The Honorable Carol M. Browner  
Director, US Environmental Protection Agency  
401 M Street SW  
Washington, DC 20460

Director Browner:

This letter is stimulated by my after reflections upon two experiences serving with EPA’s Risk Assessment Forum as an academic technical expert evaluating the risk-assessment process, and its resulting reports concerned with toxic waste incineration. These exercises, I judge, were not successful, and their results not likely to help with sensible decisions. I discuss the problems leading to this conclusion, and suggest reforms.

Respectfully,

Halstead Harrison  
Professor, Atmospheric Sciences  
University of Washington  
Seattle, WA 98195-1640  
<harrison@atmos.washington.edu>

Public concern and congressional mandate require assessments of risks to public health associated with toxic waste incineration. A consulting industry provides these assessments, following guidelines from the Environmental Protection Agency [EPA].

Responding to the national interest, new money flows into the science of risk assessments, and new research improves the precision and depth of the data and of our understanding of the many processes affecting risks. The evolution of public concerns is also dynamic, but this process has been marked by partiality and litigation. As each new guideline-influenced assessment appears ... too often after the facilities are built and the momentum of commitment too ponderous to reverse ... critics appear to challenge both the assessment and the facilities on grounds of faulty protocols and neglected risks. This irritates managers facing pressing choices about what to do with the toxic wastes, who are frustrated by regulatory mandates that not unreasonably appear to be transitory and politicized.
The "Old Paradigm":

As they evolved through about 1996, guidelines for risk assessments of toxic waste incineration progressively concentrated on emissions of mercury, cadmium, and lead, and certain organic carcinogens, particularly dioxins, furans, and related chlorinated polycyclic molecules. Ironically, some of these molecules are not only inherent in the raw toxic wastes but may also be produced when chlorinated compounds [most plastics, insecticides, and herbistats] are burned at intermediate temperatures [400-600°F].

It has been thought that the most likely pathway through which emitted metals and persistent carcinogens may affect human health is through deposition onto the soil and leafy food crops, followed by biological concentration and accumulation in animal and human fatty tissue. Formal risk assessments typically estimate the incremental cancer risks through this path to be one or fewer "extra deaths" per million persons exposed over a lifetime [1:10^6]. Note for contrast that about a third of us die of cancer [1:3]. Many other natural risks in our lives [tornados, lightning, hurricanes, ..] also carry risks to the general population on the order of 1:10^6, and this level is generally thought "acceptable", at least by those not living in affected communities.

These latter, however, typically divide into advocates concerned with business values and job production, which are not negligible benefits, and "nimby" critics who not unreasonably point out that increments of imposed risk, however small, are not voluntarily accepted by the local sub-population at greatest risk, and that if normalized by the smaller numbers of this at-highest-risk local group, the formal risk estimates increase beyond 1:10^6, by orders of magnitude.

A Trap:

As it evolved, the "old paradigm" fell into a semantic, political, and statistical trap. In the presence of very large uncertainties .. both in the data and in the complex processes of emission, dispersion, deposition, ingestion, accumulation, and cancer induction .. it was initially hoped that if the risk-modelers were to accept pessimistic [through still plausible] upper-bound estimates at each step, and if the resulting risks then appeared acceptably small, [less than or on the order of 1:10^6], then relatively quick, simple, and cheap modeling efforts would be
adequate to assist decisions affecting proposed projects, before heavy commitments were made on their construction. In the jargon of the trade, such estimates are called "conservative".

In the last years of the "conservative" administration of the elder President Bush, however, [1990-1992], "fiscally conservative" economists in the Office of Management and Budget [OMB], correctly pointed out that "conservative" estimates carry costs of delay or exclusion of otherwise desirable projects, or of excessive investment in pollution control apparatus and governance. This is undeniably true.

Responding to the criticism, the EPA convened yet another panel of competent people to advise yet another revision of the guidelines to be followed in formal risk assessments. That panel advocated, in effect, that risk estimates should no longer be "conservative", but "central". That is, "best" guesses should be used at each step of a supposition chain, not plausibly worst guesses, and these should be accompanied by an additional formalism to assess the uncertainties of estimated risk factors. In 1994 directives from EPA mandated this practice, somewhat ambiguously, but as of 1999 the revised guidelines are not well specified, and recent risk assessments generally do not include specific, formal, and numerically expressed estimates of the uncertainties associated with estimated risks.

One reason for this regulatory lag is that the uncertainties are embarrassingly large. In the case of cancer risks from dioxin emissions through the complicated processes of dispersion, deposition, and ingestion into and through food chain, those uncertainties certainly exceed factors of 10, and likely exceed factors of 100. Thus, a "central" $1 \times 10^6$ lifetime cancer risk might in fact plausibly lie in the range between $1 \times 10^4$ and $1 \times 10^8$. The first of these ratios is considered unacceptable, the second trivial, but how does one wisely choose between them? Are analyses with these uncertainties at all useful?

Another reason for regulatory lag is, interestingly, that the newer, "central", estimates are coming in at about the same levels as the older, "conservative" guesses. Newly perceived risk paths have been added at about the same rate as the older conservative risk estimates have been centralized. That $1 \times 10^6$ ratio seems almost a constant of nature: obviously riskier facilities are cut-off early, and obviously safer ones bypass the formal process entirely.
In this situation, what should honorable decision makers do? Of what value is a formal risk assessment with such broad uncertainties? Some of those studies cost millions. What do we get for our money?

**A Shifting Paradigm:**

Meanwhile, back at the scientific farm, the risk paradigm has been shifting from nearly exclusive concerns over cancers mediated by dioxins to expanded concerns over the hormone-like behavior of many of these and similar compounds, which appear to affect sperm production and fetal development in many species, including ours. The supporting evidence for these worries is somewhat ambiguous, and perhaps alarmist. But if the claims are approximately correct then other risks than cancers are significant, and should be accounted for.

Further, quite recent studies alert us to the high and growing incidence of childhood asthma, and to convincing associations between emergency-room admissions for asthma, bronchitis, and related stresses, and acute air-pollution episodes characterized by high levels of PM2.5 [aerosol particles with aerodynamic diameters less than 2.5 micrometers].

Unlike the cancers, where incremental risks even as large as $1:10^4$ cannot be detected in the presence of large natural backgrounds, it appears that childhood asthma [with a baseline incidence of $1:10$] and adult congestive pulmonary distress [ACPD], which in many cases may be the same thing with a different label, are "canary" symptoms, where .. unlike the cancers .. statistically significant impacts of air pollution upon both health and mortality can be detected in cities with populations exceeding $10^5$. If this emerging paradigm proves correct .. as appears likely .. then asthma and ACPD should also be accounted for in formal risk assessments.

**Dose-Damage Curves:**

One confounding concern of the "new paradigm" is that acute distress .. as from asthma .. is sensitive to relatively rare [a few events per year] episodes of severely degraded air quality, not just to cumulative exposures, as has been assumed to be the case for the cancers. The dose-damage curve for asthma is likely non-linear, with lower thresholds below which
our systems do not usually trigger strong immune responses, and higher dose levels at which progressively larger numbers of persons may be acutely affected, at rates that are more than proportional to added doses.

One effect of this non-linearity is to accentuate concern for disadvantaged sub-populations at higher-than-normal risk. Thus, a $1:10^6$ risk for the population at large, may be $1:10^5$ for all children, and $1:10^4$ for asthmatic children. [Cancers are so prevalent as generally to have been assumed a common blight, with approximately uniform risk to most people. Recent genetic studies question this, however.].

Another effect is to focus air-quality modeling on episodes, rather than long-term averages ... a distinctly harder task.

Forward and Backward Risk Estimates:

A "forward" risk estimate begins with a list of troubles, assigns probabilities to each, and combines these, using standard probability theory for serial and parallel processes. A "backward" estimate looks at a climate of troubles abstracted from real measurements of historical facilities and events. Insurance firms typically operate with backward risk estimates. New technologies are forced into the forward mode, because there are no historical data.

Interestingly, when the two approaches may finally be compared with one another, it too often appears that the forward estimates overlooked a set of serious troubles, or underestimated their severity. Egregious examples of this bias include the wildly optimistic estimates leading to the Challenger and Chernobyl tragedies. For both of these, forward estimates were low by factors of $10^2$. The common failing appears to have been neglect of stupidities, or "pilot error". We naively assume that the processes operate as we have designed them, that we are rational, and that others are too.

Note that risk analyses of toxic waste incineration are performed in the forward mode.
Cost-Benefit Analyses:

We all act upon informal and largely subconscious risk and benefit assessments, but economists stumble when trying to reduce these choices into quantifiable numbers. With toxic waste incinerators, some of the benefits may be measured in dollars that need not be spent in more expensive ways. Capital and labor costs can also be measured in dollars. But costs associated with externalized health risks are not well expressed in dollars, and attempts to do so risk Dr. Strangelove excesses and a repellent algebra when attempts are made to optimize "extra deaths per dollar".

What is the dollar cost of a premature cancer death? Do you count it as a benefit that social-security costs are diminished? [NO!]

What are the dollar costs of increased incidence of childhood asthma? Are these greater than with adult congestive pulmonary distress ... essentially the same disease ... because the child is young? Or less, because the society "saves" on educational costs? [NO!] What are the dollar denominated costs of degraded scenic views? Of eagle-shell fragility modulated by DDT?

Our tort system indeed struggles to assign dollar-measured prices to these costs, but the "coefficients" [dollars/death, dollars/view, dollars/eagle] are at best subjective, controversial, and unstable.

At The Margin:

In "Economics 101" it is taught as axiomatic that wise decisions are best made "at the margin". That is, you consider the prospects of additional gain or loss, with respect to additional costs and benefits. Past investments, profits, and losses are all "sunk", and should not be weighed in present decisions for additional investment with prospect of gain, or additional insurance with prospect of loss.

This principle also holds with risk assessments: we are concerned with added risks above present baselines, and added costs of ameliorating those risks. But baseline data .. as for example of air-pollution levels, or cancer rates, or asthma incidence .. are usually poorly known and not discussed. This is particularly
poignant in rustbelt communities that are often characterized by lower-than-average educations and incomes, and a higher-than-average incidence of smoking and obesity, cancers, and childhood asthma.

"Peer" Reviews:

The stimulus to this essay was the author's involvement over several years as an external, scientific "peer reviewer" in two formal, EPA sponsored risk assessments, one concerned with a very large commercial toxic waste incinerator at East Liverpool, Ohio, the other with soil incineration at a superfund site at Lock Haven, Pennsylvania. The "peers" were narrowly charged with reviewing risk-assessment documents, prepared by engineering firms under contract with the EPA, primarily as to whether those contractors had adequately conducted their assigned tasks. Our participation in the definition of those tasks was minimal, and ineffectively late in the risk-assessment process. We were not asked to recommend acceptance or rejection of the assessments as a whole, or of their executive summaries, as would have been so were we "peer reviewing" papers submitted for publication, or research funding by federal agencies. ["Some peers are more equal than others."

Community interest in our review process was high, and was somewhat misled into an expectation that these reviews provided a last "scientific" chance to deflect the projects. Sadly, a common theme in both communities was a projection onto the EPA as being more in alliance with the projects' sponsors than with protecting citizen interests. This projection was cast with intense emotion and directed into personal attacks on the professionalism and integrity of EPA staff. Still more sadly, some of these charges were true.

My Opinions:

In the light of all these difficulties and concerns, it seems to me that:

1. The risk assessment process, as it presently operates, damages the EPA without assisting wise decisions.
2. The process is too late, too slow, and the uncertainties are too large. Diverse risks to health and the environment cannot sensibly be expressed in commensurate units. Health and deaths are not well measured by dollars, nor scenic views, nor eagles. Assessments that attempt non-dollar risks are intrinsically subjective. Assessments that neglect them are incomplete.

3. This futility is perceived by project sponsors, who largely ignore formal risk-assessments except as irritating regulatory interference: thus we perpetuate a climate of managerial derision and evasion.

4. This futility is also perceived by regulators, where risk-assessment processes grind on long after decisions have been effectively committed by heavy investments in the facilities assessed.

5. Citizens correctly perceive the process as "spin" for decisions already taken.

6. Costs and benefits are distributed to different populations. Some win, others lose. It is naive to assume that disparities between winners and losers impedes the historical, natural, and democratic process of dumping our troubles into others' back yards. Thus toxic waste incinerators are typically sited in already poor communities with high base rates for cancers and asthma.

7. There is an ethical difference between freely accepted risks, as from ski accidents, and imposed risks, as from toxic waste incineration. Stricter standards should be assumed when decision makers impose risks on non-consenting citizens who do not share in compensating benefits.

8. I have not discovered any approximately fair way around the problem of inequitably distributed costs and benefits. It is a reasonable-seeming [at least to me] suggestion that compensating benefits might be invested within affected communities ... as for example through subsidies to emergency-room care and "Medic One" services. But this suggestion is strongly rejected by all my acquaintances among the decent people who actively oppose toxic-waste incineration. If your child has cancer you want zero risks, the incinerator closed, and the rascals punished.
I recommend:

1. Risk assessments should be initiated before major capital investment, and compressed into weeks, not years. In the presence of large uncertainties, early and brief is better than late and wordy.

2. The EPA's guideline process for risk assessments excessively lags the science. Catch up is necessary.

3. Risks and benefits should be estimated at the margin. This requires baseline measurements of both air-quality and health in the affected communities. Usually, these data are missing. A vigorous program to collect and assess the baselines should be started in the earliest stages of any risk assessment process.

4. In addition to estimating risks to whole populations, we should estimate them also to identified sub-populations at exceptional risk, as for example asthmatic children.

5. The EPA should accept continuing responsibilities towards communities affected by toxic-waste incineration. Health and air-quality studies should be improved where necessary ... often greatly improved ... to evaluate effects of the facilities on those communities.

6. Air-pollution modeling and observations should be tilted towards understanding the frequencies and severities of severely stagnant episodes, rather than towards longer-term averages and their standard deviations.

7. Peer reviewers of risk-assessment documents should be asked whether the executive summaries correctly reflect the peer consensus, and whether the assessments as a whole should be accepted or rejected, as usefully contributing to wise decisions.
8. The EPA should with high priority study the effects of aerosols and odors upon asthmatic children.

9. Toxic waste incinerators should not be located on flood plains of narrow river valleys, close to housing and schools.

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Halstead Harrison  
Professor, Atmospheric Sciences  
University of Washington  
Seattle, WA 98195-1640  
<harrison@atmos.washington.edu>