific" approach to use the less stringent 5-15 pci/g not the 5 pci/g health based standard.

Read Mr. Grumbly's enclosed letter to Congresswoman Roukema (1/19/94)- then read the Jan. 26th 1994 memo - under date of December 14, 1993 - Maywood Dispute - Review of next steps after Guimond(Grumbly's new deputy) and Muszynski (EPA) meeting.

Results: EPA Region 2's position on clean up levels- (March 24, 1994), enclosed. EPA caves in - clean up at Maywood will be 5-15 not the 5 pci/g health based standard, not for unrestricted use, experimental soil washing, etc.- Maywood officials have voted to reject the cave in by EPA.

(7) Read enclosed Hazardous Waste News copies #370 and #244.

(8) Last attachment is page 6 of 1993 Annual Report- Northeast Interstate LLRWC- Statewide poll says seven in ten residents surveyed believe the best way to deal with LLRW is to ship it to a permanent facility - a permenent clean up - not like the DOE's present attempt to create a cost effective permanent disposal site in Maywood as a "clean up" of the present interim storage site.

Mr. Grumbly (DOE) apparently is interested in cost effective clean up starts - not permanent clean ups.

In 1991 Maywood voted almost unanimously for an excavate and disposal offsite clean up and along with the 7 out of 10 statewide poll, that's a lot more than the 300 member Petroleum Council or Chemical Industry Council.

Yes, one in a million is a public policy and the Legislature should now consider the public's health and not the Councils' profit goals.

Chuck Parodi
President, CCM
48 West Grove
Maywood, NJ 07607

cc. Robert Shinn, NJDEPE Commissioner
Jeanne Fox, USEPA, Region 2, Administrator
Carol Browner, USEPA Administrator
Hazel O'Leary, Secretary of Energy
U.S. Senator Lautenberg
Congressman Torricelli
Pat Schuber, Bergen County Executive
Star Ledger
The Record
The Shopper

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One-in-a-million risk

DEAR EDITOR:

As toxicologists and public health professionals involved in analyzing and understanding human health risks from environmental contaminants, we were troubled by Gordon Bishop's column, "'One-in-a-Million' Rule So Irrational It Defies Nature." This piece confuses the concept of one-in-a-million risk and misunderstands the role of science in calculating risk.

The concepts of one-in-a-million risk as used in environmental regulation applies to cancer-causing contaminants and refers to a level of risk which is calculated to result in no more than one case of cancer—over and above existing rates—among one million people exposed over a lifetime. In setting environmental standards to meet this level of health risk, the role of science is to calculate, as accurately as possible, the level of cancer-causing contaminant in the environment which will meet this level of protection.

The term parts-per-million, on the other hand, is a form of measurement often applied to the level of contaminants in the environment. Parts-per-million refers to how much contaminant is present in soil, water or air. One part-per-million in soil, for instance, means that one gram of contaminant is found among one million grams of soil. Despite the fact that both terms use the word million, these two terms, one-in-a-million risk and part-per-million, are as different as apples and oranges. If a chemical (such as beryllium, to use Mr. Bishop's example) occurs in the environment, either naturally or through human activities at a level of six parts-per-million, this tells us nothing about risk—one-in-a-million or otherwise. In writing that limiting environmental cancer risk to one-in-a-million "defies nature" because beryllium naturally occurs at six parts-per-million, Mr. Bishop confuses these ideas and is likely to confuse his readers.

The column also seems to be confused when it states that an environmental standard protecting against one-in-a-million additional cancers is not based on sound science. The decision to protect the public from exposure to environmental carcinogens at a one-in-a-million risk level, or any other risk level, is not a scientific decision. It is a public policy decision. It is a decision based on the level of risk with which the public is comfortable. Science does not tell us how much risk the public is willing to accept from the environment.

The role of science in setting environmental risk levels is only to calculate how much contaminant can be present in the environment to achieve that goal. The column seems to be saying that if New Jersey conducted sounder science its scientists would be more correct in telling the public how much risk it should be willing to accept. Again, a case of apples and oranges.

Alan H. Stern, Gloria B. Post,
Thomas A. Ledoux and Leslie J. McGeorge,
Department of Environmental Protection and Energy,
Division of Science and Research,
Trenton, N.J.

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and regulatory tools a local government will need in order evaluate vacant property and to gather information needed t market the property for potential use. The law also makes Ne Jersey's statutes consistent with the federal Superfund law b providing that a local government which obtains contaminate property by foreclosure is not responsible for contaminatio that existed on the site prior to their foreclosure; and, th law provides money for local governments who want to remediat a site.

S-1070 also provides financial assistance to persons who cannot obtain private market financing or who are voluntarily cleaning up a site under the Department's Voluntary Cleanup Program.

S-1070 provides the basis for the development of remediation standards. The law directs the Department to develop threshold levels which if met, will satisfy the Department's remediation requirements. The law also provides finality coupled with a recognition that remediation standards can change if the risk to public health and the environment changes.

The law provides flexibility by recognizing the limitations of technology in remediating contaminated sites while encouraging the use of permanent remedies. The law also recognizes that cleanups should be performed consistent with intended use of the property. Industrial properties need not be remediated to the same level as residential properties, yet, under either scenario, New Jersey workers and citizens are protected to the same level of risk.

The risk management criteria in the law, which provides that all New Jersey citizens be protected to a contaminant specific one in one million cancer risk level and no adverse impact level for non-carcinogens, is a fundamental policy decision. Because this decision was a topic of continuing debate, S-1070 convenes a Commission to evaluate the risk management decision in the law, and requires the Commission to report back to the Governor and the Legislature regarding its review.

Some have publicly stated that the risk management criteria contained in S1070 makes New Jersey's cleanup requirements more stringent than any other state. This is untrue. It is true that New Jersey may be the only state which has embodied risk management criteria in <u>statute</u>. However, most other states incorporate a one in one million risk management criteria in their regulations or as policy.

S-1070 also fundamentally changes the way in which the Department requires financial assurance by essentially eliminating the unintended consequence of having a business fund two times the cleanup costs. I am sure you have all heard of businesspersons who wanted to cleanup, but could not afford the costs of both cleanup and financial assurance. The law incorporates a provision which requires certain persons, in lieu of posting financial assurance, to pay into a pool which

LANCE Miller (NJDEPE)
COMMENTS ON S-1070 (4)
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The Record

Nuclear experiments continuing

Editor, The Record:

When one lives within 300 feet of a contaminated waste site for over 30 years under the license of the Atomic Energy Commission and Nuclear Regulatory Commission, one is not surprised by the recent disclosures about nuclear experimentation on human beings. All anyone has to do is look at the record of cleanups or, more accurately, lack of them.

The experimentation goes on with whoever lives near contaminated sites, such as the Wayne Interim Storage Site. The history of this thorium-contaminated site is mired in the inability of our state and federal agencies to protect human life.

Our political system, along with federal agencies, have fallen prey to the unethical behavior that permeates this country. Citizens don't have rights unless we have the money to ensure them. As usual, the victims are powerless to overcome the obstacles foisted upon us because we aren't on a level playing field with those who have money and power to influence the behavior of the agencies involved. Why were laws and regulations circumvented to accommodate W.R. Grace, former owners of the site? Money and political influence, which we the victims do not possess.

ANDREW DROL
Wayne, Jan. 23

NORTH JERSEY
TUESDAY, FEBRUARY 22, 1994

4.

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RACHEL'S HAZARDOUS WASTE NEWS #371

Providing news and resources for environmental justice -- January 6, 1994

CHEMICALS AND HEALTH--Part 3

Several studies of industrial dumps and contaminated water supplies during the last decade have reported adverse health effects among exposed human populations.[1] The principal health findings include:

- Significantly reduced stature (height) for a given age among children who lived near Love Canal, the chemical waste dump in Niagara Falls, N.Y., compared to a control group of children living further from the dump.[2]
- A higher prevalence of birth defects and liver disease among persons living near a thorium waste disposal site in Wayne, New Jersey, compared to persons living further away from the site.[3] (Thorium is a naturally-occurring radioactive element processed on this site by a private firm under contract to the old Atomic Energy Commission, now called the Department of Energy.)
- Low birth weight and birth defects in California children born in census tracts having waste disposal sites.[4]
- Enlargement of the liver (hepatomegaly) and abnormal liver function tests reported in residents exposed to solvents from a toxic waste dump in Hardemann County, Tenn.[5]
- Dermatitis, respiratory irritation, neurologic symptoms and pancreatic cancer at 7 waste disposal sites.[6]
- Significantly elevated rates of illness, including chronic kidney disease, stroke, hypertension [high blood pressure], heart disease, anemia, and skin cancer in a population exposed to toxic metals (cadmium and lead) from mine wastes in Galena, Kansas.[7]
- Leukemia (cancer of the blood-forming cells) among a group of children drinking water contaminated with industrial solvents in Woburn, Mass. In addition, a study of 4936 pregnancies and 5018 residents of Woburn aged 18 or younger revealed significant positive associations between intake of contaminated water and birth defects of the central nervous system, eye, ear, and face (e.g., cleft palate), as well as abnormalities of the chromosomes.[8]
- In Lowell, Mass., a group of 1049 people living 1200 feet from a large chemical waste dump was higher in self-reported complaints of wheezing, shortness of breath, cough, and persistent colds; irregular heart beat; constant fatigue and bowel dysfunction, compared to people living 2 and 3 times as far from the dump.[9] This study examined the possibility of recall bias (people selectively remembering health problems, or chemical exposures) and concluded that recall bias did not explain the findings.
- In Hamilton, Ontario, a study of people who lived and/or worked near an industrial dump revealed significantly elevated rates of the following conditions: bronchitis; difficulty breathing; cough; skin rash; arthritis; heart problems (angina [chest pain] and heart attacks); muscle weakness in arms and legs; tremors, cramps, and spasms; headaches; dizziness; lethargy; balance problems; and mood symptoms (anxiety, depression, insomnia, irritability, and restlessness) compared to populations living further from the site.[10] Recall bias was examined and rejected as the source of these problems.
- A survey of 2039 persons in 606 households living near the Stringfellow Acid Pits in Riverside County, California revealed significantly elevated rates for the following conditions: ear infections; bronchitis; asthma; angina [chest pain]; skin rashes; blurred vision; pain in the ears; daily cough for more than a month; nausea; frequent diarrhea; unsteady gait; and frequent urination.[11] Recall bias was examined and rejected as the cause of these problems.
- In Tucson, Arizona, a study of 707 children born with heart defects revealed that 35% of them were born to parents living in a part of the city where the water supply was contaminated with industrial solvents (trichloroethylene [TCE], and dichloroethylene). The rate of birth defects of the heart was three times as high among people drinking the contaminated water, compared to people in Tucson not drinking contaminated water.[12]
- A study of 296 women experiencing a spontaneous abortion during the first 27 weeks of pregnancy, compared to 1391 women having live births, revealed an association between spontaneous abortion and drinking water contaminants (detectable levels of mercury, or high levels of arsenic, potassium and silica).[13]
- Residents of Bynum, North Carolina, drinking raw river water contaminated by industrial and agricultural chemicals, have developed cancers 2.4 to 2.6 times more often than expected.[14]

To summarize: Epidemiological studies cannot prove a cause and effect relationship. Nevertheless, available information indicates that hazardous waste dumps can harm, and have harmed, humans living nearby. Likewise, contaminated water supplies have harmed people.

The problem of waste dumps is continuing to grow. As the National Research Council of the National Academy of Sciences said in 1991, "A limited number of epidemiologic studies indicate that increased rates of birth defects, spontaneous abortion, neurologic impairment, and cancer have occurred in some residential populations exposed to hazardous wastes. We are concerned that other populations at risk might not have been adequately identified." And the Council said, "Millions of tons of hazardous materials are slowly migrating into groundwater in areas where they could pose problems in the future, even though current risks could be negligible."[15]

There is a move afoot now in Washington, and in the mass media, to divert attention away from the

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problem of toxic wastes. The goal seems to be to cut funding for the federal Superfund program of toxic waste cleanup. It seems clear that such a move, if successful, will result in increased health costs for the American people.

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[1] For a review of several studies, see Arthur C. Upton, Theodore Kneip and Paolo Toniolo, "Public Health Aspects of Toxic Chemical Disposal Sites," *Annual Review of Public Health* Vol. 10 (1989), pgs. 1-25.

[2] Beverly Paigen, Lynn R. Goldman, Mary M. Magnant, Joseph H. Highland, and A.T. Steegman, Jr., "Growth of Children Living Near the Hazardous Waste Site, Love Canal," *Human Biology* Vol. 59 (June 1987), pgs. 489-508. See also, Lynn R. Goldman and others, "Low Birth Weight, Prematurity and Birth Defects in Children Living Near the Hazardous Waste Site, Love Canal," *Hazardous Waste and Hazardous Materials*, Vol. 2 (1985), pgs. 209-223; see also Beverly Paigen and others, "Prevalence of Health Problems in Children Living Near Love Canal," *Hazardous Waste and Hazardous Materials*, Vol. 2 (1985), pgs. 23-43. And see: Nicholas J. Vianna and Adele K. Polan, "Incidence of Low Birth Weight Among Love Canal Residents," *Science* Vol. 226 No. 4679 (December 7, 1984), pgs. 1217-1219.

[3] G. Reza Najem and Lisa K. Voyce, "Health Effects of a Thorium Waste Disposal Site," *American Journal of Public Health* Vol. 80 (April 1990), pgs. 478-480.

[4] Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, U.S. Department of Health and Human Services, *California: Birth Defects Study* (Atlanta, Ga.: Agency for Toxic Substances and Disease Registry, 1990). See also: Gary M. Shaw and others, "Congenital Malformations and Birthweight in Areas with Potential Environmental Contamination," *Archives of Environmental Health* Vol. 47 (March/April 1992), pgs. 147-154, which showed increased risk of malformations of the heart and circulatory system (though not a risk of low birthweight) among children born to California mothers residing in census tracts having waste disposal sites.

[5] Channing R. Meyer, "Liver Dysfunction in Residents Exposed to Leachate from a Toxic Waste Dump," *Environmental Health Perspectives* Vol. 48 (1983), pgs. 9-13.

[6] Barry L. Johnson, "Testimony by Barry L. Johnson, Ph.D., Assistant Surgeon General, Assistant Administrator, U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry [ATSDR], Before the Subcommittee on Superfund, Recycling, and Solid Waste Management, United States Senate, May 6, 1993," pg. 10, citing various studies by ATSDR.

[7] John S. Neuberger and others, "Health Problems in Galena, Kansas: A Heavy Metal Mining Superfund Site," *The Science of the Total Environment* Vol. 94 (1990), pgs. 261-272.

[8] J. Cutler and others, "Childhood Leukemia in Woburn, Massachusetts," *Public Health Reports* Vol. 101 (1988), pgs. 201-205. See also V.S. Byers, "Association between clinical symptoms and lymphocyte abnormalities in a population with chronic domestic exposure to industrial solvent contaminated domestic water supply and a high incidence of leukaemia," *Cancer Immunology and Immunotherapy*, Vol. 27 (1988), pgs. 77-81; and: S. W. Lagakos and others, "An Analysis of Contaminated Well Water and Health Effects in Woburn, Massachusetts," *Journal of the American Statistical Association* Vol. 81 (1986), pgs. 583-196. Because none of the chemicals in Woburn water were previously known to cause leukemia, the leukemia association was questioned; see B. MacMahon, "Comment on the Article, 'An Analysis of Contaminated Well Water and Health Effects in Woburn, Massachusetts,'" *Journal of the American Statistical Association* Vol. 81 (1986), pgs. 597-599.

[9] David Ozonoff and others, "Health Problems Reported by Residents of a Neighborhood Contaminated by a Hazardous Waste Facility," *American Journal of Industrial Medicine*, Vol. 11 (1987), pgs. 581-597.

[10] Clyde Hertzman and others, "Upper Ottawa Street Landfill Site Health Study," *Environmental Health Perspectives* Vol. 75 (1987), pgs. 173-195.

[11] Dean B. Baker and others, "A Health Study of Two Communites [sic] Near the Stringfellow Waste Disposal Site," *Archives of Environmental Health* Vol. 43 (Sept./Oct., 1988), pgs. 325-334.

[12] Stanley J. Goldberg and others, "An Association of Human Congenital Cardiac Malformations and Drinking Water Contaminants," *Journal of the American College of Cardiology* Vol. 16, No. 1 (July, 1990), pgs. 155-164. See also: Cleo P. Loeber Mary J. C. Hendrix, Steven Diez De Pinos, and Stanley J. Goldberg, "Trichloroethylene: A Cardiac Teratogen in Developing Chick Embryos," *Pediatric Research* Vol. 24 (1988): pgs 740-744. And: Brenda V. Dawson, Paula D. Johnson, Stanley J. Goldberg, and Judith B. Ulreich, "Cardiac Teratogenesis of Trichloroethylene and Dichloroethylene in a Mammalian Model," *Journal of the American College of Cardiology* Vol. 16 (November 1, 1990), pgs. 1304-1309.

[13] Ann Aschengrau and others, "Quality of Community Drinking Water and the Occurrence of Spontaneous Abortion," *Archives of Environmental Health* Vol. 44 (September/October 1989), pgs. 283-290.

[14] J. Scott Osborne III, Carl M. Shy, and Berton H. Kaplan, "Epidemiologic Analysis of a Reported Cancer Cluster in a Small Rural Population," *American Journal of Epidemiology* Vol. 132, No. 1 (July 1990), pgs. S87-S95.

[15] Anthony B. Miller and others, *Environmental Epidemiology, Volume 1: Public Health and Hazardous Wastes* (Washington, D.C.: National Academy Press, 1991), pgs. 10, 257.

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TO:

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Peter and Louise Tonell
475 Berger Avenue
Maywood NJ 07607

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State of New Jersey
Department of Environmental Protection and Energy
Division of Responsible Party Site Remediation
CN 028
Trenton, NJ 08625-0028

1993 APR 12 PM 2:10

Scott A. Weiner
Commissioner

Karl J. Delaney
Director

Ms. Susan Cange, Site Manager
Former Sites Restoration Division
Department of Energy
Field Office, Oak Ridge
P.O. Box 2001
Oak Ridge, TN 37831-8723

APR 08 1993

Dear Ms. Cange:

Re: Maywood and Wayne Sites - Identification of New Jersey ARARs

Please be advised that the New Jersey Department of Environmental Protection and Energy (NJDEPE) is in receipt of your March 5, 1993 correspondence with regard to the referenced subject.

A State of New Jersey proposed goal for excess cancer risk of 1×10^{-6} lies within the variability of natural background radiation. This in turn requires that "practical" remedial levels be set at natural background levels so that exposures approach those received from natural sources. As a general point, naturally occurring background radiation levels are approximately 97 mrem/yr for cosmic, terrestrial and internal exposures, excluding radon.

Exposure to surface external gamma radiation from radium - 226, thorium - 232, thorium - 228, and its decay products in contaminated surficial soils, may pose a significant cancer risk. In order to achieve near background levels as noted above and in accordance with NJDEPE requirements, soil radium - 226 and thorium - 232 concentrations should not exceed 5 pCi/g with a minimum of one foot of clean/firm fill cover material. Estimates indicate that "untreated" surface soils containing 5 pCi/g of radium - 226 will result in a dose of 60 mrem/yr, equivalent to a lifetime cancer risk of 1.5×10^{-3}. Contaminated "untreated" surface soils containing 5 pCi/g of thorium - 232 along with decay products may result in a dose of approximately 100 mrem/yr and an attributable cancer risk of 2×10^{-3}. By comparison to natural gamma radiation levels, these exposures may be considered to effectuate a doubling of naturally occurring gamma radiation exposures. As an aside it should be noted that radiation environmental standards near nuclear power plants and for low and high level radioactive waste disposal sites restrict allowable levels of exposure to approximately 25% of background.

In summary, the NJDEPE is not yet in a position to provide specific New Jersey state ARAR's for soil, ground water, surface water and air for radiological contamination. However, such levels will be provided as they become available. Nevertheless, the above discussion shall serve as guidance in the absence of such ARAR's and shall be used in evaluating pertinent USDOE proposals.

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If you have any questions concerning the above please feel free to contact me at (609) 633 - 1455.

Sincerely,

Nicholas L. Marton, MPH
Research Scientist II/Case Manager
Bureau of Federal Case Management

c: Jonathan Berg, BFCM
Steve Byrnes, BEERA
Greg Rapp, BGWPA
Bob Stern, BER
Jeff Gratz, USEPA

NMCEPA:DOEAJAR.NLM

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State of New Jersey
Department of Environmental Protection and Energy
Division of Responsible Party Site Remediation
CN 028
Trenton, NJ 08625-0028

1993 APR 12 PM 2:10

Scott A. Weiner
Commissioner

Karl J. Delaney
Director

Ms. Susan Cange, Site Manager
Former Sites Restoration Division
Department of Energy
Field Office, Oak Ridge
P.O. Box 2001
Oak Ridge, TN 37831-8723

APR 08 1993

Dear Ms. Cange:

Re: Maywood Site - Performance Criteria and use of Treated Soil

Please be advised that this office is in receipt of your March 17, 1993 correspondence. The New Jersey Department of Environmental Protection and Energy (NJDEPE) does not concur offers with the United States Department Of Energy's (USDOE) proposed use of radiologically contaminated soils containing no more than 15 picocuries per gram (pCi/g) of radium and thorium as fill material. The following comprises NJDEPE concerns with regard to the suggested 15 pCi/g guidelines:

1) The NJDEPE maintains that the maximum concentration for radium-226 should not exceed 5 pCi/g. At this level, an estimated 4 picocuries per liter (pCi/l) of radon would be added to the lowest indoor level of a residential structure (2.5 pCi/l is the statewide average). Such a concentration would translate to an approximate lung cancer risk of 2×10^{-2}. The proposed 15 pCi/g level would potentially triple the resultant indoor radon concentration and the attendant lung cancer risk.

2) The proposed use of 6" of clean fill over radium contaminated soils at concentrations of 15 pCi/g is not acceptable. The USEPA reports indicate that a minimum of two feet of clean fill (@1 pCi/g) is necessary to cover 15 pCi/g soils to reduce indoor radon levels in slab-on-grade homes to 4 pCi/g or lower. Additionally, the suggested 15 pCi/g radium - 226 guideline exceeds the NRC Technical Branch position with regard to releasing uranium and thorium contaminated sites for unrestricted use.

Therefore, in light of the above discussion, the NJDEPE maintains that the proposed guideline of 15 pCi/g with a 6" cover of clean fill is not sufficiently protective of human health. Furthermore, the NJDEPE recommended substitute guideline is a maximum of 5 pCi/g for radium contaminated soils with a minimum of two foot of clean fill as cover.

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If you have any questions concerning the above please feel free to contact me at (609) 633 - 1455.

Sincerely,

Nicholas L. Marton, MPH
Research Scientist II/Case Manager
Bureau of Federal Case Management

c: Jonathan Berg, BFCM
Steve Byrnes, BEERA
Greg Rapp, BGWPA
Bob Stern, BER
Jeff Gratz, USEPA

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II
JACOB K. JAVITS FEDERAL BUILDING
NEW YORK, NEW YORK 10278-0012

1993 MAY 26 PM 1:29

MAY 21 1993

Ms. Susan M. Cange, Site Manager
Former Sites Restoration Division
Department of Energy
Field Office, Oak Ridge
P.O. Box 2001
Oak Ridge, TN 37831-8723

Re: EPA Comments on DOE's draft final Proposed Plan and Feasibility Study - Environmental Impact Statement for the Maywood Site, Maywood, New Jersey (April, 1993)

Dear Ms. Cange:

In accordance with Chapter XIV of the Federal Facilities Agreement (FFA) between the Environmental Protection Agency (EPA) and the Department of Energy (DOE), EPA has reviewed the April, 1993 draft final Proposed Plan and Feasibility Study - Environmental Impact Statement for the Maywood Site (FS), Maywood, New Jersey. As written, EPA cannot concur with DOE's proposed alternative: Phased Action and Offsite Disposal. One issue that has been substantively been resolved through discussions has been an agreement to address groundwater contamination in a separate decision document. Another issue, which is one that we have not raised in previous comment letters but has become a very significant concern to the Agency, is one of cleanup levels.

In the draft final proposed plan and FS, DOE identifies the following remedial action objectives for residual soil contamination taken from 40 CFR 192:

> 5 pCi/g averaged over the first 15 centimeters (cm) below the surface, and
>
> 15 pCi/g averaged over 15 cm thick layers more than 15 cm below the surface.

These numbers were developed to support the Uranium Mill Tailings Control Act of 1978 ("the Act"). Title I of the Act specifies standards for disposal (Subpart A of 40 CFR Part 192) and cleanup (Subpart B) of uranium mill tailings at sites designated under Section 102(a)(1) of the Act. Title II specifies standards for disposal (not cleanup) of uranium (Subpart D) and thorium (Subpart E) tailings at NRC licensed disposal sites. Since the Maywood site is neither a designated site under Title I nor proposed to be an NRC licensed disposal site, neither the Title I nor the Title II standards are directly applicable at Maywood. However, the concentration limit for surface soil (5 pCi/g radium 226) in Subpart B is a health-based standard and can be reasonably applied as a relevant and appropriate requirement for radium 226 or combined radium 226 and radium 228 (a daughter product of thorium 232), because these materials present similar health risks (external gamma exposure).

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The concentration limit for subsurface soil (15 pCi/g radium 226) in Subpart B is not a health-based standard and cannot be applied in situations for which it was not intended. The distinction is documented in the materials accompanying the promulgation of Subpart B. This criterion is only suitable as a measurement criterion for use in locating discrete caches of high activity tailings at uranium mill sites that were deposited in subsurface locations. It is EPA's position that, if the intent of the proposed remedial action is to allow unrestricted access to the site, either in the current or future use scenario, then the appropriate soil concentration cleanup criteria should be 5 pCi/g through all soil layers regardless of depth.

Consistent with Section XVI (Dispute Resolution), Paragraph B, of the FFA, we consider the time period beginning with your receipt of these comments to be one of "informal dispute resolution." We are willing to meet with you to discuss our concerns and possibly resolve this issue during this thirty day timeframe.

If you have any questions, please call me at (212) 264-6667.

Sincerely yours,

Jeffrey Gratz, Project Manager
Federal Facilities Section

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ACTION CRITERIA
FOR SUPERFUND REMOVAL ACTIONS
AT THE KERR-McGEE RESIDENTIAL AREAS SITE
WEST CHICAGO, ILLINOIS

Introduction

Under the provisions of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (commonly known as Superfund), as amended by the Superfund Amendments and Reauthorization Act of 1986, the United States Environmental Protection Agency (U.S. EPA) is authorized, among other things, to take response actions whenever there is a release or threat of a release of a hazardous substance into the environment. The National Priorities List (NPL) is a list of hazardous waste sites across the country that are eligible for U.S. EPA response actions under Superfund.

The U.S. EPA has listed four sites in the vicinity of the City of West Chicago, Illinois, on the NPL. The primary contaminants of concern at these sites are radioactive thorium and its decay products derived from ore processing operations at a factory in West Chicago, now known as the Kerr-McGee Chemical Corporation West Chicago Rare Earths Facility ("factory site"). Three of the NPL sites became contaminated when the processing wastes (thorium mill tailings) were removed from the factory and used primarily as fill material in and around the City of West Chicago. These sites are known as:

(1) Kerr-McGee (Residential Areas) site,
(2) Kerr-McGee (Sewage Treatment Plant) site, and
(3) Kerr-McGee (Reed-Keppler Park) site.

The fourth site became contaminated when discharges and runoff from the factory site traveled via a storm sewer into nearby Kress Creek and downstream to the West Branch of the DuPage River. This site is known as:

(4) Kerr-McGee (Kress Creek/West Branch of DuPage River) site.

It is important to note that the Residential Areas site may encompass not only residential properties, but also institutional, commercial and municipal properties. Although primarily contaminated because thorium mill tailings were used as fill, some of the properties may have become contaminated due to windblown material from the factory site.

The Kerr-McGee factory site from which the contamination originated has not been listed on the NPL; it is regulated under the licensing authority of the Illinois Department of Nuclear Safety (IDNS). Decommissioning, clean-up and closure of the factory site currently is being addressed under that authority.

Purpose and Intent

The purpose of this document is to establish criteria for U.S. EPA's response actions at contaminated properties ("Residential Areas") that are not part of the Sewage Treatment Plant, Reed-Keppler Park or Kress Creek/West Branch of DuPage River sites. Those three NPL sites will be addressed by U.S. EPA in separate actions.

112797

ted States Government

Department of Energy

Oak Ridge Operations

emorandum

TE: January 26, 1994

TO OF: EW-93:Cange

CT: DOCUMENTATION OF BI-MONTHLY PROJECT MANAGERS MEETINGS

TO: PDCC File:

Bi-Monthly Projec: Managers Meetings were held with Jeff Gratz on October 8 and again on December 14, 1993. The following is a list of topics discussed at each of these meetings.

October 8, 1993

- Maywood Dispute
  - EPA will be writing their decision now that Oct. 5 has come and gone.
- Wayne Document Schedule
  - BRA will be delivered November 18
  - FS will be delivered October 29
  - PP will be delivered November 30
- Onsite Activities
  - DOE plans to collect additional samples from Sheffield Brook during EM in response to EPA comments on the FS.

December 14, 1993

- Maywood Dispute
  - Review of next steps after Guimond & Muszyniski meeting
- Plans for radon testing in Maywood
  - Schedule is to test in Feb.
  - Plan will be sent in Jan.
- Wayne Document Schedule
  - DOE can expect EPA comments on the FS in December and the PP in January.

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Department of Energy
Washington, DC 20585

January 19, 1994

FALL 1993

"Perspectives" is a regular feature of EM Progress.

Thomas Grumbly, Assistant Secretary for Environmental Restoration and Waste Management, has promised that future decisions about nuclear waste disposal facilities will be based on science, not politics. Fulfilling this pledge will be difficult, but an increasingly aware public will accept nothing less. ★

courtesy of CCM.

The Honorable Marge Roukema
Member, United States House
of Representatives
1200 East Ridgewood Avenue
Ridgewood, New Jersey 07450

Dear Congresswoman Roukema:

This responds to your November 24, 1993, letter regarding the differences that have arisen with the Environmental Protection Agency (EPA) over standards for the cleanup of thorium-contaminated soils.

We are currently working with EPA to develop appropriate cleanup criteria for sites like Maywood, Lodi, and Rochelle Park. My new deputy is an Assistant Surgeon General in the Public Health Service and was the acting assistant EPA administrator responsible for Superfund and hazardous waste management. He is very knowledgeable about the basis for setting the standard in the first place, and recently travelled to New York at my request to discuss this matter with his former colleagues. My deputy informs me that the two agencies are discussing options that will provide appropriate health protection and yet enable the Department of Energy to be efficient in its use of Federal resources so more communities like Maywood can have cleanup occur at a more rapid pace.

While added cost and time are important elements of this dispute, our highest priority remains the protection of public health and the safety of your constituents. Please let me know if we can help you answer any questions posed by your constituents while we work with EPA to resolve our differences.

IS THIS DOE SCIENCE?

Sincerely,

Thomas P. Grumbly
Assistant Secretary for Environmental
Restoration and Waste Management

cc:
The Honorable Marge Roukema
U.S. House of Representatives
Washington, D.C. 20515-3005

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decontaminated to the following limits prior to termination of the license:

> "Concentrations of radionuclides in soil above background concentrations for total radium, averaged over areas 100 square meters, shall not exceed:
>
> A) 5 picocuries per gram of dry soil, averaged over the first 15 centimeters below the surface; and
>
> B) 15 picocuries per gram of dry soil, averaged over layers of 15 centimeters thickness more than 15 centimeters below the surface."

The State requirements in Section 332.150(b) of the Illinois Administrative Code were based on the federal standards in 40 CFR 192.12(a). When the federal standards in 40 CFR 192 were developed over a decade ago, the 5 picocuries per gram (pCi/g) standard was a health based standard, but the 15 pCi/g standard for subsurface soil was technology based, reflecting instrument limitations in locating subsurface deposits. The 15 pCi/g limit is not a health-based standard, and should not be applied to situations in which a health-based standard is appropriate, or to situations that differ substantively from those for which it was derived.

The 15 pCi/g limit was developed as a practical measurement tool for use in locating discrete caches of high activity tailings (typically 300-1000 pCi/g) that were deposited in subsurface locations at mill sites or at nearby properties. The subsurface soil standard in 40 CFR 192 was originally proposed as 5 pCi/g. The final standard was changed, not because the health basis was relaxed, but rather in order to reduce the cost to DOE of locating buried tailings - under the assumption that this would result in essentially the same degree of cleanup at the DOE sites as originally proposed under the 5 pCi/g criterion. The use of a 15 pCi/g subsurface criterion allowed the DOE to use field measurements rather than laboratory analysis to determine when buried tailings had been detected. It is only appropriate for use as a cost-effective tool to locate radioactive waste in situations where contaminated subsurface materials are of high activity and are not expected to be significantly admixed with clean soil. The 15 pCi/g subsurface criterion was not developed for situations where significant quantities of moderate or low activity materials are involved, such as at the Residential Areas site. Therefore, the 15 pCi/g subsurface criterion is not appropriate for use at the Residential Areas site, and thus is not an ARAR. The 5 pCi/g standard, on the other hand, was developed as a health-based standard and is appropriate for use at the Residential Areas site.

Although the soil concentration standard in the regulation is written in terms of an average over an area of 100 square meters, areal averaging will not be conducted during discovery and characterization. This approach is conservative and should minimize the chances of not identifying contamination during the discovery and characterization surveys.

(6.)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION II

JACOB K. JAVITS FEDERAL BUILDING

NEW YORK, NEW YORK 10278-0012

2 3 MAR 1994

Mr. Joe La Grone
Manager, Oak Ridge Operations Office
U.S. Department of Energy
P.O. Box 2001
Oak Ridge, Tennessee 37831-8501

Re: EPA Region 2's Position on the Dispute Regarding Cleanup Levels for Radionuclide Contamination at the Maywood Chemical Company Superfund Site, Maywood, NJ

Dear Mr. La Grone:

You and I, as members of the Senior Executive Committee (SEC), have conferred in an attempt to resolve the dispute regarding cleanup levels for radionuclide contamination in soil at the Maywood Chemical Company Superfund Site. Although we were not able to resolve the dispute within the timeframe allocated to us in the Federal Facility Agreement (FFA) between the Department of Energy (DOE) and the Environmental Protection Agency (EPA), I directed my staff to continue working with DOE in performing site-specific risk analyses prior to formulating my final position on the dispute. The purpose of this letter is to notify you, as the DOE representative on the SEC, of my position on the dispute regarding radionuclide cleanup levels for soil at the Maywood Site, pursuant to Chapter XV (Resolution of Disputes) of the FFA. Based on recent discussions between George Pavlou of my staff and Les Price of yours, I understand that this position, as presented in the attachment, is acceptable to DOE, and will be incorporated into the revised Proposed Plan for the Maywood site.

In accordance with Chapter XV of the FFA, DOE may, within 21 days of my issuance of this position, issue a written notice elevating the dispute to the Administrator of EPA for resolution. In the event that DOE elects not to elevate the dispute within the 21 day period, DOE will be deemed to have agreed with EPA Region 2's position with respect to the dispute as presented herein. As noted above, it is my understanding that EPA's position is acceptable to DOE, and that DOE will not elevate the dispute to the Administrator.

I commend our respective staffs for their efforts in resolving this dispute and look forward to finalizing the Proposed Plan without further undue delay. If you have any questions on the above matters, please do not hesitate to call me at (212) 264-2525.

Sincerely,

William J. Muszynski, P.E.
Acting Regional Administrator

Attachment

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6.

EPA Region 2's Position on Cleanup Levels at Maywood

EPA Region 2's position on cleanup levels at the Maywood Site must be put into the context of the actions which DOE outlined in its draft final Proposed Plan for the Maywood Site (April 1993): DOE selected Alternative 6 - *Phased Action and Offsite Disposal* - as the proposed remedy. This alternative consisted of two "phases" of activities. In Phase I, the pile of approximately 35,000 cubic yards of contaminated dirt and debris at the Maywood Interim Storage Site (MISS) would be removed and sent to a commercial disposal facility. Phase I also included the complete excavation of the residential properties, including the unremediated portion of the Ballod property. Phase II would include the treatment of the remaining accessible contamination at the Maywood Site (the commercial and government properties which include Stepan Company, the Sears property, and the DOE owned MISS). The "clean stream" from the treatment process would be backfilled on the MISS and portions of the Stepan and Sears properties (over which would be placed a foot of clean cover), and the concentrated residuals would be disposed of at an off-site commercial disposal facility. DOE has also expressed an interest to treat the soil in the MISS pile if, during its removal, treatment becomes viable and cost effective. EPA Region 2 agrees with these proposed actions, but not the cleanup levels associated with them. Below is my position, which, if acceptable to DOE, should be incorporated into a final Proposed Plan.

Phase I (Cleanup of the MISS and Residential Properties):

The preferred alternative for the Maywood site is a phased action, in which soil contaminated above a specified criterion would be excavated, and the disposition of the excavated materials will differ for different phases of the project. During Phase I, contaminated soil from the residential properties, the unremediated portion of the Ballod property and the Maywood Interim Storage Site (MISS) waste pile will be excavated and shipped off-site for commercial disposal in accordance with applicable regulations. As proposed by DOE, if during removal of the MISS pile, treatment becomes viable and cost effective, treatment of the MISS pile may be instituted. Excavated areas on residential properties will be backfilled with clean fill material. Surface and subsurface soil at residential properties and the unremediated portion of the Ballod property will be remediated to 5 pCi/g above background.

Phase II (Cleanup of the Commercial/Government Properties):

Phase II will immediately follow Phase I. During Phase II remediation activities, subsurface soil on commercial/government properties will be excavated and removed to a level of 15 pCi/g above background with an "as low as reasonably achievable" (ALARA) goal of 5 pCi/g above background. On the basis of a site-specific risk analysis, these levels are deemed protective for currently zoned commercial/industrial properties. Most excavated areas will be backfilled with clean fill material. Any property that is subject to backfilling of treated material during Phase II (the MISS, and possibly portions of the Stepan and Sears property) will be covered by at least 30 cm of clean fill "to grade." Treated residuals will be at a concentration no greater than 15 pCi/g above background. Consistent with ALARA, if the soil treatment technology, at the time of its implementation, proves capable of treating soils to lower residual concentrations in a cost-effective manner, then DOE shall adopt a lower concentration limit for replacement of treated soils.

DOE will institute ALARA during its field excavation and removal program at commercial/government properties. For the proposed actions, an ALARA goal of 5 pCi/g for Ra-226 and Ra-228, combined, above background, will be instituted for subsurface soils. The design

RACHEL'S HAZARDOUS WASTE NEWS #370

Providing news and resources for environmental justice -- December 30, 1993

CHEMICALS AND HEALTH--Part 2

The Assistant Surgeon General of the U.S. Public Health Service, Barry L. Johnson, told Congress in May 1993 that living near a hazardous waste site "seems [to be] associated with a small to moderate increased risk of some kinds of birth defects and... some specific cancers."[1] Since 1986 Johnson has been Assistant Administrator of the Agency for Toxic Substances and Disease Registry [ATSDR], the unit of the Public Health Service that Congress created to deal with hazardous waste health issues.

Johnson told Congress that "health investigations of communities around some... hazardous waste sites have found increases in the risk of birth defects, neurotoxic disorders, leukemia, cardiovascular [heart and circulatory system] abnormalities, respiratory and sensory irritation, and dermatitis [skin disorders]."

Johnson told Congress there were 1331 dump sites on the official Superfund list, as of last May. He said industrial solvents are present at 87% of the sites; inorganic compounds (such as lead) at 87%, and pesticides at 50% of the sites. He said 41 million Americans live within 4 miles of 1134 Superfund sites that were studied. On average, 3325 people live within one mile of each site; since there are 1331 listed sites, this means a total of 4.6 million Americans live within a mile of an official Superfund site today.

Johnson said a typical site contains more than 100 different chemicals; "such mixtures may be much more toxic than any of the individual chemicals," he told Congress. [The situation is actually somewhat worse than Johnson described. U.S. Environmental Protection Agency (EPA) analyzed leachate at 13 representative hazardous waste sites from across the country. Only 4% of the organic chemicals in the leachate were identified by gas chromatography/mass spectroscopy [GC/MS], but this 4% included 200 individual chemical compounds, including 13 metals. "The unidentified 96%" of the organic chemicals is "of unknown toxicity," the National Research Council said when it reported EPA's findings in 1991.[2]]

To illustrate the point that even a single chemical can cause real problems, Johnson discussed the industrial solvent trichloroethylene (the second-most common chemical found at Superfund sites, after lead). He said, "An increasing body of scientific evidence indicates past exposures to hazardous substances can cause latent [delayed] adverse health effects. Recent findings from the ATSDR exposure registry of approximately 5000 persons exposed in the past to trichloroethylene (TCE) in drinking water showed registrants reporting elevated rates of diabetes, stroke, elevated blood pressure, and neurologic problems."

Johnson then described two large cancer studies that compared the health of people in counties with hazardous waste sites to the health of people in counties without hazardous waste sites. Both studies found an increased frequency of cancers in counties with hazardous waste sites. A 1983 study reported that age-adjusted gastrointestinal (GI) cancer death rates were higher than national averages in 20 of New Jersey's 21 counties (for the period 1968-1977). The environmental variables that correlated most closely with elevated death rates were population density, urbanization, and presence of toxic waste disposal sites.[3] A 1989 study looked at 593 hazardous waste sites in 339 U.S. counties (in 49 states) where contaminated ground water was the sole source for drinking, during the period 1970-1979.[4] (*See RHWN #127.*) Excess cancer deaths were found in counties with hazardous waste sites compared to counties without hazardous waste sites for the following kinds of cancers: lung, bladder, esophagus, stomach, large intestine, and rectum for white males; and cancers of the lung, breast, bladder, stomach, large intestine, and rectum for white females. Non-whites were not studied.

Johnson described a study by the New Jersey Department of Health of reproductive effects associated with contaminated drinking water.[5] Public drinking water systems were evaluated in 75 towns in northern New Jersey. The study looked at all live births and stillbirths (excluding chromosomal defects and plural births) during the period 1985-1988 in the 75 towns. The 75 towns were not know to have excessive health problems. Although some water systems had levels of certain contaminants above federal standards at the time of the study, contamination levels in the 75 towns are thought to be typical of U.S. water supplies, Johnson told Congress.

In the 75 towns, statistically significant associations were found for the following: total trihalomethanes [the chemicals formed in drinking water supplies when chlorine is added to kill germs] were associated with low term birth weight, intrauterine growth retardation, central nervous system defects, and major heart defects. Trichloroethylene (TCE) was associated with neural tube defects [defects of the spinal cord and brain] and oral cleft defects [for example, cleft palate]. Carbon tetrachloride was associated with low term birth weight, intrauterine growth retardation, central nervous system defects, and oral cleft defects. Dichloroethane was associated with major heart defects, and dichloroethylenes were associated with central nervous system defects.

Johnson then described a large study of birth defects among children whose mothers lived near waste dumps in New York state. "A particularly important study[6] examined the association between congenital malformations in children and maternal proximity to hazardous waste sites in the state of New York," Johnson told Congress. Researchers at the Yale University School of Medicine and the New York

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RACHEL'S HAZARDOUS WASTE NEWS #244

Providing news and resources to the Movement for Environmental Justice -- July 30, 1991

DANGERS OF LOW-LEVEL RADIATION

A study published earlier this year in the *Journal of the American Medical Association* reveals that the occurrence of leukemia (cancer of the blood-forming cells) is 63% higher among white male atomic workers at the Oak Ridge National Laboratory (ORNL) than among all U.S. white males. ORNL, in Oak Ridge, Tennessee, has been a federal research and development laboratory for U.S. nuclear weapons development since 1943.

If its findings are confirmed by additional research, this study will affect the future of every part of the nuclear industry, including electric power reactors, weapons factories and medical uses.

The study compared radiation exposures and deaths among 8318 workers hired by ORNL between 1943 and 1972; the workers' health status was followed through 1984. Previous studies of these individuals--the latest being 1977-- had not shown any unusual cancer problems. It was during the period 1977-1984 that the excessive cancers began to appear. At end of the study period (1984), 1524 of the 8318 workers had died. Study of these workers in the future will be provide important additional information.

The research team reporting these results--several of whom are employed by ORNL--was clearly distressed by its own findings because very few workers at ORNL received radiation doses greater than those permissible for radiation workers today. Of nearly 88,000 individual records of an annual dose received by a worker at ORNL, only 135 exceeded the yearly dose limit permissible today, which is 5 rem per year. Most of the workers in the study received total radiation doses well below what is permissible today. Nearly 75% of the ORNL workers had cumulative radiation doses of less than one rem total exposure throughout their employment. This study therefore casts doubt on the safety of today's radiation standards for atomic workers.

Even more importantly, the study provides reason to doubt the safety of the allowable limits for radiation to which the general public can legally be exposed today. If the risks revealed by this study are confirmed, it could force a lowering of permissible radiation exposures to workers and to the public, thus affecting the design and operation of nuclear power plants, the shipment of nuclear materials by truck and by train, the packaging and burial of nuclear wastes in the ground, exposures allowed during medical procedures, and on and on. Today the general public can legally be exposed to 1/10th of a rem per year. An individual exposed to this legal limit for 10 years would achieve a total exposure larger than that received by 75% of the workers at ORNL.

This study was very carefully done and was not rushed into print hastily. The last year of the study period was 1984 and the study appeared in print in 1991. Clearly, a great deal of thought and analysis went into this study before it was finally published. An unusual aspect of the study is that the authors have made available a 19 page supplement that discusses the statistical techniques they employed. [Order National Auxiliary Publication Service document 04849 for $7.75 from NAPS c/o Microfiche Publications, P.O. Box 3513, Grand Central Station, NYC, NY 10163-3513.].

The study not only reveals an elevated risk of cancer among workers exposed for long periods to low doses of radiation; it also shows that the risk of cancer increased as the exposure to radiation increased. In other words, there was an observable relationship between dose (amount of radiation) and response (cancer). This observable dose-response relationship is important in convincing scientists that the relationship between small doses of radiation and leukemia is most likely one of cause and effect and not pure chance.

Furthermore this new study makes an important contribution to a debate that has been going on for two decades between groups that might be called "high dose danger advocates" vs. "low dose danger advocates." The reason for the debate is that most data on harm from radiation are derived from events in which humans received high doses of radiation in short periods. The best-known such event was the bombing of two Japanese cities in 1945. Yet most radiation exposures to humans are not high doses delivered quickly but are low doses delivered over decades. The core of the debate is how to judge what the effects of low doses will be on humans, given that most of the available data are derived not from low-dose studies but from high-dose studies. (The various arguments were presented in some detail

State Department of Health (NYDOH) studied 27,115 births and concluded that, overall, women living within a mile of an inactive dump have a 12% greater chance of bearing a child with a major birth defect, compared to women living further than a mile from a dump. (See *RHWN #313*.)

The researchers looked at 590 inactive dump sites in 20 northern New York Counties. Among the 590 sites studied, 90 were ranked as "high risk" sites because there was documented evidence that chemicals had migrated off the sites. The study found that women living within a mile of any of these 90 sites had a 63% greater chance of bearing a child with a major birth defect, compared to women living further than a mile from all of the 90 sites.

In sum, Johnson's testimony forces the conclusion that toxic waste dumps are hazardous to human health.

[To be continued.]

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[1] "Testimony by Barry L. Johnson, Ph.D., Assistant Surgeon General, Assistant Administrator, U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, Before the Subcommittee on Superfund, Recycling, and Solid Waste Management, United States Senate, May 6, 1993." Thanks to Diane Heminway of the Citizens Environmental Coalition, Medina, NY, for alerting us to this testimony, and thanks to Dr. Johnson's staff for providing copies of the ATSDR studies referred to in his testimony.

[2] Anthony B. Miller and others, *Environmental Epidemiology Vol. 1; Public Health and Hazardous Wastes* (Washington, D.C.: National Academy Press, 1991), pg. 107.

[3] G. Reza Najem and others, "Gastrointestinal Cancer Mortality in New Jersey Counties and the Relationship with Environmental Variables," *International Journal of Epidemiology* Vol. 12 (1983), pgs. 276-289.

[4] Jack Griffith and others. "Cancer Mortality in U.S. Counties with Hazardous Waste Sites and Ground Water Pollution." *Archives of Environmental Health* Vol. 44, No. 2 (March/April 1989), pgs. 69-74.

[5] Frank Bove and others. *Report on Phase IV-A: Public Drinking Water Contamination and Birthweight, Fetal Deaths, and Birth Defects, a Cross-Sectional Study.* (Trenton, N.J.: New Jersey Department of Health, April 1992). See also Frank Bove and others, *Report on Phase IV-B: Public Drinking Water Contamination and Birthweight, and Selected Birth Defects* (Trenton, N.J.: New Jersey Department of Health, May 1992).

[6] Sandra A. Geschwind and others. "Risk of Congenital Malformations Associated With Proximity to Hazardous Waste Sites," *American Journal of Epidemiology*, Vol. 135 (1992), pgs. 1197-1207.

SLAPPed

As the controversy over the toxicity of dioxin mounts, a respected environmental writer on the subject is finding himself defending a $4 million libel lawsuit filed by a retired Monsanto Co. scientist.[1] Dr. Peter Montague, founder and director of the grassroots-oriented Environmental Research Foundation, was sued by Monsanto epidemiologist William Gaffey who claims he was libeled in an article Montague wrote in the March 1990 issue [#171] of *Rachel's Hazardous Waste News*. The subject of the article was alleged fraud in dioxin studies conducted by Gaffey and his Monsanto colleagues.

Montague's supporters say the case is a classic SLAPP, a lawsuit filed by a corporation to stifle citizen opposition (the acronym stands for Strategic Lawsuit Against Public Participation). Prior to the lawsuit against Montague, Monsanto's alleged fraud was receiving widespread attention and even created momentum for expanding payments to Vietnam veterans exposed to dioxin-contaminated Agent Orange....

Montague based his article on a memo, "Newly revealed Fraud by Monsanto," prepared by EPA scientist Dr. Cate Jenkins. Montague's article also quoted documents from a lawsuit brought by Missouri residents against Monsanto, which revealed numerous discrepancies in the Monsanto studies.

The lawsuit could help resolve some of the controversy over dioxin, since the key issue at trial is expected to be whether what Montague wrote (and Jenkins alleged) is true or not....

Reached at his home in St. Louis, Gaffey said, "I'm afraid we're completely unable to talk until [the trial] is completely finished or much further along."

[This lawsuit is now pending in federal district court in St. Louis; a trial date has not yet been set.]

[Happy New Year.]

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[1] Except for items inside square brackets, this article and headline are reprinted with permission from *Environmental Action* (Winter, 1994), pg. 8. *Environmental Action* is published quarterly by Environmental Action Foundation, 6930 Carroll Ave., Suite 600, Takoma Park, MD 20912; phone (301) 891-1100. Subscriptions are $25/year for individuals.

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in *RHWN #184 and #185.*)

The study of ORNL workers indicates that low doses of radiation delivered slowly (over decades) are about 10 times more efficient at producing cancer in humans than are high doses of radiation delivered quickly. (One possible explanation for such a phenomenon would be that high radiation doses kill cells outright whereas low doses merely damage cells which can then go on to cause cancer.)

The ORNL study shows that chronic exposure to low doses of radiation is about 10 times more efficient at producing cancer than one would expect, based on studies of bomb survivors in Japan.

This is not the first study of atomic workers that reached such a conclusion. An investigation of British atomic workers published in 1988 reported very similar results,[1] so the ORNL study confirms the earlier British work. This is definitely not good news for people who are enthusiastic about expanding nuclear technologies because many nuclear technologies would be difficult and very expensive to redesign to reduce human exposures to radiation. In the case of nuclear power plants to generate electricity, and nuclear weapons, a philosophy of *prevention* would very likely provide the least-cost solution to the problem.

As if to confirm that this study is really bad news for every part of the nuclear industry, the *Journal of the American Medical Association* printed an editorial to accompany the study. It says, "If correct, the conclusions of Wing et al [and others] are highly significant" meaning that they deal a severe blow to people who have argued for decades that low doses of radiation are inconsequential. The editorial then goes on to stake out an interesting position for a medical journal; it is called "There's no free lunch" and it basically says, "Hey--you want the benefits of nuclear weapons and nuclear-generated electricity and nuclear medicine? Then you've got to expect that some people will be killed as a result." The editorial does not even discuss the possibility of redesigning nuclear facilities to provide lower doses; inherent in such an omission is the unstated conclusion that redesign would be prohibitively expensive.

Get: Steve Wing, Carl M. Shy, Joy L. Wood, Susanne Wolf, Donna L. Craig, and E.L. Frome, "Mortality Among Workers at Oak Ridge National Laboratory," *Journal of the American Medical Association* Vol. 265, No. 11 (March 20, 1991), pgs. 1397-1402. Request a free reprint from Dr. Wing at Department of Epidemiology, CB 7400, University of North Carolina, Chapel Hill, NC 27599-7400.

[1]V. Beral, P. Fraser, L. Carpenter, M. Booth, A. Brown, and G. Rose, "Mortality of Employees of the Atomic Weapons Establishment, 1951-1982," *British Medical Journal*, Vol. 97 (1988), pgs. 757-770.

[2]William R. Hendee, "There's No Free Lunch; The Benefits and Risks of Technologies," *Journal of the American Medical Association* Vol. 265, No. 11 (March 20, 1991), pgs. 1437-1438.

Additional reading we recommend:

Catherine Caufield, *Multiple Exposures; Chronicles of the Radiation Age* (Chicago: University of Chicago Press, 1990). $13.95. [See *RHWN #200, #201, #202*.]

John W. Gofman, *Radiation-Induced Cancer from Low-Dose Exposure: An Independent Analysis* (San Francisco, CA: Committee for Nuclear Responsibility [C.N.R. Book Division, P.O. Box 11207, San Francisco, CA 94101], 1990. $29.95. [See *RHWN #184*.]

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NORTHEAST INTERSTATE LLRW COMMISSION 1993 ANNUAL REPORT

NEW JERSEY

The New Jersey Low-Level Radioactive Waste Disposal Facility Siting Board (Board) has responsibility for LLRW management in New Jersey. The Board's responsibilities include: (1) development of the siting criteria, the waste disposal plan and the methodology to apply the siting criteria; (2) site selection; (3) oversight of construction, operation, and closure of the facility; and (4) implementation of a public participation and information program.

Background

After studying siting efforts throughout the nation and Canada, the Board shifted its focus to a volunteer siting process during fiscal year 1993. The Board adopted a policy entitled *Seeking a Volunteer Community to Host a Disposal Facility As An Alternate Site Identification Methodology*. To enhance this innovative approach, the Board suspended a previously approved statewide screening process and gave the Radioactive Waste Advisory Committee (Advisory Committee) responsibility for developing and recommending a voluntary siting plan for New Jersey. The Advisory Committee, assisted by the New Jersey League of Women Voters and the New Jersey Department of Public Advocate as neutral facilitators, sought input from various citizen groups throughout the state. These neutral facilitators conducted "stakeholder" meetings with representatives of the State's labor organizations, emergency response organizations, generators of radioactive waste, professional land-use planners and the environmental community. The meetings focused on identifying information, safeguards and benefits that would prompt communities to consider hosting a LLRW disposal facility.

Since the Board's inception, New Jersey LLRW generators have fully supported the Board's efforts, including the voluntary siting approach. Over a year ago, generators organized as the *New Jersey Radioactive Materials Management Group*. Generators played a key role in amending the State's Siting Act to provide a permanent source of funding for the siting effort through a generator fee assessment program. In addition, generators continue to work closely with the Board to develop educational materials that will be used during the voluntary siting program.

A statewide poll conducted in fiscal year 1993 indicated that seven in ten residents surveyed believe the best way to deal with LLRW is to transport it to a permanent facility. Approximately the same percentage of residents polled believe that disposing of LLRW at a specially designed, technologically advanced facility is the environmentally responsible course of action. In addition, they believe that this issue must be resolved now and not left for future generations to solve.

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SCIENTIFIC BASIS FOR THE SELECTION OF THE ONE IN ONE MILLION CANCER RISK: ALTERNATIVE STANDARDS AND METHODOLOGIES

Comments Presented to:

ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT
STUDY COMMISSION
135 WEST HANOVER STREET, ROOM 319
TRENTON, NEW JERSEY

Presented by:

COLLEEN RANNEY, M.P.H.
PRINCIPAL SCIENTIST
CAMP DRESSER & McKEE INC.
EDISON, NEW JERSEY

APRIL 11, 1994

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Comments to the Environmental Risk Assessment and Risk Management Study Commission

Camp Dresser & McKee Inc. (CDM) is pleased to present these comments to the Environmental Risk Assessment and Risk Management Study Commission concerning the appropriate risk management level and risk assessment methodologies for establishing cleanup standards for environmental pollutants. We understand that it is the duty of the commission to:

1. "examine and assess the scientific basis for selecting the risk management standard ofone in one million"; and

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

Our comments are presented below and address primarily the first issue, that is, the appropriateness of the risk management standard of one in one million.

1. *Mandating all cleanups to the one in one million risk level without regard for technical feasibility and cost is irresponsible and ignores the origin of the one in one million criterion and its application in the federal regulatory arena.*

As stated by others commenting before the Commission, there is no scientific basis for the selection of one in one million as the criterion for developing cleanup standards for environmental pollutants. The use of the one in one million risk level by the U.S. Environmental Protection Agency (EPA) is as a "point of departure" as stated in the NCP, for determining the appropriate target level for each site. Prior to its use by EPA, the U.S. Food and Drug Administration (FDA) had established 10^{-6} as a screening level for deciding when a substance should be evaluated. Therefore, for both EPA and FDA, one in one million is considered a "de minimus" level, risks below this level are considered too small to be of regulatory concern.

In establishing Maximum Contaminant Levels (MCLs) under the Safe Drinking Water Act, EPA uses one in one million as a goal, balancing risk protection with evaluation of technical feasibility and cost. The MCLs for many chemicals have been set at the one in ten thousand risk level for reasons of feasibility, analytical detection limits and/or cost of compliance. In promulgating these standards, EPA has acknowledged the 10^{-6} point of departure but has also stated that the final risk level (10^{-4}) is protective of public health.

Therefore, while one in one million can be stated as a goal for setting cleanup standards, technical feasibility and cost of compliance must be considered. To be responsible, information concerning the prevalence of a pollutant must be collected, as well as the costs to remove the pollutant, prior to establishing standards. EPA collects this information before promulgating standards under the Safe Drinking Water Act. NJDEPE must collect and evaluate this information before mandating across-the-board cleanup standards based on the one in one million risk level.

CDM recommends that New Jersey adopt policy that is more similar to the federal government, establishing a range of acceptable risk levels, using 10^{-6} only as point of departure for where

regulatory intervention may be needed. Generic cleanup standards should only be developed when full information concerning the prevalence of a pollutant and its cost to be remediated is available. This information should be used in establishing the cleanup standards, balancing the calculated risk level, the location and likelihood of exposure and the costs of cleanup.

2. *The risk level chosen for cleanup standards is a policy decision which should be made in the context of other risk-based policy decisions legislated in New Jersey.*

While it is unusual for a legislature to explicitly establish such policy (more often it is left to the regulatory agency to set the levels in response to the legislative intent), the legislature's actions are appropriate if the policy being established reflects the concerns and desires of the public. Admittedly, the public's perception of risk is extremely influenced by the media and its focus on hazardous waste sites because they make good "stories". However, when given choices and appropriate comparisons to everyday risks, the public, or its representatives, can make reasonable decisions concerning risk management.

It may be useful to compare this issue to the debate about whether to raise the speed limit on highways to 65 m.p.h. This issue is also one which dealt with risk--the increased risk of traffic fatalities or injuries associated with a 10 m.p.h. increase in the speed limit. The public and its representatives were able to make reasonable decisions concerning the speed limit issue, sometimes accepting risks that are much higher than the 10^{-6} level legislated for pollutant cleanup standards.

Before mandating the risk level upon which cleanup standards should be based, the public and its representatives should be shown how these risks compare to risks they take in their everyday lives, both through their choice (i.e., tobacco smoking) and unavoidable risks such as those presented by background levels of radiation. In addition, the public must be shown how the risks calculated from traditional animal tests, extrapolated to sensitive human population, actually compare to the consequences observed. (For example, how the animal tests on tobacco smoking compare to the observed lung cancer mortality.) In this way, the uncertainty of the risk assessment science can be put into perspective against the backdrop of the actual risks accepted by the public in their everyday lives.

3. *The risk level chosen for a cleanup standard must be appropriate in the context of thebackground risk for a pollutant.*

As a final comment, CDM cautions that the choice of a risk management level on which to base cleanup standards cannot be made without consideration of the background risks of pollutants. The background level of exposure to environmental contaminants is estimated at 10^{-3} to 10^{-2} due to naturally-occurring and regulated substances in food, air and the earth around us. To set cleanup standards for some substances that are lower than the background concentrations for those substances is unrealistic. NJDEPE has acknowledged this in stating that their cleanup standards should always be taken as an increment above the background concentrations established for that substance. However, given the variability of environmental concentrations, the cleanup standard should not be established within the variability of the background concentration. Setting standards within this variability will result in cleanup of soil that is actually not influenced by site contamination, i.e., that is actually part of natural background.

For example, naturally-occurring arsenic in soils and drinking water can present risks on the order of 10^{-3}. A 10^{-6} standard for arsenic in drinking water would be about 20 ug/l. However, the background concentration in many localities in the U.S. exceeds 50 ug/l with a variability of about 10 ug/l. Setting a 5 ug/l standard above the background level of 50 ug/l would not be meaningful or demonstrable, given the variability expected for the environmental concentrations.

Likewise, for radionuclide contaminants such as radium and uranium, with background concentrations in New Jersey representing 10^{-3} risk levels, cleanup standards must be established in significant increments relative to the background level. In fact, radiation presents a perfect example of the inappropriateness of setting risk management levels at 10^{-6} across the board for all contaminants for all situations. It is virtually impossible to measure the concentration associated with one in one million above the background level of naturally-occurring radionuclides. In fact, the detection limit for radionuclides is very nearly the background concentration (which has an associated risk of 10^{-3}).

In summary, cleanup standards should be based on a range of acceptable risks, balancing the technical and cost issues associated with compliance against the desired risk protection level. The risk managment level should be chosen within the context of other risk management decisions made in our society and should be adjusted to reflect the background levels of a substance and the variability of the data at the background level.

[doc\hannock\risk]

State of New Jersey
Department of Environmental Protection and Energy

Robert C. Shinn, Jr.
Commissioner

April 11, 1994

Dr. Michael Gallo, Chairperson
Environmental Risk Assessment and Risk
Management Study Commission
Research Office #109
675 Hoes Lane
Piscataway, NJ 08854

Dear Dr. Gallo,

On behalf of the Department of Environmental Protection and Energy, I am pleased to present to you, and the entire Environmental Risk Assessment and Risk Management Study Commission, the attached reports to assist in your deliberations as mandated by P.L. 1993, c.139. The reports are formal submittals to the Commission.

The first report, "Considerations in Selecting a Carcinogen Risk Level and Controlling Exposure at Contaminated Sites" presents background information on the nature of risk and the concept of "acceptable risk", the regulatory need for generic soil standards approach used by the U.S. Environmental Protection Agency (USEPA), and discussion of the use of engineering and institutional controls to mitigate exposure.

The second report, "A Review of Methodologies And A Sample Approach For Soil Standards Development" reviews the major alternative risk assessment methodologies which are available at both national and state levels for use in developing soil cleanup standards. The report also provides a general sample approach which we hope the Commission will find useful in demonstrating many of the considerations involved in developing soil remediation standards.

We trust these documents will assist the Commission in its deliberation. Should you have any questions please feel free to contact either Dr. Robert Tucker at (609) 984-6071 or Assistant Commissioner Lance Miller at (609) 292-1250. They are always available to discuss these issues in greater depth with the Commission if you so desire.

Sincerely,

Robert C. Shinn
Commissioner

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State of New Jersey
Department of Environmental Protection and Energy

Robert C. Shinn, Jr.
Commissioner

MEMORANDUM

MAR 3 1 1994

TO: ROBERT C. SHINN, Commissioner
Department of Environmental Protection and Energy

FROM: LANCE R. MILLER, Assistant Commissioner
Site Remediation Program

RICHARD V. SINDING, Assistant Commissioner
Policy and Planning

SUBJECT: TRANSMITTAL OF REPORT TO THE ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

In June 1993, the Legislature established in P.L. 1993, c. 139 (section 47) the Environmental Risk Assessment and Risk Management Study Commission. Its purpose is two-fold:

> "(1) To examine and assess the scientific basis for selecting the risk management standard of one in one million for the purposes of P.L. 1993, c. 139 and to consider and assess alternative scientific 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."

The Commission, chaired by Dr. Michael Gallo of Rutgers University, held public hearings on the above issues on March 9, 10, and 11, 1994. Dr. Robert Tucker, Director of the Division of Science and Research, is the DEPE's non-voting member on the Commission and attended two of the hearings. Assistant Commissioner Miller attended all of the hearings. Although no DEPE testimony was presented at the hearings, the Commission has provided an opportunity for written comments to be submitted until April 11, 1994.

On behalf of DEPE's Soils Cleanup Standards Committee, we are pleased to present for your review and approval a report to the Commission entitled "Considerations in Selecting a Carcinogen Risk Level and Controlling Exposure at Contaminated Sites". This report, the first of two reports which we anticipate being presented to the Commission, discusses the issue of "acceptable risk", presents an objective discussion of the generic standards approach and the site-specific approach and discusses the use of engineering and institutional controls to mitigate exposure and control remediation costs. The second report will focus on alternative risk assessment methodologies and will follow shortly.

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We would like this report included as part of the formal comments presented to the Risk Study Commission which must be submitted by April 11, 1994 (the close of the comment period). To assist in expediting the submittal process, we have also attached a draft letter to Dr. Gallo for your approval.

Thank you for your consideration of this report to the Commission.

Attachments

c: Mark Smith, Chief of Staff
Director Tucker, DSR
Members of the Soils Cleanup Standards Committee

Considerations in Selecting a Carcinogen Risk Level and Controlling Exposure at Contaminated Sites

Prepared by
New Jersey Department of Environmental Protection and Energy
Soils Cleanup Standards Committee
March 1994

I. Overview

The New Jersey Department of Environmental Protection and Energy (DEPE) has adopted as the primary approach for site remediation the establishment of generic soil remediation standards which can be used on many sites rather than the United States Environmental Protection Agency (USEPA) approach which relies on baseline site-specific risk assessment analyses. While P.L. 1993, c.139 allows for site-specific risk assessments to develop site-specific remediation standards, the emphasis in the law is on the development of contaminant-specific or generic soil standards (see section 35 of P.L. 1993, c. 139). The setting of generic soil standards involves the application of sound scientific principles and the public's perceptions of "acceptable risk" which result in the management of risk through remedial actions.

The DEPE believes that reliance solely on baseline site-specific risk assessments will impede remediation of contaminated sites in New Jersey. The lengthy debate and analyses required for a decision using a baseline site-specific risk assessment approach may be warranted for the relatively small number of Superfund sites (109 in New Jersey; 1,250 nationally) but it is not workable for the over 39,000 known and suspected contaminated sites in New Jersey.

The DEPE is presently using interim soil cleanup criteria, which are a combination of Tables 3-1 and 7-1 from the February 1992 rule proposal (24 NJR 373), with corrections, for case-by-case remediation decisions until final standards are promulgated (Soil Cleanup Criteria, February 1994). These criteria were derived by DEPE using risk assessment methods established by USEPA to be protective of human health. The chemical-specific health based criterion is only one factor in the setting of a cleanup standard however. The DEPE must consider other applicable and relevant promulgated criteria such as standards for ground water quality and surface water quality in order to develop a soil remediation standard for a site.

The determination that all New Jersey citizens should be protected to a contaminant exposure level which does not exceed an established risk level for carcinogens, and has no adverse impact for non-carcinogens, is a risk management or fundamental policy decision which has been made by the Legislature in P.L. 1993 c. 139. In P.L. 1993, c. 139, the Legislature established as the risk management policy basis a 10-6 risk level for carcinogens, and a Hazard Index of one for non-carcinogens. Under the legislative scheme, standards would be developed for individual contaminants based on this risk policy and would not take into account multiple contaminants. The Soil Cleanup Criteria (SCC) already in use by the DEPE are generally based on these risk management policy guidelines while other SCC are based on analytical capability (e.g., polyaromatic hydrocarbons) or natural background (e.g., arsenic). Also the impact to ground water numbers in the SCC were not directly developed using the USEPA risk management guidelines. Rather, these standards were developed so that the ground water quality standards (which are primarily based on a 10-6 risk level for carcinogens) are not impacted.

The Legislature also established in P.L. 1993, c. 139 the Risk Assessment and Risk Management Study Commission to examine the basis for the carcinogen risk level. The DEPE believes that the setting of a risk level rests firmly in the public policy arena and is not a scientific issue. The policy nature of the risk level does not imply that remediation standards are not based on sound science

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but that the risk level serves as a starting point in the technical evaluation of the myriad factors involved in developing soil remediation standards.

This paper will present four areas of consideration for the Risk Assessment and Risk Management Study Commission:

- background information on risk, risk assessment, risk management and the concept of acceptable risk;
- the regulatory approach to setting standards;
- consistency with other remediation standards; and
- the economic issues associated with risk level and site remediation.

II. The Language of Risk

A. The Nature of Risk

Risk, or the probability of an event such as cancer occurring in an individual, is generally portrayed by the following basic formula:

Risk = Toxicity X Concentration X Exposure

Control of any of the components in the formula can effectively reduce the risk to a population. For example, using engineering and institutional controls can reduce or eliminate the exposure factor from the formula. Another example might be to modify the concentration of a contaminant through treatment or removal techniques thereby effectively reducing the risk. Both of these are examples where risk management techniques were employed to reduce the overall risk to a population.

B. Determination of Acceptable Risk

Environmental managers have sought a defensible "acceptable risk" level for many years, particularly for those contaminants where scientific evidence which demonstrates a threshold in the dose-response curves is lacking (e.g., carcinogens). Such an acceptable level is necessary for setting standards, due to the fact that achieving a zero risk level for these substances is generally considered an unattainable goal if any level of exposure is present.

There is no scientific means to select an "acceptable risk" level. All potential methods pose severe technical, political and ethical problems including: formal analysis (e.g., cost-benefit), reliance solely on past actions, and surveying the public (e.g., Fischhoff et al., 1980; Salem et al., 1980; and Kasperson and Kasperson, 1983). None of these methods is truly objective or superior, and they produce inconsistent results.

Furthermore, there is no scientific evidence that the public accepts **any** a priori "acceptable risk" level. Citizens recognize that a risk level of 1 X 10-6 is smaller than 1 X 10-4, and may make personal decisions (e.g., choosing not to test for radon in indoor air or for chemicals in private wells) that imply that some level of risk is at least "tolerable," if not acceptable. However, data suggests that most citizens do not accept even a 1 X 10-6 risk level ("what if that one person in a million is in my family?"). This is particularly true for hazards that are involuntary (i.e., imposed on them by others) which describes most environmental problems, such as contaminated sites (e.g., Slovic, 1987). Thus, public attitudes cannot be used to justify or reject any specific "acceptable risk" level.

Therefore, the only basis for setting any acceptable risk level is a policy decision that smaller risks are not worth society's attention (the "de minimis" criterion). Whatever the basis for such a decision, it is indeed a policy determination, even if decisions leading to this choice (e.g., that threshold evidence is lacking) are based upon scientific judgments. Any chosen risk level

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is no more (and no less) scientific than higher or lower levels that might be set.

C. Risk Assessment

Risk assessment, as it pertains to contaminated sites, is "an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action)", (USEPA, 1989). The baseline risk assessment contributes to the site characterization and subsequent development, evaluation, and selection of appropriate response alternatives. The components of a risk assessment include data collection and evaluation; exposure assessment; toxicity assessment; and risk characterization. The risk characterization step integrates the toxicity and exposure assessments into qualitative and quantitative expressions of risk, illustrating the major assumptions, scientific judgments and any estimates of the uncertainties embodied in the risk assessment process. Risk characterization serves as a bridge between risk assessment and risk management.

USEPA uses the results of the baseline risk assessment to:

(1) determine whether additional response action is necessary at a site;
(2) modify preliminary remediation goals;
(3) support selection of the "no action" remedial alternative, where appropriate; and
(4) document the magnitude of risk at a site, and the primary exposure pathways of that risk.

The setting of generic standards uses the same risk assessment equations and assumptions identified above, except that the risk level is set at a pre-determined level for carcinogens (e.g., 1 X 10-6). Thus, in the manipulation of the risk assessment equations for a given risk level, the generic standards approach derives the contaminant concentration for a given risk level. For example, to derive the generic standard for a contaminant, a series of standardized assumptions are used in the calculations in the absence of site-specific data and the result is the concentration of the contaminant. The contaminant concentration is then used as the generic standard for that medium.

D. Remedy Selection and the Mitigation of Risk

Risk management seeks to control or mitigate risks and reduce the probability of exposure. The selection of the appropriate remedial action is, in effect, risk management. This is achieved through either removal or treatment of contaminants or by the use of engineering or institutional controls. It is in this step that other factors such as community acceptance, cost reasonableness, technical feasibility, land use and other regulatory constraints are evaluated as well.

III. The Regulatory Approach to Setting Standards

The DEPE's overall goal in developing generic soil remediation standards is to derive a basis for consistent decision-making that is supported by scientifically developed human health toxicological and exposure factors. The primary bases for the numeric standards are the human health-based criteria derived from the data on adverse effects of the contaminants. Human health-based criteria are developed based on the carcinogenic potency factors for those contaminants treated as carcinogens and on reference doses for all other contaminants. Practical considerations, including analytical limitations, are also considered in developing the final numeric cleanup standards. If these practical considerations result in a level greater than the health-based criterion, the numeric cleanup standard is based on those other considerations.

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A. Development and Application of Generic Standards

The first step in development of a contaminant-specific risk assessment involves hazard identification. This involves evaluation of data from humans and experimental animals to determine the toxic effects of concern, particularly whether the contaminant is to be considered a carcinogen for the purposes of risk assessment. The approach to be used is dependent on whether or not the chemical is considered a carcinogen, as described below.

Risk assessments for carcinogens are based on the assumption that no threshold exists for carcinogenesis. This means that there is some risk of cancer following exposure to any dose of a carcinogen, and that there is no level of exposure at which no risk of cancer occurs. Therefore, it is necessary to choose a risk level when performing a risk assessment for carcinogens in order to develop a numerical criterion.

In contrast, risk assessments for toxic effects other than carcinogenicity are based on the assumption that a threshold exists for toxicity. In the risk assessment for non-carcinogens, the goal is to develop a level at which no adverse physiological effects are anticipated. Therefore, it is not necessary to choose a risk level for risk assessment of non-carcinogens.

For most carcinogens, the DEPE uses the 1 X 10-6 or one-in-one million risk level in humans as the definition of negligible (de minimis) risk as specified, most recently, in P.L. 1993, c.139. It should be noted that the health-based criterion must sometimes be modified by additional factors to determine the final cleanup standard. Such considerations include background levels, particularly for inorganics and analytical limitations on the quantification of the level of contamination. Therefore, the final standard developed may be set at a level which exceeds the risk level chosen as the basis for the health-based criteria.

Additionally, New Jersey has addressed carcinogens where the weight of the evidence of carcinogenicity is weaker (Class C carcinogens) differently than other types of carcinogens based on an alternate set of considerations. This is exemplified in the NJ Drinking Water Standards, the NJ Ground Water Quality Standards, the NJ Surface Water Quality Standards and in the February 1992 rule proposal for soil standards. Specifically, for the Class C carcinogens where there was also a chronic reference dose available, a health-based criterion was developed using a hazard index of one and then dividing that number by 10 as an additional uncertainty factor. If there was no chronic reference dose available for a Class C carcinogen, then the health-based criterion was developed as a carcinogen but at the 10-5 risk level (see the NJ Ground Water Quality Standards 7:9-6.7(c)4 for details). This approach for Class C carcinogens has been used for many years by USEPA's Office of Drinking Water (50 FR 46936, Nov. 13, 1985).

When the determination is made that a site has contamination above standards, responsible parties are required to take some degree of remedial action. The decision as to whether or not to conduct any level of remedial action has already been determined through the findings of levels of contamination above the standards.

B. Comparison of USEPA Site-Specific Risk Assessment Approach with the Generic Standards Approach

It should be noted that, given the same site, that the decision to remediate may vary based on whether the USEPA baseline site-specific risk assessment approach or the use of generic standards is employed. For example, using the USEPA baseline site-specific risk assessment approach the site would be submitted to extensive site specific risk assessment analyses which are conducted concurrent with the Remedial Investigation/Feasibility Study. According to USEPA "Risk Assessment Guidance for Superfund" (1989), the outcome of that risk assessment process is a risk level for carcinogens. If that risk level was between 10-4 and

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10-6, USEPA would have the option of proceeding with a remedial action. Less than 10-6 would usually generate a "no action" alternative and above 10-4 would usually mandate some level of remedial action.

The term often used to refer to the USEPA decision model described above is a "risk range." Another aspect of the USEPA approach is that the site-specific risk assessment incorporates a model which determines the site risk from all of the contaminants found at a site. This involves combining risks from the total number of environmental contaminants through all media and exposure routes. Therefore, when multiple contaminants are present or a single contaminant is present in more than one medium, the total site risk may be higher than 1 x 10-6, even though it is possible that the risk level for individual contaminants does not exceed a 1 X 10-6 risk level.

With the use of generic standards, the same site would be handled differently. The concentrations of individual contaminants present at the site would be evaluated against the individual contaminant standards and, if determined to be above standards, some degree of remediation would be required to reduce those concentrations to comply with the standards. However, although individual contaminant exposure might be mitigated to comply with a 10-6 based standard, there might be a higher total site risk.

There are a number of advantages and disadvantages to each approach. The USEPA approach involves a high degree of site specificity. In addition, this approach can be very labor intensive and is subject to more professional judgment in its application. The USEPA baseline site-specific risk assessment approach, however, does provide greater site specific flexibility as the risk assessment is based on actual site conditions.

The use of generic soil standards for site remediation is a more expedient and consistently applied method. This approach requires less professional judgment in its application to individual sites and less site specific risks are evaluated. However, generic standards may be based on conservative assumptions.

P.L. 139, c. 139 requires the development of generic standards. The DEPE believes that this is an approach which is consistent with other DEPE standards. In addition, under P.L. 1993, c. 139, the option of conducting a site-specific risk assessment to develop site-specific remediation standards is still available provided that it is consistent with the USEPA guidance.

IV. Consistency with Standards for Other Media and Soil Standards of Other States

A. Risk Levels Used in Other Environmental Media and Programs

When considering the risk levels for situations of environmental contamination, it is important to be aware of the intended use of the risk level. Risk levels may be used as the basis for several different types of decisions, including health-based criteria, final regulatory standards, site-specific decisions, or contaminant-specific guidance which has not been promulgated as a decision or standard. Travis (1987) reviewed 132 regulatory decisions for which risk estimates were available, and concluded that action was always taken when risk estimates exceeded 4 X 10-3 and never taken when risk was below 1 X 10-6.

A summary of the risk levels used as a basis for other DEPE and USEPA standards is presented below:

A. Drinking Water: USEPA sets its Maximum Contaminant Level Goals (analogous to health-based criteria) for carcinogenic drinking water contaminants at zero. This is a theoretical target which is not practically implementable as a standard. The final USEPA standard, or Maximum Contaminant Level is to be set as close to the goal as feasible, and is derived after taking into account factors such as analytical

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limitations, treatability (i.e., technical feasibility) and cost. When these factors are taken into account, USEPA's final Maximum Contaminant Levels for carcinogenic drinking water contaminants range from 1 X 10-4 to 1 X 10-6.

In contrast, New Jersey's 1984 A-280 Amendments to the New Jersey Safe Drinking Water Act specify a target risk level of 1 X 10-6 for ingestion of carcinogenic drinking water contaminants for a lifetime. Based on language in the Amendments, DEPE has incorporated analytical limitations and treatment considerations into the drinking water standards for some contaminants, as needed. This means that the final standard for some carcinogenic contaminants is above the 1 X 10-6 risk level.

B. Surface Water: USEPA had previously recommended a risk range of 1 x 10-5 to 1 x 10-7 for carcinogens for the human health-based ambient water quality criteria (45 Fed. Reg. 79318 , Nov. 28, 1980). Currently, USEPA recommends a 1 x 10-6 level for these criteria and recently adopted criteria applicable to New Jersey at that risk level. DEPE has finalized its Surface Water Quality Criteria based on the 1 x 10-6 level (N.J.A.C. 7:9B) with the exception of Class C carcinogens as discussed in section III.A. of this paper.

C. Ground Water: DEPE's final ground water standards use a 1 x 10-6 risk level as the basis for the human health-based carcinogen criteria (N.J.A.C. 7:9-6). Similar to the drinking water standards, NJDEPE has incorporated analytical limitations and treatment considerations into the ground water standards for some contaminants, as needed. This means that the final standard for some carcinogenic contaminants is above the 1 X 10-6 risk level and includes the Class C exceptions as discussed in section III. A. of this paper.

In summary, the 1 X 10-6 risk level is used as the carcinogenic risk level target in New Jersey for all of the above contaminant-specific standard setting activities except for Class C carcinogens as previously discussed.

B. Comparison of New Jersey to Other States

In June 1993, USEPA conducted a survey of ten states regarding their soil cleanup level programs (USEPA, 1993). In general, the survey found that the states surveyed used a generic one-in-one million contaminant specific cancer risk level in soil as established by USEPA guidance. Some states, including New York and Texas, indicated that higher risk levels (1 X 10-5) are used for contaminants where the weight of the evidence for carcinogenicity is weaker (Class C carcinogens). As noted in section III.A. of this paper, New Jersey's Soil Cleanup Criteria uses alternate considerations (availability of the chronic reference dose) and therefore the 10-5 risk level is not routinely used for all Class C carcinogens.

Every state surveyed indicated the use of generic standards in some way. Some states indicated that they have the option to use site-specific calculations for contaminants which have no set standard. Every state surveyed also provided for variation in exposure assumptions resulting in the setting of different standards for direct contact, residential/industrial use, or for excavation workers.

IV. Economic Issues Associated with Risk Level and Site Remediation

A. P.L. 1993, c. 139 Background

In 1993 the New Jersey Legislature recognized the practical and technical limits to the remediation of contaminated sites and expressed the desire to provide property owners and the persons responsible for the remediation of the contamination (the responsible parties) with flexibility in determining the

appropriate remedial actions for their site. The legislature was responding to the statements by the regulated community that previous cleanup oversight and technical requirements by DEPE did not allow sufficient consideration of the economics and practicality involved in conducting a "complete" site remediation.

The legislature responded by providing a variety of options within the P.L. 1993, c. 139 legislation which address many critical components to the entire discourse on site remediation such as:

- differential cleanup standards by land usage,
- finality of cleanups,
- the use of various engineering and institutional controls to mitigate exposure,
- cost differential as a means for selecting the remedial action,
- the use of permanent remedies, and
- the option to use health-based standards to achieve unrestricted use of the property for future development.

P.L. 1993, c. 139 establishes the Risk Assessment and Risk Management Study Commission and directs the Commission to critically evaluate the risk management basis for remediation standards and risk assessment methods and to make recommendations to the legislature and Governor for future cleanup standard setting activities.

In its support of P.L. 1993, c. 139, DEPE recognized and advocated that remedial action decisions are to be based on factors such as technical practicality, community acceptance, land use, cost evaluation and use of engineering and institutional controls rather than the previous "cleanup to the maximum extent practical." The idea that cleanups should be performed consistent with the intended use of the property is a relatively new concept in environmental management. This provision allows that properties to be remediated are to be protective of human health according to their intended use. It is still mandatory that the final remedial actions be protective of human health and the environment.

B. Engineering and Institutional Controls under the Industrial Site Recovery Act (ISRA):

P.L. 1993 c. 139 provides for the use of engineering and institutional controls to manage the risk of actual exposure to contaminated soil. Section 22 of P.L. 1993, c. 139 defines institutional controls as:

> "a mechanism used to limit human activities at or near a contaminated site, or to ensure the effectiveness of the remedial action over time, when contaminants remain at a contaminated site in levels or concentrations above the applicable remediation standard that would allow for unrestricted use of that property".

Institutional controls include, without limitation, "structure, land and natural resource use restrictions, well restriction areas and deed notices".

Engineering controls are also defined in section 22 of P.L. 1993, c. 139 as:

> "any mechanism to contain or stabilize contamination or ensure the effectiveness of a remedial action".

Engineering controls may include, without limitation, "caps, covers, dikes, trenches, leachate collection systems, signs, fences and access controls".

P.L. 1993, c. 139 clearly stresses that controlling exposure is a viable remedial option. Thus, the DEPE may approve remedies that include engineering and institutional controls to mitigate exposure from contaminants. For example, after delineating the extent and nature of the contamination, the DEPE may determine that encapsulation and restrictions of record will be sufficient to

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control the existing contaminant exposure. Engineering controls including capping and fencing with continued maintenance along with restrictions of record can reduce the risk to human health and the environment to established risk levels. The current property owner must agree to any institutional controls and restrictions which may impact the future use of the property before a non-permanent remedy may be implemented.

C. The Impact of a Set Risk Level to Remediation Costs

Experience in the remediation of contaminated sites has shown that there is no direct or linear relationship of risk level to remediation cost. In most cases it is the site-specific characteristics of the site, the remedy selected and the desired risk to be achieved which govern costs. For example, a higher level of protection may be achieved at less cost through the use of certain engineering and/or institutional controls (e.g., capping) than the installation of removal and/or treatment systems (e.g., excavation and ground water pump and treat systems) which may achieve a less stringent standard. The use of engineering and/or institutional controls in the above example could achieve (if all appropriate institutional and long term maintenance provisions were assured), a 1 X 10-6 risk through the elimination of the exposure pathway. By comparison, a removal and/or treatment remedy may only achieve a 1 X 10-4 risk level if only those soils above that risk level were treated. DEPE experience with remediation costs has shown that, given the diverse range of risk management options associated with contaminated soils, that there is no direct correlation between achieving an "acceptable risk" level and remediation costs.

CONCLUSIONS

This paper is summarized by the following key points for the consideration of the Risk Assessment and Risk Management Study Commission in the conduct of their deliberations:

1. To develop health-based generic soil standards for carcinogens, the establishment of a set cancer risk level is required;

2. Many factors other than the risk level are incorporated into the setting of a generic standard;

3. The 1 X 10-6 risk level has been used by other states as well as DEPE and USEPA for other media-specific standards; and

4. P.L. 1993, c. 139 allows for engineering and institutional controls to mitigate exposure, greatly reducing the economic burden of site remediation.

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Members of the Soils Cleanup Committee

George H. Klein, Division of Publicly Funded Site Remediation, Assistant Director, Program Support Element, serving as chairperson

Ron Corcory, Division of Responsible Party Site Remediation, Assistant Director, Responsible Party Cleanup Element
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Robert C. Shinn, Jr.
Commissioner

M E M O R A N D U M

TO: Robert C. Shinn, Commissioner
Department of Environmental Protection and Energy

THROUGH: Lance Miller, Assistant Commissioner
Site Remediation

THROUGH: Richard V. Sinding, Assistant Commissioner
Policy and Planning

FROM: Robert K. Tucker, Director
Division of Science and Research

SUBJECT: Transmittal Of Second DEPE Report To Environmental Risk Assessment And Risk Management Study Commission.

DATE: April 7, 1994

As described in a March 31, 1994 memorandum to you from Assistant Commissioners Sinding and Miller, DEPE's Soils Cleanup Standards Committee anticipates providing two reports to the Environmental Risk Assessment and Risk Management Study Commission. The first report entitled "Considerations In Selecting A Carcinogen Risk Level And Controlling Exposure At Contaminated Sites", was transmitted to you along with the March 31 memorandum.

We are pleased to present for your review and approval the second report to the Commission entitled "A Review Of Methodologies And Sample Approach For Soil Standards Development". This report reviews alternative risk assessment methodologies which are available at the national and state level for use in developing soil cleanup standards. The document also provides a generic sample approach which we have developed for the Commission's consideration.

We would like this report included as part of the formal comments presented to the Risk Study Commission which must be submitted by April 11, 1994 (the close of the comment period). To assist in expediting the submittal process, we have also attached a draft letter to Dr. Gallo for your approval.

Thank you for your consideration of this report to the Commission.

Attachment
c: Mark Smith, Chief of Staff
Members of the Soils Cleanup Standards Committee

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Considerations in Selecting a Carcinogen Risk Level and Controlling Exposure at Contaminated Sites

Submitted to
The Environmental Risk Assessment and Risk Management
Study Commission

Prepared by
New Jersey Department of Environmental Protection and Energy
Soils Cleanup Standards Committee
March 1994

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REVIEW OF METHODOLOGIES AND A SAMPLE APPROACH FOR SOIL STANDARDS DEVELOPMENT

Division of Science and Research
Department of Environmental Protection and Energy
March 1994

Submitted to
The Environmental Risk Assessment
and Risk Management Study Commission

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INTRODUCTION

Soil standards for the remediation of toxic chemicals associated with contaminated sites have been the object of numerous state and federal efforts over the past decade. The principal advantage of a standard over a site specific risk assessment is the reduction of the effort required to obtain scientifically justifiable cleanup decisions. The concept of a soil standard ranges from a single unmodifiable target concentration of a given chemical in soil to a more flexible approach where some site specific variables are allowed to modify the standard.

The development of soil standards involves the linkage of a great number of theoretical chemical fate and transport equations to human and animal toxicologic dose response data. It is an enormously complicated undertaking for which there is currently no one solution agreed upon by the scientific community or among regulatory agencies.

The focus of this review is those models which predict that concentration of a chemical in soil which will have no adverse effects on human health. Other environmental targets (such as wildlife) will be considered in a separate project. Contaminants move from the source (soil) to a receptor (person) by numerous pathways and result in a dose of toxicant which is judged to be either above or below a level of concern for long term human health. The highest level in soil for which there is no predicted adverse human health effect is considered to be the standard.

In contrast to existing site risk assessments where media concentration measurements are possible, standard setting involves the creation of scenarios for yet to be encountered exposure situations. The suite of individual exposure pathways which are used to develop a scenario must be broad enough to encompass all future land uses of interest. While there is general agreement on many of the important pathways of human exposure from soil, such as incidental ingestion of soil, groundwater, and inhalation of volatiles, there is little consensus on the particular models which best describe these pathways.

One of the most important regulatory guidance documents for soil standards is the USEPA Office of Research and Development "Risk Assessment Guidance for Superfund: Volume 1 Human Health Evaluation Manual Part B" (USEPA 1991). This document is based on policies in the Final Rule of the National Oil and Hazardous Substances Pollution Contingency Plan, March 8, 1990. There are 11 human exposure pathways to toxic chemicals in soil listed in the Risk Assessment Guidance for Superfund. Models for quantifying these exposures, however, are only provided for 4 of them. The risk assessor is directed to look elsewhere for models for the remaining pathways.

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Numerous private sector and government entities have proposed strategies for soil risk assessment. All are subject to some degree of criticism. This paper presents a review of some important approaches gleaned from dozens of references. It also provides a synthesis of different methods in a sample approach which might be considered in the effort to develop a strategy useful in the cleanup of contaminated sites in New Jersey.

RISK ASSESSMENT METHODOLOGY

Quantitative health risk assessment is the process by which the probability of harm is estimated from environmental exposure to toxic chemicals. The National Research Council (NRC) in 1984 defined the overall terminology and is still the most widely cited reference for a description of the methodology (NRC 1984). The central idea in risk assessment is that there is some dose of a toxic chemical for which there are no or virtually no adverse health effects even with prolonged or lifetime exposure. This assumption is based upon observational (epidemiologic) or experimental (animal bioassay) data. Whether or not certain environmental exposure situations would be predicted to result in harm is a judgement based as much on policy and convention as on scientific fact. For example, the choice of an acceptable potential increase in the incidence of cancer or the size of an uncertainty or safety factor to apply to non-carcinogens are either policy decisions or decisions based on limited technical information. The utility of this approach, even though it is lacking in complete scientific justification, is that it produces a high degree of consistency for decisions in many different applications. In principle the cleanup of benzene from contaminated soil can be to the same degree of protection as is provided by the standard for benzene in drinking water.

The NRC described four steps in the risk assessment process, hazard identification, dose response assessment, exposure assessment, and risk characterization. Hazard identification is the type of adverse health effect which is caused by the chemical in question. Effects could be: liver damage, birth defects, cancer, metabolic disruptions or one of any number of systemic toxicologic outcomes. A single chemical may cause multiple hazards depending on dose. The USEPA has reviewed the literature on hundreds of chemicals and identified the hazard for each chemical associated with low level chronic exposure.

Dose response assessment is obtained from known chemical exposure data for the toxicologic endpoint (hazard identification) of concern. The dose response assessment is the most important of the biological information used in the construction of the risk assessment. Smaller doses result in effects in smaller percentages

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of animals or people. The point at which the dose is so small so as to cause no or negligible effect on the population under study is the benchmark which calibrates all risk assessments. For example, liver damage is not found to occur in a rat population below a dose of 2mg/kg-day of a given toxic chemical after lifetime exposure... The USEPA Integrated Risk Information System (IRIS) and Health Effects Assessment Summary Tables (HEAST) databases contain this information for most of the chemicals for which soil standards have been contemplated by either the USEPA or the state of New Jersey. In some cases the primary toxicology literature must be reviewed to develop benchmarks.

There are many point estimates of common exposure related variables such as soil ingestion rate, length of residence in a home, body surface area and weight which after much debate have been quantified and described in USEPA guidance documents. These point estimates do not describe the distribution of the exposure variables and discussions regarding many of these estimates still continue. However, for some variables such as ingestion of drinking water, reasonable distribution data are available.

Exposure assessment for some risk assessments is relatively straight forward. For drinking water standards, for example, the exposure assessment currently used is the assumption of an ingestion of two liters of water per day. Inhalation and dermal routes of exposure to contaminants in potable water are not currently considered in drinking water standards setting. For soil standards, many avenues of exposure have been considered by numerous agencies, individuals, and institutions. The exposure routes are often called pathways. Some chemicals may be volatile, leave the soil, enter the air and be inhaled by an individual living or working on the contaminated ground. Other chemicals may wash out of the soil and enter the groundwater and become part of a drinking water supply. Most chemicals will, to some extent, be involved in many different pathways. The physical and chemical properties of the agent, as well as the properties of the environmental media through which it travels, affect its predominance in one pathway or another. Chemical fate and transport modeling results in an estimated concentration of contaminant in an environmental medium such as air, water or food. This concentration then becomes the source of the human dose by ingestion, inhalation or dermal absorption. Each site of contamination is associated with a unique constellation of physical properties which results in a probability of human exposure which would be different from any other site with the same degree of contamination. A single set of standards for chemicals in soil necessarily involves the selection of typical site properties such as soil type or slope of the land. However, if the selection of model variable values is site specific then standards for the same chemical will differ from site to site.

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The risk characterization step is the combination of the dose response assessment with the exposure assessment. If, for example, 0.2 mg/kg-day is the dose of a chemical which will cause no harm, how much of this chemical can be in soil such that the dose will not be exceeded in a person by all pathways of exposure? In site specific risk assessments all exposures are summed to a total dose. The risk at this dose is reported based on the dose response information for that chemical. For the purpose of standard setting, equations are rearranged to solve for the concentration in a medium at a predetermined level of protection.

There are two quantitative approaches for risk assessment. For carcinogens, a low dose extrapolation model is used to describe the dose response relationship at environmental levels of exposure. The response is assumed to be linear with no threshold. This requires the selection of a de minimus level of risk at which to calculate a benchmark dose. For non-carcinogens, a safety or uncertainly factor is applied to the highest dose at which no effects are observed (NOAEL) in animals or people. There is assumed to be a threshold for non-cancer effects. The NOAEL divided by the uncertainty factor (usually between 10 and 1000) is expected to bring the benchmark dose below the threshold for human effects.

FATE AND TRANSPORT CONSIDERATIONS

No single set of fate and transport equations exist which can with great confidence predict the movement of a chemical in soil through multiple media such as air, water and food and ultimately to an internal dose to a person. The physicochemical and thermodynamic properties of a chemical result in interactions with soil which retard or enhance its ability to move in the environment. Most chemical fate models consider one medium at a time. For example, most air models do not address interaction with soil or water. They usually predict air concentration at some distance from a source such as a stack given particular meteorologic conditions. Chemicals may, however, move from soil to air and then be absorbed by the cuticle of a plant which is consumed and, therefore, becomes a dose. Boundary conditions between media must be estimated so that transfer between media can be calculated.

There are two fundamental approaches to chemical fate modeling; concentration or fugacity based. Concentration based models require a starting concentration estimate in a medium. Transport ratios from one medium to another result in the apportionment of the chemical mass into the respective media. This is accomplished algebraically by multiplying the starting concentration by transport factors to obtain the concentration in the next medium. Chains of factors will move the contaminant through linked environmental media such as air to soil to water to fish to people.

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The transport factors may either be linear or be described by an appropriate power function. Most of the existing modeling schemes use concentration based equations. Fugacity models, which are based on thermodynamic equilibria, can also predict such intermedium transfer. Chemical and medium properties determine the final equilibrium concentrations in multiple media. Fugacity models, however, depend on assumptions which may not be true for all or even most fate and transport problems. Assumptions of well mixed compartments and dispersion dominated chemical mobility are necessary. Situations for which convection and physical processes such as impaction predominate largely disrupt fugacity only based modeling and concentration based equations are called for.

MONTE CARLO ANALYSIS

Monte Carlo analysis is a computational technique which permits arithmetic or algebraic operations to be performed on equations whose inputs are probability distributions rather than single numbers. This is accomplished through iterative random sampling of the individual distributions and combination of each iteration's samples according to the mathematical form of the overall equation. The outcome of this procedure is itself a distribution reflecting the probability of any numerical solution to the equation. The practical implication of this approach for risk assessment is that risk (or risk-based soil concentrations) can be calculated using the entire distributional range for inputs which have significant variability in the population. The current methodology for estimating risk requires that inputs whose possible values are, in fact, distributed in the population be represented by a single numerical value (point estimate). Regardless of whether the point estimate is selected as the mean, an upper percentile estimate, or some other estimate of the distribution, no single value can adequately represent an entire distribution. Possible examples of such inputs include daily inhalation volume, soil ingestion rate, time spent inside and outside a residence, years lived in a given residence, body weight and food consumption rate. While Monte Carlo analysis holds promise for generating more realistic estimates of risk and risk-based standards, it is important to realize that this approach is no better than the input information on which it must rely. Therefore, incomplete or inaccurate distributional input data can result in faulty and misleading risk-based distributional estimates. At the present time, there is no guidance on the federal or state level for the proper protocol for selecting and combining distributional data for Monte Carlo analysis of risk. In addition, no consensus exists in the regulatory or scientific communities on default specifications for distributions of commonly used variables in risk-based standard setting.

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REVIEW OF APPROACHES FOR DEVELOPING SOIL STANDARDS

Overview

The USEPA Office of Research and Development has guidance for the development of risk-based preliminary remediation goals known as "Risk Assessment Guidance for Superfund: Volume 1 Human Health Evaluation Manual Part B" (USEPA 1991). A question arises as to the necessity of reviewing other non-superfund sources for additional information on soil risk assessment. It is recognized and stated in USEPA 1991 that other sources must be consulted to model site specific conditions not anticipated or defined in current Superfund publications. This point is expressed in numerous sections of the guidance, page 17: Remediation standards may be modified due to "the potential for human exposure from other pathways at the site"; page 19: "When risk-based preliminary remediation goals are to be calculated on site-specific conditions, the risk assessor should modify the full equations, and/or develop additional ones."; page 20: "The risk-based preliminary remediation goal for each chemical should be calculated by considering all of the relevant exposure pathways. Total risk refers to the combined risk for a single chemical from all exposure pathways for a given medium"; page 23: "Additional exposure pathways (e.g., inhalation of particulates, inhalation of volatiles, ingestion of food crops contaminated through airborne particulate deposits, consumption of groundwater contaminated by soil leachate) are possible at some sites."; page 25: "Additional exposure pathways (e.g., dermal exposure) are possible at some sites... In the default case illustrated below, intakes from the three exposure pathways are combined"; page 51: "Risk equations for exposure pathways that are not listed below can be developed and combined with those listed, in particular, dermal exposure and ingestion of groundwater contaminated by soil leachate".

Non-Governmental Models

A review article published by Jessiman (1992) compared the output of ten soil standard models (British Columbia Assessment Criteria, Alberta Soil Guidelines, Ontario Decommissioning Guidelines, Quebec ABCs, NJ acceptable soil contaminant levels, USEPA Public Health Evaluation Manual, US Army Primary Pollutant Limit Values, California Site Mitigation Decision Tree, California Technical Standard, and Aid for Evaluating the Redevelopment of Industrial Sites (AERIS)) when applied to one site in Vancouver. He observed that the models fell into two categories; those with one cleanup number for each chemical regardless of site conditions and those which would accept site specific conditions as determinants of the chemical specific cleanup number.

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The two approaches were called absolute and relative respectively. The absolute approach will result in the same chemical concentration at different sites but different risks. The relative approach will produce different concentrations but the same risks for the same chemical at different sites. The absolute approaches are easy to use while the relative approaches are data intensive. The two methods produced cleanup concentrations for the same chemical which differed by several orders of magnitude. In a summary table of a comparison of significant pathways of exposure across all models it was found for inorganics that ingestion accounted for 99% of all exposure. The other tabulated pathways were dust inhalation, vapor inhalation, and dermal uptake from soil and water. In contrast, for organics, dermal contact with soil and water accounted for about 50% of the dose, with ingestion making up most of the remainder. For both inorganics and organics the ingestion component was divided into soil, water, and crop. Of these three categories, crop exposure was most often the largest contribution to ingestion for the total of 23 chemicals examined.

In Paustenbach (1992) the point is made that there are many different and conflicting approaches to developing cleanup levels within the states and federal government. In an attempt to provide a common metric for site analysis, a list of the seven most important exposure scenarios is presented. They are: residential, industrial, agricultural, recreational, groundwater, wildlife and aquatic species, and runoff/erosion of particulates to waterways. The pathways of exposure within these scenarios relevant to human health are: soil/dust ingestion, dermal uptake, garden vegetable and crop ingestion, ingestion of fish which have been contaminated by surface runoff, uptake by grazing animals, dust inhalation, and groundwater contamination. Paustenbach ranks incidental ingestion of soil as the most important route of exposure followed by dermal contact and ingestion of garden vegetables.

A multimedia chemical transport and transformation model, GEOTOX, was used by McKone (1991) to estimate concentrations of contaminants in air (particulate and gas phase), soil, drinking water and surface water. There are different exposure pathways pertaining to each media considered as a source. For example, there are three pathways associated with contaminated air and five with contaminated soil. Those specific to soil are: indoor inhalation of soil contaminants; ingestion of fruits, vegetables, and grains; ingestion of milk and meat contaminated by soil; soil ingestion; and dermal uptake from soil. The model was run for arsenic, tetrachloroethylene and trinitrotoluene. It was found that the ingestion pathways of fruit, vegetables, and grains were the most important contributors to dose.

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RISK ASSISTANT, developed by Hampshire Research Institute Inc. (Hampshire 1991), is a microcomputer-based software system which contains formula for 14 pathways of exposure. This software was funded by USEPA with contributions and reviews by NJDEPE and the California Environmental Protection Agency. It is a generalized risk assessment package and is not specific for soil. As a consequence, the starting point for the analysis is a concentration in a medium such as indoor air, water, or fish. The necessary intermedia transport equations are for the most part not included. The pathways considered are: ingestion of drinking water, inhalation of vapors while showering, ingestion of homegrown meat and dairy products, ingestion of homegrown fruits and vegetables, inhalation of vapors inside the residence and vapors outside the residence, ingestion of fish and shellfish, ingestion of water while swimming, inhalation of particulates inside the residence and outside the residence, and ingestion of soil by a child and by an adult. The media considered are: groundwater, surface water, biota, soil, air, and sediment.

ASTM (American Society for Testing Materials) has produced a second draft of a document entitled ASTM Guide for Risk-Based Corrective Action at Petroleum Release Sites (ASTM 1994). This does not currently represent an ASTM standard and is undergoing peer review. It is not available outside of the ASTM technical committee and the peer review group. The goal of the task group is "to produce a standard that is accepted by state regulatory agencies and can be incorporated in corrective action programs." It has been developed for gasoline and fuel oil spill and tank leaks. The fate and transport equations, however, are suitable for other volatile and semivolatile compounds. For the pathways considered, approaches used in this document are consistent with guidelines contained in the USEPA "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Part A" (USEPA, 1989). The pathways are:

- Inhalation of vapors
- Ingestion of groundwater
- Inhalation of outdoor vapors originating from dissolved hydrocarbons in groundwater
- Inhalation of indoor vapors originating from dissolved hydrocarbons in groundwater
- Ingestion of surficial soil, inhalation of outdoor vapors and particulates emanating from surficial soils, and dermal absorption resulting from surficial soil contact with skin
- Inhalation of outdoor vapors originating from hydrocarbons in subsurface soils
- Inhalation of indoor vapors originating from subsurface hydrocarbons
- Ingestion of groundwater impacted by leaching of dissolved hydrocarbons from subsurface soils

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State Models

The state of New Jersey proposed rules for the cleanup of contaminated sites in 1992 (NJR 1992). Numerical soil standards were proposed for over 100 contaminants. The pathways considered were soil ingestion, contamination of ground water and inhalation. It was also stated that contamination of surface water bodies due to erosion of soil could be considered due to contaminant incorporation into the food chain. Comments were requested on how best to model this pathway. Vapor migration into structures was approached with a trigger level soil gas concentration which would require further investigation. This proposed rule was withdrawn and work is proceeding to revise the proposed methodology including the incorporation of additional important pathways of exposure, and site specific considerations.

A joint study issued by the USEPA, NJDEPE, and New York State Department of Environmental Conservation (NYDEC), entitled Incineration 2000 Phase II Report and published in January 1993 (NYDEC 1993), evaluated the impact of hundreds of incinerators in the New York/New Jersey metropolitan area on human health. Many indirect pathways were considered in addition to direct inhalation of emissions. These included ingestion of outdoor soil, ingestion of indoor dust, breast milk, homegrown vegetables, freshwater fish, saltwater fish and shellfish. These equations would be equally valid for soil risk assessment. The highest risks were associated with inhalation.

The state of California has developed a model (CalTOX 1993) which is still in draft stage but is potentially the most advanced of all reviewed models. Intake equations are the same as those used by the USEPA with two modifications. First, there is a multimedia total exposure model and second it is used stochastically (not a single risk level but a Monte Carlo derived distribution of risk is presented). CalTOX contains fugacity based multimedia fate and transport equations. Fugacity equations are based on mass flux (movement) between media and on the physicochemical and thermodynamic properties of the pollutant. The advantage of this approach is that multiple media can be analyzed at once and there is no double counting resulting from a single initial concentration moving to several different media simultaneously. That pollutant mass which is available from the soil to the air is subtracted from the pollutant mass which moves to the groundwater. Fugacity based equations also provide a check on the overall media transport logic. With concentration based equations it is possible through their inherent uncertainty that more mass could end up in the air than was ever present in the contaminated soil. This could not happen with a fugacity approach; CalTOX imposes conservation of mass and accounts for gains or losses from each compartment as well

as for the entire system. There are 23 pathways of human exposure in CalTOX:

- Inhalation of gases and particulates in outdoor air
- Inhalation of gases and particulates transferred from outdoor air to indoor air
- Inhalation of soil vapors that migrate to indoor air
- Inhalation of soil particles transferred to indoor air
- Indoor inhalation of contaminants transferred from tap water
- Ingestion of fruits, vegetables, and grains contaminated by transfer of atmospheric chemicals to plant tissues
- Ingestion of meat,milk, and eggs contaminated by transfer of contaminants from air to plants to animals
- Ingestion of meat, milk, and eggs contaminated through inhalation by animals
- Ingestion of mother's milk contaminated by inhalation of air
- Human soil ingestion
- Ingestion of fruits, vegetables, and grains contaminated by transfer from soil
- Ingestion of meat, milk, and eggs contaminated by transfer from soil to plants and animals
- Ingestion of meat, milk, and eggs contaminated through soil ingestion by animals
- Ingestion of mother's milk contaminated by ingestion of meat and vegetables
- Ingestion of tap water
- Ingestion of irrigated fruits, vegetables, and grains
- Ingestion of meat, milk, and eggs from animals consuming contaminated water
- Ingestion of fish and sea food
- Ingestion of surface water during swimming or other water recreation
- Ingestion of mother's milk contaminated by ingestion of water
- Dermal contact with soil
- Dermal contact in baths and showers
- Dermal contact while swimming

USEPA Models (Superfund)

The Risk Assessment Guidance for Superfund, Part B (USEPA 1991), reflects current EPA guidance for developing soil cleanup levels. Pathways of exposure are suggested for two land use scenarios, residential and commercial/industrial. Default equations are only provided for some of the pathways. It is the responsibility of the risk assessor to find appropriate equations for the other pathways in these two generic exposure scenarios. For the residential land use scenario the following pathways are given. Default equations are only provided in USEPA 1991, for those in capitals.

- •INGESTION OF SOIL
- •Inhalation of Particulates
- •Inhalation of Volatiles
- •Exposure to Ground Water Contaminated by Soil Leachate
- •Ingestion Via Plant Uptake
- •Dermal Absorption from Gardening

Pathways for the commercial/industrial land use scenario:

- •INGESTION OF SOIL
- •INHALATION OF PARTICULATES
- •INHALATION OF VOLATILES
- •Exposure to ground water contaminated by soil leachate
- •Inhalation of particulates from trucks and heavy equipment

Draft Soil Screening Level Guidance, USEPA September 1993 (USEPA 1993) is a response to the USEPA Administrator's request for a 30 day study to outline options for accelerating the rate of cleanups at Superfund sites. There are changes in this guidance from USEPA 1991, the existing guidance. In USEPA 1993, it is explicitly stated that soil saturation by a chemical is a trigger level for cleanup. This is not a health based effect but a property of the soil and chemical's physical properties. There is also a separate child ingestion rate of 200 mg/day for non-carcinogens which is higher than the integrated rate of 114 mg-yr/kg-day which is reported in USEPA 1991. A quantitative approach for the soil to groundwater pathway is given. It consists of four equations, each appropriate to a screening level, which represent different levels of treatment of the same site. The simplest, most stringent, and least data intensive equation is level 1. If this level is above the level found at the site than no further work is required. The higher level equations are more data intensive and site specific but also are likely to result in higher cleanup concentrations. Monte Carlo analysis is suggested for use in this guidance but only for the groundwater pathway. In summary, the pathways considered are:

- •Ingestion of soil
- •Inhalation of volatiles and fugitive dusts
- •Migration of contaminants through soil to an underlying potable aquifer

Assessing Potential Indoor Air Impacts for Superfund Sites, September 1992 (USEPA 1992) was developed by EPA to assess the risk for occupants of buildings near Superfund sites. Contaminated water or soil can lead to volatilization of chemicals and movement through the soil to building interiors. Pressure differences between buildings and the surrounding soil gas can lead to the withdrawal of soil gas to interior living spaces. Wind speed, indoor-outdoor temperature differences, vented equipment such as

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bathroom and kitchen fans or oil and gas furnaces and fireplaces can lead to less than ambient pressures in the lower areas of buildings. Typically pressure differences are small, between 1 and 10 pascal. This difference can lead, however, to the building sucking in soil gases through cracks and openings in below grade walls. Several tiers of screening equations lead to quantitative estimates of the relationship between soil and or groundwater contamination to soil gas and, thereby, interior concentrations of contaminants. The only pathway considered in this document is soil gas to building interiors.

USEPA Models (Non-Superfund)

Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions, January 1990 (USEPA 1990) is an Interim Final EPA report with quantitative models sufficient for a multi-pollutant, multimedia human exposure assessment. The focus of this document is risk assessment of stationary source combustion facilities. There are pathways, however, which consider the effect of emissions which are deposited on the ground. The pathways for human exposure relevant to soil risk assessment are:

- Daily intake from plants
- Daily intake from contaminated animal tissue
- Soil ingestion
- Dermal intake
- Surface water intake
- Fish contaminated from surface soil runoff

Promulgated regulations which have relevance to quantitative soil risk assessment appear under the authority of the Clean Water Act. This act mandates the USEPA to develop regulations to protect the public health and the environment from the adverse effects of pollutants that may be present in sewage sludge. The Sludge Risk Assessment Branch of the Office of Science and Technology of the Office of Water developed the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) (USEPA 1992a). In these regulations there is a basis and background which describes 14 pathways of human exposure to land applied sewage sludge. Many of these pathways are relevant to soil risk assessment as needed for contaminated site cleanup. The basis and background is very extensive (2000 pages) and documents the quantitative approach and data requirements for the pollutant fate and transport analysis. The application of sewage sludge to farmland presents a fate and transport modeling problem which for many purposes is analogous to a contaminated site. Those pathways which are used to examine pollutant transport to a human receptor from surface application of sludge and are useful for soil risk assessment are:

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- Plant uptake and ingestion of plants
- Uptake in livestock and ingestion by people
- Surface runoff into streams, uptake in fish and fish consumption by people
- Soil to air and inhalation
- Soil to groundwater

Discussion

The reviewed models indicate a large variation in approaches to estimating human exposure from contaminated land. There are a core of 5 pathways (ingestion of soil, inhalation of vapors and particulates, ingestion of food products and water) which predominate in most exposure assessments. The algorithms, however, differ. Very little of the fate modeling has been validated. It is, therefore, difficult to identify superior approaches. Not all of the exposure assessments start with soil as the source of the contamination. At some point, however, soil enters into the web of exposure routes and these non-soil targeted references (e.g., air source models) can be utilized. Only CalTOX has fugacity based equations. This is an advantage for multimedia modeling but requires complex software for implementation. Many of the concentration based equations used in the other approaches can be solved with a hand calculator. No one of the reviewed risk assessment approaches is in itself comprehensive. Deficiencies or omissions of certain pathways are often acknowledged by the authors with instructions to look elsewhere. This is particularly true for USEPA guidance. Therefore, in order to satisfy the requirement of a reasonably comprehensive exposure assessment to derive soil standards, it will be necessary to combine a number of approaches.

SAMPLE APPROACH, SYNTHESIS[1]

The following list of fate and transport equations encompasses the most likely exposure scenarios for residents of New Jersey to pollutants found at contaminated sites. The equations were for the most part selected from the references which have been described earlier in this document. There are now six more pathways included in the approach than there were proposed in NJR 1992. For two pathways, soil gas to basements and soil to groundwater equations were derived by staff of the Division of Science and Research or their contractors specifically for New Jersey conditions.
The pathways and their origin are as follows:

[1]The information provided in this section is not sufficient by itself to calculate chemical specific values. Further documentation can be provided on request.

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Pathway Model	Reference
Soil ingestion	USEPA 1991
Dermal absorption from soil	USEPA 1989
Particulate inhalation	USEPA 1991
Volatile inhalation	USEPA 1991
Vegetable consumption	Hampshire 1991
Fruit consumption	Hampshire 1991
Soil gas to basements	Sanders & Stern 1994
Soil to groundwater	Korfiatis & Talimcioglu 1991
Erosion to sediments	USEPA 1992a
Soil saturation	USEPA 1991

These pathways are described by 27 equations as listed in Tables 1,2 and 3. For each pathway there may be as many as four equations which describe residential and non-residential exposure conditions for carcinogens and non-carcinogens. The difference between residential and non-residential is the amount of time of exposure and the assumption of children living on a residential site. A soil standard is derived by using typical site conditions and running all the models. The standard is determined by the pathway producing the most stringent contaminant concentration in soil. If this standard is exceeded at any particular site it is possible to use site specific conditions for a more accurate risk determination. Using all pathways for 105 chemicals (those considered by New Jersey in the NJR 1992 proposal) the trigger soil concentrations ranged from 0.000048 mg/kg for endosulfan in a residential scenario to 410,000 mg/kg for zinc for a non-residential condition. Detection limit, ecological considerations and background levels have not yet been incorporated into this standard setting scheme.

Pathway Descriptions

Soil Ingestion

Adults ingest a small but measurable amount of soil as a result of everyday activities. Exposure scenarios include the transfer of soil from hands to food, or food which has been in contact with soil. For children, this pathway is more important. Small children explore their environment with their hands and mouths resulting in the incorporation of soil into their diets. This is a widely studied route of exposure with many adequate models for its quantification.

Dermal Absorption

A portion of the contamination present in the soil will pass through the skin and enter the blood and thereby become a dose. The chemical properties of the agent, the amount of soil per unit

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area of skin, and the length of time of contact are the major variables which determine dose. In general the more fat soluble the contaminant the more the absorption.

Particulate Inhalation

Soil may be a source of particulate matter to the air, which is then inhaled. Modeling approaches include wind driven and vehicle caused dust generation. Outdoor soil may be become part of indoor dust. Both outdoor and indoor sources of soil are modeled to estimate a dose from this route. Variables include particle size, amount of vegetative cover, precipitation, and friability of the soil surface.

Volatile Inhalation

Chemical properties, such as vapor pressure, determine the importance of this route of exposure. Contaminated soil may result in elevated concentrations of certain solvents in the ambient air. Modeling has been conducted to predict on site, outdoor concentrations. Assumed average wind-speed is also an important variable.

Vegetable and Fruit Consumption

Vegetables and fruits grown in contaminated soil may take up some of the contaminant which is then ingested with this food. The worst case for vegetables is for root crops which contain lipids and retain chemicals with lipophilic properties. There is experimental justification for this pathway derived from food crops grown in contaminated soil. For fruits to become contaminated there is a partition necessary from soil into the transpiration stream of the plant. Fruits for the purpose of this modeling are considered to be aerial edible portions of the plant.

Soil Gas to Basements

This is a special case of the soil volatilization pathway where soil contaminants volatilize and enter buildings through subsurface walls. Reductions in air pressure inside buildings due to numerous reasons will cause soil vapors to enter the structure. The model accounts for ventilation and a first order degradation of the source.

Erosion to Sediments

This pathway leads to a dose by uptake of the contaminant into fish. It is very dependant on assumptions of site size, distance to a waterway, slope of the land, and size of drainage basin. Bioconcentration factors are used to estimate fish concentrations of contaminants. Assumptions regarding portion of diet attributable to locally caught fish are also required.

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Soil Saturation

This is the only equation which does not represent a route of exposure to soil contamination. The concentrations predicted by this model determine at what point pooling of the contaminant will occur. At soil saturation levels the volatilization model is no longer valid because neither the partial pressure of the contaminant nor air can be determined in the interstitial soil pore spaces.

ISSUES AND CONCLUSIONS

A justification for remediating the chemical contamination of soil down to the levels of cleanup standards is that soil may act as a vehicle for administering a dose of that chemical to people. The process of quantifying this event requires the use of data and assumptions of uneven quality and variability. Uncertainties require choices among competing assumptions, and this process fosters debate. The major areas for decision making in the soil standard development process are in the choice of exposure scenarios, pathways, fate models, and parameters.

An exposure scenario is one of a small number of major classes of future activities which predisposes participants in those activities to have contact with chemical contamination. Exposure scenarios have been created for non-residential and residential situations. Exactly what types and how much of different activities make up the scenario is a matter of judgement. Questions such as whether or not truck traffic is likely to occur on a typical non-residential site and how many years the average person lives in one home are examples of the decisions relevant to non-residential and residential scenarios, respectively. Additional exposure scenarios could be constructed for agricultural or recreational activities.

Pathways of exposure are the components of exposure scenarios. There are generally between 5 and 20 pathways per scenario. Some or most of the pathways may overlap between scenarios. All pathways of the sample approach given in this paper overlap between residential and non-residential scenarios, with the exception of fruit and vegetable consumption which only appears in the residential scenario. The quantitative expression of the same pathway, ingestion of soil for example, may differ between different scenarios. The residential scenario includes children and the non-residential includes only adults. Pathway selection also depends on regional considerations. In New Jersey, for example, groundwater, surface water, and aquatic systems are perhaps more important to consider than in drier states.

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Each pathway could be described by numerous alternative fate models. The soil to groundwater pathway has been quantitatively described by many different models. Often the difference is a result of the capabilities of various models to accommodate site specific data. Therefore, a decision on how much site specific data to require or allow will determine the selection of a model. Models also differ with respect to their foundation in chemical and thermodynamic theory. Either fugacity or concentration based equations can be applied to the same site data for the purpose of fate and transport analysis. These choices are made by the analyst or policy-maker. Models function by the mathematical combination of numerous point estimates of variables such as organic carbon content of soil, years spent at a site, vapor pressure of a chemical, etc. There is an option of using distributions of these variables instead of point estimates. This would require probabilistic techniques such as Monte Carlo analyses.

There are often ten to one hundred variables or parameters needed to implement any particular pathway model. For soil remediation standards development an estimate is needed for every one of these before the calculation can be completed. Because standards are created for future conditions for which no site specific measurements are available, they all must be estimated for a typical site. The parameters fall into human activity, site characteristics, and chemical property categories. Human activity includes estimates of dietary intake (e.g., fish), residence time, working hours, inhalation rate, soil ingestion rate, etc. Site characteristics are such parameters as soil type, weather, proximity to water, slope of the land, vegetative cover, and site size. Chemical properties include toxicity, vapor pressure, octanol-water partition coefficient, and Henry's Law constant.

Variability and uncertainty surround each of these parameters. They could all take on any one of a number of values and herein lies the substance of debate. Many hundreds of independent judgements are required for the generation of a soil standard for a single chemical. Not all of the variables have equal importance in determining the numeric value of the outcome. Errors or misjudgments in some variables would hardly effect the result while for other variables the effect would be large. A sensitivity analysis would be required to distinguish between the two.

The Department of Environmental Protection and Energy has reviewed the numerous options and approaches currently available for the many quantitative aspects of soil remediation standards development, and has presented many of these procedures in this document. The Department looks forward to exploring these various approaches further with the Environmental Risk Assessment and Risk Management Study Commission in the context of P.L. 1993, c.139.

TABLE 1
PATHWAY EQUATION NUMBERS/NAMES FOR SAMPLE APPROACH

Equation #	Pathway Name
1	Soil ingestion, residential, carcinogen
2	Soil ingestion, residential, non-carcinogen
3	Soil ingestion, non-residential, carcinogen
4	Soil ingestion, non-residential, non-carcinogen
5	Soil ingestion, child, residential, carcinogen
6	Soil ingestion, child, residential, non-carcinogen
7	Dermal, residential, carcinogen
8	Dermal, residential, non-carcinogen
9	Dermal, non-residential, carcinogen
10	Dermal, non-residential, non-carcinogen
11	Particulate inhalation, residential, carcinogen
12	Particulate inhalation, residential, non-carcinogen
13	Particulate inhalation, non-residential, carcinogen
14	Particulate inhalation, non-residential, non-carcinogen
15	Volatilization, residential, carcinogen
16	Volatilization, residential, non-carcinogen
17	Volatilization, non-residential, carcinogen
18	Volatilization, non-residential, non-carcinogen
19	Vegetables, residential, carcinogen
20	Vegetables, residential, non-carcinogen
21	Fruits, residential, carcinogen
22	Fruits, residential, non-carcinogen
23	Gas to basements
24	Soil to groundwater

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25	Erosion, carcinogen
26	Erosion, non-carcinogen
27	Soil saturation

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TABLE 2
PATHWAY EQUATIONS FOR SAMPLE APPROACH

1. $C_s = \frac{(RL)\,(BW)\,(Dy)\,(L)}{(SF)\,(EFr)\,(EDr)\,(Ra)}$

2. $C_s = \frac{(Dy)\,(BW)\,(RfD)}{(EFr)\,(Ra)}$

3. $C_s = \frac{(RL)\,(BW)\,(Dy)\,(L)}{(SF)\,(EF)\,(ED)\,(Ro)}$

4. $C_s = \frac{(Dy)\,(BW)\,(RfD)}{(EF)\,(Ro)}$

5. $C_s = \frac{(RL)\,(BWc)\,(Dy)\,(L)}{(SF)\,(EFr)\,(EDrc)\,(Rc)}$

6. $C_s = \frac{(Dy)\,(BWc)\,(RfD)}{(EFr)\,(Rc)}$

7. $C_s = \frac{(Dy)\,(BW)\,(RL)\,(L)}{(EFr)\,(SA)\,(SF)\,(AF)\,(ABS)\,(EDr)}$

8. $C_s = \frac{(Dy)\,(BW)\,(RfD)}{(EFr)\,(SA)\,(ABS)\,(AF)}$

9. $C_s = \frac{(Dy)\,(BW)\,(RL)\,(L)}{(EF)\,(SA)\,(SF)\,(AF)\,(ABS)\,(ED)}$

10. $C_s = \frac{(Dy)\,(BW)\,(RfD)}{(EF)\,(SA)\,(ABS)\,(AF)}$

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11. $$C_s = \frac{(Dy)\,(BW)\,(PEF)\,(RL)\,(L)}{(EFr)\,(IRr)\,(Si)\,(EDr)}$$

12. $$C_c = \frac{(Dy)\,(BW)\,(PEF)\,(RfDi)}{(EFr)\,(IRr)}$$

13. $$C_s = \frac{(Dy)\,(BW)\,(PEF)\,(RL)\,(L)}{(EF)\,(IR)\,(Si)\,(ED)}$$

14. $$C_s = \frac{(Dy)\,(BW)\,(PEF)\,(RfDi)}{(EF)\,(IR)}$$

15. $$C_s = \frac{(1x10^{-10})\,(Koc)\left(2.5x10^{9}x\dfrac{0.012}{0.35+\dfrac{4.2x10\text{-}5Koc}{H}}\right)\frac{1}{2}}{H(Si)}$$

16. $$C_s = \frac{(RfDi)\,(Koc)\,4.9x10^{-5}\left(2.5x10^{9}\dfrac{0.012}{0.35+\dfrac{4x10^{-5}(Koc)}{H}}\right)^{\frac{1}{2}}}{H}$$

17. $$C_s = \frac{1.4x10^{-10}\,(Koc)\left(2.5x10^{9}x\dfrac{0.012}{0.35+\dfrac{4.2x10^{-5}(Koc)}{H}}\right)\frac{1}{2}}{H(Si)}$$

18. $$C_s = \frac{(RfDi)\,(Koc)\,5.1x10^{-5}\left(2.5x10^{9}x\dfrac{0.012}{0.35+\dfrac{4.2x10^{-5}(Koc)}{H}}\right)\frac{1}{2}}{H}$$

19. $$C_s = \frac{(RL)\,(BW)\,(L)\,(Dy)\,(Koc)\,(OC)}{(SF)\,(EDr)\,(EFr)\,(Rv)\,(Fv)(10^{0.77(\log Kow)-1.52}+0.82)}$$

20. $$C_s = \frac{(RfD)\,(BW)\,(Koc)\,(OC)}{(Rv)\,(Fv)(10^{0.77(\log Kow)-1.52}+0.82)}$$

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21. $$C_s = \frac{(RL)\,(BW)\,(L)\,(Dy)\,(Koc)\,(OC)}{(SF)\,(EDr)\,(EFr)\,(Rf)\,(Ff)\,(0.784 - ((\log(Kow) - 1.78)^2 / 2.44))}$$

22. $$C_s = \frac{(RfD)\,(BW)\,(Koc)\,(OC)}{(Rf)\,(Ff)\,(0.784 - (\log(Kow) - (1.78)^2 / 2.44))}$$

25.* $$C_s = \frac{(12)\,(KDsw + 62,500)}{(SF)\,((BCF)\,(FM)\,(Pf)\,(0.04) + 2)}$$

26. $$C_s = \frac{(RfD)\,(1.2 \times 10^7)\,(KDsw + 62,500)}{(BCF)\,(FM)\,(Pf)\,(0.04) + 2}$$

27. $$C_s = (Kd)\,(Sol)\,(nm) + (Sol)\,(Om)$$

*Equations 23 and 24 are on software

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TABLE 3
PARAMETER VALUES FOR SAMPLE APPROACH

Symbol	Definition	Value[2]	Units
ABS	Absorption factor	0.01 organics 0.001 metals	Unitless
AF	Adherence factor	$2x10^{-6}$	kg/cm^2
BCF	Biological concentration factor	chemical specific	L/Kg
BW	Body weight, adult	70	Kg
BWc	Body weight, child	15	Kg
Cs	Soil standard	chemical specific	mg/Kg
Dy	Days per year	365	days/yr
ED	Exposure duration, non-residential	25	yrs
EDr	Exposure duration residential	30	yrs
EDrc	Exposure duration child, residential	6	yrs
EF	Exposure frequency	250	days/yr
EFr	Exposure frequency, residential	350	days/yr
Ff	Fraction of dietary fruit which is contaminated	0.3	dimensionless
FM	Food chain multiplier	1	dimensionless
Fv	Fraction of vegetables contaminated	0.4	dimensionless
H	Henry's law constant	chemical specific	$atm-m^3$
IR	Inhalation rate non-residential	20	m^3/day
IRr	Residential inhalation rate	15	m^3/day
Kd	Soil-water partition coefficient	chemical specific	cm^3/g

[2]Reference for all numeric values is USEPA 1989 and 1991. Reference for chemical specific entries is Hampshire 1991.

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Koc	Organic carbon partition coefficient	chemical specific	cm^3/g
KDsw	Partitioning coefficient between solids and liquids within the stream	chemical specific	L/kg
Kow	Octanol-water partition coefficient	chemical specific	dimensionless
L	Lifetime	70	yrs
nm	Soil moisture content	0.16	dimensionless
OC	Organic carbon content of soil (fraction)	0.001	dimensionless
Om	Soil moisture content	0.2	L-water/kg-soil
PEF	Particulate emission factor	$4.6x10^9$	m^3/Kg
Pf	Ratio of pollutant concentration in edible fish to whole fish	0.5	dimensionless
Ra	Adult residential soil ingestion rate	$1x10^{-4}$	Kg/day
Rc	Child soil ingestion rate	$2x10^{-4}$	Kg/day
Rf	Rate of fruit consumption	0.14	Kg/day
RfD	Reference dose	chemical specific	mg/Kg/day
RfDi	Reference dose, inhalation	chemical specific	mg/Kg/day
RL	Acceptable incremental cancer risk level	$1x10^{-6}$ [3]	unitless
Ro	non-residential adult soil ingestion	$5x10^{-5}$	Kg/day
Rv	Consumption rate of vegetables	0.2	Kg/day
SA	Arm surface area	2,300	cm^2/event
Si	Slope factor inhalation	chemical specific	$(mg/kg-dy)^{-1}$
SF	Slope factor	chemical specific	$(mg/kg-dy)^{-1}$
Sol	Solubility	chemical specific	mg/L water

[3] $1x10^{-6}$ is derived from S1070 pending review by the Environmental Risk Assessment and Risk Management Commission

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April 8, 1994

Environmental Risk Assessment and
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Legislative Office Building
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Trenton, NJ 08625-0068

RE: Written Testimony
Scientific Basis for 10^{-6} Remediation Standard

Dear Commission Members:

I have provided oral testimony, w ranscript on Thursday March 10, 1994, I will not repeat that testimony exce or two paragraphs:

> To investigate the scientific basis for 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 Wiener. Commissioner Wiener said, "There is no scientific basis", he continued to say that risk level is something that should be legislated. In other words the one-in-a-million standard is political.
>
> As a practical matter the department has already had to retract the one-in-a-million risk level for arsenic, own carcinogen. During January of 1993 the Department set the level rsenic at 2 mg/kg. Then, during January of 1994 the Department raised level to 20 mg/kg. It seems the one-in-a-million risk of 2 mg/kg, made nat the natural soil in New Jersey exceeded the cleanup standard. The A stant Commissioner of NJDEPE, Lance Miller has authored an article[1] stating that natural soils in New Jersey vary from 0.02 to 48.9 mg/kg.

The NJDEPE has already adopted a one-in-a-million risk level for setting the informal cleanup criteria (except arsenic), and as a basis of withdrawn regulatory proposals. This is the same State Agency which owns and operates recreational lakes and marinas, where the risk of death from boating accidents is 1.19×10^{-2}.

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[1] Miller, Lance, 1993, Site Remediation News, v.5 no. 1, pg. 3

The use of one-in-a-million risk level for exposure to chemicals as a remedial action standard just does not make sense.

By reference in this letter I include as part of my written testimony excerpts from the book "Toxic Terror: The Truth Behind the Cancer Scares", by Elizabeth M. Whelan, Sc.D., M.P.H. Those excerpts which are to be read and considered as part of the testimony are Chapter 1, pages 41 to 90 inclusive, and the Appendix, pages 441 to 467 inclusive. The included portions are marked for your quick reference. (This unusual step of including portions of a published book was taken, because the copyright royalty made xerox of the portions more expensive than outright purchase of the required 15 copies.)

The selected portions of this book provide a good, referenced overview of the issues which are central to setting risk levels, and interpreting cancer incidence studies. In my opinion the Commission should discuss the uncertainty and errors inherent in any cancer study made on animals and then extrapolated to humans. Significant weight should be given to evidence of cancer-risk deduced from occupational exposure records. In my opinion the included portions of the enclosed book provides a basis for beginning that discussion.

On the topic of risk assessment methodology I can not offer the opinion of one who routinely performs these calculations. But as a scientist it does not make sense that redundant conservative assumptions are necessary in performing these assessments. The risks we face every day far exceed the initial "one-in-a-million" assumption. Compounding this with redundant assumptions wastes precious monetary resources in cleanup, without providing any measurable benefit. There are limited resources available for cleanup, we should use correct assumptions which then allow us to concentrate those dollars into those areas which need the most attention.

Finally, please consider your task carefully as scientists, examine the facts and let the facts speak for themselves. Rational thought should prevail in setting the appropriate risk level. In my opinion a range in risk-level makes sense. USEPA uses 10^{-4} to 10^{-6} as an acceptable range, it makes sense that this should also be acceptable in the State of New Jersey.

Sincerely,

J. Mark Zdepski

enclosure: Book

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