Review of the Drake Chemical Site Risk Assessment Report
(Weston, November, 1997)

Douglas J. Crawford-Brown
Director, Institute for Environmental Studies
University of North Carolina at Chapel Hill
January 28, 1998

Introduction

This review focuses on the methods used in the Risk Assessment Report to characterize human health risks from operation of the Drake Chemical Site remediation plan for incineration of contaminated materials. Ecosystem risk assessment is not reviewed here, except to the degree that the ecosystem assessment relies on the same information generated for the human health risk assessment (e.g. the same characterization of pollutant concentrations in the air and water). The purpose of the review is to understand whether the Risk Assessment Report (including the separate report on fugitive emissions) contains an accurate characterization of the risks from the proposed remediation plan, and whether this characterization justifies the claim that the risks are known with reasonable confidence to be acceptable.

To answer this question, I focus on several issues:

Did the structure of the risk assessment follow the structure commonly found in the field of risk assessment and recommended by the EPA?
Did the methodology used in the risk assessment follow best practices in the field of risk assessment?
Did the characterization of risk include consideration of all contributions to that risk?
Did the characterization of risk include formal consideration of uncertainty as outlined by the EPA in their Guiding Principles for Monte Carlo Analysis (EPA, January, 1997)?
Did the characterization of risk include formal consideration of variability, particularly the risk to sensitive subpopulations, as outlined by the EPA in their Guiding Principles for Monte Carlo Analysis (EPA, January, 1997)?
Did the characterization of risk include interaction between compounds and routes of exposure?
Does the decision that the risk is acceptable follow clearly from formal considerations of uncertainty and variability?

These issues have been chosen because they are the ones raised most commonly in debates about the risk of environmental pollutants, and are at the heart of risk-based decisions.

There is an important caveat to this review: I did not try to reproduce the calculations performed in the Risk Assessment Report. The models used in that report to estimate risks are all standard models used in risk assessment, and I have no reason to believe they
were operated improperly in performing the calculations given in that report. I will focus, instead, on what went into those calculations, whether all relevant calculations were performed, and whether the results of those calculations justify the conclusions drawn by the EPA (i.e. that the Drake Chemical Site remediation plan for incineration poses acceptable human health risks). The remainder of this report focuses on each of the questions I raised above.

**Did the structure of the risk assessment follow the structure commonly found in the field of risk assessment and recommended by the EPA?**

The assessment did follow the general structure of risk assessments. There is consideration of source terms, dispersion into the appropriate environmental media (air, water, soil and food), exposure routes (inhalation, ingestion, dermal absorption), exposure-response modeling, uncertainty analysis and variability analysis. The only issue I raise here is that the “structure” of a risk assessment includes two considerations. The first is the way in which the risk assessors put together the material for the assessment. I see no problems with the structure of the assessment in this sense. The second issue, however, is more problematic. The “structure” of a risk assessment also includes the structure of the social process by which the assessment is performed. As recognized in the NRC Report Science and Judgment in Risk Assessment, risk assessments involve judgments that may differ between individuals performing an assessment. It is for this reason that relevant stakeholders might be expected to have some input into the process of assessment at key points before the risk characterization stage. The reason is that it becomes very difficult for stakeholders to track through a large assessment “after the fact”, since many of the most controversial assumptions remain hidden within the methodologies (e.g. the computer codes) and the effect of alternative assumptions cannot be assessed in the time allotted for review. I don’t know the history of citizen involvement in this particular risk assessment, so I will not make comments on whether best practice was or was not followed in this case.

**Did the methodology used in the risk assessment follow best practices in the field of risk assessment?**

The models used to estimate exposures and subsequent risks are those generally used in such assessments. By this, I mean that none of them are state-of-the-art models of pollutant dispersion (e.g. there are much more sophisticated air and surface water dispersion models available), but they are typical of the simpler models used in risk assessments. The state-of-the-art models are significantly more costly, take much longer to run, require more site-specific data, and are more suited to research than regulatory decision-making. I believe the Risk Assessment Report is based on models that are appropriate for this kind of assessment.

I am less comfortable with several other aspects of the methodology, however. As I will describe in other sections, I do not believe the methodology in treating interactions...
between pollutants, in assessing variability of risk, and in assessing uncertainty are
sufficient. The reasons for my concern in these three areas are discussed below.

**Did the characterization of risk include consideration of all contributions to that risk?**

The main question here is whether the assessment considered all pollutants likely to be
released and all pathways of exposure. With respect to the pollutants released, the
chemicals and metals examined in the assessment are appropriate and are those that would
be selected in essentially all incinerator risk assessments. I believe the appropriate
chemicals and metals were examined.

With respect to exposure scenarios, Table 5.5 indicates that the most important
subpopulations and exposure pathways generally were considered. The inclusion of dairy
consumption in the subsistence farmer scenario was a good decision, since milk
consumption can be an important pathway for some of the "driving compounds" (i.e. the
chemicals that dominate the final risk).

I am less comfortable with the decision in Chapter 5 to exclude the subsistence fisherman
scenario. For many of the chemicals and metals considered, the persistence in the
environment is significant. This means the potential for exposure will exist for decades.
The authors assume there are no subsistence fishers present in the area at the moment, and
that probably is correct. But that raises the question as to whether the EPA is protecting
the population against risks imposed by existing lifestyles, or ensuring that the air, water,
soil and food are acceptable for other reasonable lifestyles which a person might wish to
adopt in the future. Since subsistence fishing is a reasonable lifestyle (being practiced
elsewhere in the US), this scenario should be included in the assessment, especially since it
has been included by the EPA in other incinerator risk assessments.

The choice to exclude completely the Casatena Reservoir as a water source (see Page 4.2-
1) also violates the principle discussed above. While this site currently is not used as a
water source, it has been used in the past and may be used in the future (particularly if
residential development is significant). Again, the goal of protection of public health is
best served by protecting potential water supplies, and not simply protecting currently
used supplies. This concern is offset partially by the fact that this facility is likely to be in
operation only for a short period (a few years), but modeling should confirm that storage
of pollutants in lake sediment will not adversely affect the ability to use the Casatena
Reservoir in the future.

**Did the characterization of risk include formal consideration of uncertainty as
outlined by the EPA in their Guiding Principles for Monte Carlo Analysis (EPA,
January, 1997)?**

This is where the Risk Assessment Report is particularly weak. The goal of a regulatory
decision presumably is to protect the public health with reasonable confidence. As outlined
in the Guiding Principles for Monte Carlo Analysis (EPA, January, 1997), an uncertainty
analysis should allow the Agency to determine the confidence with which it can be stated that the Drake incinerator will not pose an unacceptable risk of cancer and non-cancer effects. This confidence typically is given in the form of a cumulative confidence distribution. Such a distribution shows the confidence with which the assessor can state that the excess probability of cancer is less than $10^{-6}$, $10^{-5}$, $10^{-4}$, etc (or a hazard quotient of less than 1.0, 2.0, etc).

The current assessment does not provide this information. It is entirely too subjective and qualitative. The decision to simply rank the sensitivity of the risk estimates to different parameters as high, medium and low, and then to make judgments as to whether the parameter tends to over or under-estimate the risk, is unacceptable. The decision-maker is left with no way to determine where in the cumulative confidence distribution the final risk estimate lies (other than to say that it is “out in the upper tail”). Since the level of confidence needed to justify selection of a remediation strategy can differ appreciably between stakeholder groups, and between individuals in a group, the lack of a formal characterization of the cumulative confidence distribution severely weakens the assessment as a decision-making tool. This is in spite of the fact that formal, quantitative uncertainty analyses are performed routinely in risk assessment for situations of equal complexity (so the argument that the Drake situation is too complex for a formal uncertainty analysis cannot be supported).

I generally have no qualms about the particular judgments made in the assessment with respect to whether a particular parameter will tend to over or under-estimate the risk. The one significant place where I disagree is in the blanket statement that the slope factors and reference doses used are all likely to be conservative at low doses. While scientists generally agreed previously that the linearized multistage model overpredicts risk at low doses, there is increasing evidence of non-linear dose-response behavior for some pollutants which can cause the linearized multistage model to under-predict the risk at low doses. The blanket treatment of uncertainty in dose-response relationships used in the assessment is unwarranted in light of the current science and should be re-examined on a compound-by-compound basis. It also is not the case that all slope factors and reference doses already represent upper 95% confidence limits. Again, this issue must be examined on a case-by-case basis.

The problem of poor treatment of the uncertainty analysis becomes particularly important for the case of exposures to mercury (see Page 9.5-1). The report states that mercury is not of concern despite the fact that hazard quotients are above 1.0 for some scenarios. The reasoning is that the estimates of the hazard quotient are far into the upper tails of the cumulative confidence distribution and, therefore, the “real” hazard quotient is likely to be less than 1.0. No evidence as to “how far” these estimates lie in the tails is given. This argument is entirely too qualitative and subjective. The conservatism in parameters would need to be extreme to overcome what currently is an order of magnitude and more exceedance for mercury. There is no reason why a formal uncertainty analysis cannot be performed for this source of risk, and the assessment will not follow best scientific practice until this performed.
In addition, the report must rely on slope factors and reference doses for a wide class of chemicals and metals for which these parameters are not available. This is a problem faced by all risk assessments for incineration, so the authors cannot be faulted for the paucity of data. Still, this means that the risks estimated in the report are not necessarily upper-bound estimates on the risk, since they do not include accurately estimated risks from a significant number of pollutants. The report states (see Page 6.1-3) that the provisional values used in the assessment will tend to be more conservative than those that would be developed under a more full Agency review, but no evidence is given for this statement. In any event, there will be cases where the provisional values are less conservative, and this uncertainty as to whether the provisional values are more or less conservative should be reflected formally in the uncertainty analysis. Otherwise, the reader is left only with the authors subjective judgment of the degree of conservatism. There has already been a great deal of scientific research on issues related to structure-activity relationships and regressions of toxicity across classes of chemicals, and none of this research is reflected in the current report. The Agency should subject the extrapolations of risk coefficients used in this assessment to external peer review before they are used.

At the very least, the report should consider the possible risks posed by the chemicals and metals for which slope factors and reference doses are not available, using different assumptions as to their relative toxicities (e.g. assuming the toxicities are zero, assuming they are the same on a per-mass basis as the chemicals and metals examined, etc). This would at least give an indication of how far off the risk estimates in the report might be. The most conservative approach would be to delay the risk assessment until at least preliminary slope factors and reference doses can be developed, using such techniques as structure-activity relationships and regressions.

**Did the characterization of risk include formal consideration of variability, particularly the risk to sensitive subpopulations, as outlined by the EPA in their *Guiding Principles for Monte Carlo Analysis* (EPA, January, 1997)?**

The assessment does include consideration of sensitive subpopulations. These are represented by the various exposure groups, which include different activities (e.g. subsistence farming) and age groups (e.g. young children). The report does not, however, include assessments of the risk to the subpopulation of subsistence fishers (which can be a significant pathway, particularly for mercury and dioxins). Equally significant, it does not consider formally subpopulations defined by prior disease (e.g. asthmatics). It is evident in scientific studies, particularly those associated with air emissions, that diseased groups often represent the most sensitive subpopulations. Appropriate subpopulations defined by prior disease should be defined for each chemical or metal, and it should be ensured that slope factors and reference doses applicable to those subpopulations are reflected in the assessment.

The risks to infants, particularly due to ingestion of mother’s milk, and to children in general following in-utero exposures, are inadequately addressed in the report. The report
does contain an attempt to quantify risks from ingestion of mother's milk for a small group of the chemicals, but no estimates are given for the vast majority of the chemicals and metals to which mothers will be exposed. It certainly is the case that estimating these risks is extremely difficult given the lack of reliable data for the large majority of compounds.

Still, some attempt should be made to assess the in-utero exposure effects where data are available, and then to at least consider the risks from other in-utero exposures through the uncertainty analysis. In the absence of these estimates, it cannot be stated that the risks are "upper bound" or conservative, or that a full variability analysis has been performed.

I also have a concern over the lack of a formal variability analyses in the report. As outlined in the Guiding Principles for Monte Carlo Analysis (EPA, January, 1997), a variability analysis should allow the Agency to determine the fraction of the population with an unacceptable risk of cancer and non-cancer effects. This fraction typically is given in the form of a cumulative frequency distribution. Such a distribution shows the fraction of the population with an excess probability of cancer of less than $10^{-6}$, $10^{-5}$, $10^{-4}$, etc (or a hazard quotient of less than 1.0, 2.0, etc). Such variability analyses are now performed routinely in risk assessment, with distributions of parameter values taken from reports such as the EPA's Exposure Factors Handbook. The present assessment will not conform to best scientific practice until a variability analysis is performed.

**Did the characterization of risk include interaction between compounds and routes of exposure?**

Interactions between routes of exposure from facility releases are included since risks from the different routes are summed for a given chemical or metal. For the non-cancer endpoints, however, the assessment does not account for existing background exposures. The assessment should address the question of whether existing background levels might be sufficiently high to preclude any incremental addition from a specific chemical and/or metal. This will be particularly important for dioxin and dioxin-like compounds which act by similar mechanisms.

Interactions between different carcinogens are included since the reported lifetime carcinogenic risk (see Table ES-1) includes the sum of the risks from all carcinogens examined in the study. Non-additive interactive effects, which include both synergism (the sum of the risks from separate carcinogens being greater than the sum of their individual effects) and antagonism (the sum of the risk from separate carcinogens being less than the sum of their individual effects) should have been considered in the uncertainty analysis but was not.

Interactions between different non-carcinogens are included since the reported hazard index is obtained from the sum of the hazard quotients from different chemicals and metals. As with the carcinogens, however, non-linear and non-additive interactions have not been considered in the uncertainty analysis. The authors are correct in stating that the additive model will tend to overstate risks from non-carcinogens when that addition includes chemicals and metals that act on different organs and by different mechanisms.
Still, an attempt should be made to identify mixtures where the interaction might be more than additive, at least for the purpose of the uncertainty analysis.

The decision to not add hazard quotients for the ecosystem risk assessment has been based on the fact that the reference doses generally were developed by looking at the most sensitive indicator species, and that these species will tend to differ between the separate chemicals and metals. This certainly is true in general, but there may be cases where a single species experiences effects from a wide range of the pollutants, even if it is not the most sensitive indicator species. These cases should be identified, and it should be confirmed that even in these cases the hazard index does not exceed 1.0.

**Does the decision that the risk is acceptable follow clearly from formal considerations of uncertainty and variability?**

No, this is not the case, for several reasons. First, ignoring the hazard quotient for mercury (which exceeds 1.0) precludes such a decision. The assessment does not present a formal uncertainty analysis supporting this conclusion (i.e. the conclusion that mercury risks are very much overstated), nor does it include a sensitivity analysis to determine the possible impact of this conclusion on the final judgment that the incinerator risks are acceptable. This component of the assessment does not meet standards of best scientific practice.

Second, the regulatory goal should be to protect some specified fraction of the population against an unacceptable probability of cancer or hazard index, and to do this with a specified level of confidence. In the absence of a formal uncertainty and variability analysis resulting in a cumulative confidence distribution and cumulative frequency distribution, respectively, the logical basis for the decision cannot be tracked and may be incorrect. The treatment of variability and uncertainty within the assessment does not meet standards of best scientific practice, and makes it impossible to determine the quality of the final decision. Techniques are readily available to perform the necessary analyses, have been used in other assessments, and should be applied to the present assessment.

Third, the risks from ingestion of mother's milk for a large number of the chemicals and metals, as well as the risks to infants for a smaller number, have not been determined in this assessment. The implicit assumption is that these risks would not affect the final decision. This assumption is unwarranted at present without a more scientific review of the potential impact on the risk estimates.

Fourth, the assessment for many of the chemicals and metals is based on extrapolation across routes of exposure and from other compounds. The effect of this extrapolation on the overall uncertainty in the risk has not been addressed adequately in the report, so it is not possible at present to determine if this source of uncertainty would alter any decisions.

These four major points call into question any conclusion that this remediation option will pose acceptable human health risks. As a caveat, however, I must also note that these concerns do not demonstrate that the incinerator will in fact cause unacceptable risks. It is
simply the case that the lack of a formal uncertainty and variability analysis, the existence of large gaps in the data base (requiring untested extrapolations which have not been subjected to full peer review), the finding that the hazard quotient for mercury may exceed 1.0, and the relative lack of information on risks to the fetus and infant, preclude any formal demonstration that specific percentiles of the distribution of risks in the exposed population have been characterized accurately.