Variability and Uncertainty Associated in National Air Toxics Assessments

1 Overview

This discussion will help you understand why it's important to use the results to answer only those questions for which the assessment is suitable.

Variability: Emissions, air concentrations, exposures and risks are not the same throughout the U.S., and are not the same for everyone. Some geographic areas have higher concentrations than others. There are some periods of time when the concentration is higher at a given location than at other times. Some individuals have an exposure and/or risk below the national average, while others have an exposure and/or risk above the national average. For these reasons it is necessary to have some idea of how the ambient air concentration, exposure, and risk from hazardous air pollutants (HAPs) varies throughout the U.S. This information comes from a process is called *variability analysis*.

Uncertainty: The EPA seeks to protect health with reasonable confidence. But scientific estimates of air concentrations, exposures and risks always involve assumptions that simplify the real situation but make the assessment possible given available information and resources. These assumptions introduce uncertainties into the results, since there is never complete confidence that the assumptions are entirely correct. It is necessary to understand the size of these uncertainties, the level of confidence that can be placed in any statement you might find related to the assessment, and how this confidence affects the ability to make reasoned decisions. This information comes from a process is called *uncertainty analysis*.

2 Variability

2.1 Introduction – How do these results apply to an individual?

The NATA analysis focused on the variation of ambient air concentrations, exposures and risks among geographic areas of the U.S. This included variations in:

1) Location and amount of emissions from different sources;
2) Movement and fate of HAPs compounds within the atmosphere in different parts of the country; and
3) Daily activities of different people.

The smallest geographic area considered was a Census tract. Census tracts tend to be small in densely populated areas but may be very large in sparsely populated areas. The assessment did not consider variation in the ambient air concentration within Census tracts, using instead a typical ambient air concentration from a single location near the center of the tract. It also did not consider variations in the susceptibility and sensitivity of people within a Census tract, since the focus was on comparing typical exposures and risks in different tracts. As a result, it is possible that individual exposures and/or risks may differ by perhaps a factor of 10 in either direction. You should interpret the exposure and/or risk as being a typical one for the geographic area in which you live, but not necessarily *your* risk.

For these reasons the results of the NATA analysis do not allow a comparison of ambient air concentrations, exposures and/or risks between two individuals or even between two specific

Census tracts, but they do allow you to understand the variation in typical values for these quantities between counties or states and to a lesser degree between Census tracts. Your personal values, however, may differ from the typical value for your county or state if you: (1) live in a part of the geographic area that has a higher or lower than typical value; (2) have an activity pattern that causes a higher or lower exposure than is typical; or (3) are more (or less) susceptible than the typical person used in this assessment.

2.2 What are the components of variability?

The NATA results show how air concentrations, exposures and risks vary broadly across geographic regions of the country. They do not fully characterize how these three quantities vary between individuals, except to the extent these individuals live in different geographic regions and have the values typical of a Census tract in that region. They also do not characterize how emissions and ambient air concentrations vary geographically or with time within a Census tract.

To understand this difference, consider the reasons why two places might have different ambient air concentrations or why two individuals might experience different risks from HAPs:

Temporal variation. Sources do not emit HAPs at constant rates. These rates vary over time. Similarly, the meteorological conditions that affect dispersion in the atmosphere vary over time. This means the ambient air concentration at a given location can vary over time.

Geographic variation. Different locations are at different distances from a source, and may be closer to other sources. They also vary with respect to meteorological conditions that affect dispersion in the atmosphere. As a result, the ambient air concentration may vary between different locations.

Variation in locations of individuals. Two individuals might live at different locations within the same Census tract. The ambient concentration estimated for the tract can only approximate conditions at all locations in the tract, and different locations within that tract may have different average ambient concentrations, and therefore also exposures and risks.

Variation in activity for individuals. Two individuals might live at the same location but engage in different activities (called an "activity pattern") during each day. The concentration indoors often is different from the concentration outdoors. If one person spends more time indoors than another person, there will be a difference in the average air concentration to which the two are exposed, even though the ambient air concentration is the same. Similarly, one person might spend more time in a car, exposed to an air concentration that is typical near roads. The net effect of these factors will be that the concentration of each HAP in the air actually breathed by these two individuals will be different. The *exposure* differs for these two individuals.

Variation in susceptibility or sensitivity. Two individuals might live at the same location and engage in the same activities, but one person might be more *susceptible* or *sensitive* than another. Susceptibility or sensitivity refers to the extent to which an individual (1) takes a hazardous air pollutant (HAP) into the body, (2) transports it into an organ or tissue that might be adversely affected by it, and/or (3) develops the adverse effect. Individuals who are more susceptible or sensitive may have the highest concentration of the HAP in their organs or tissues or the highest chance of severity of a health effect, even when the exposures are the same for both individuals. For example, people breathe at different rates; two individuals placed into exactly the same air may bring different amounts of a HAP into their bodies. The amount of a HAP reaching an organ or tissue may also vary between individuals, even if they both bring the same amount into their lungs. The length of time the HAP remains in the body may differ. Finally, the innate sensitivity to the effect may vary even at equal doses in the tissues. The net effect of these factors is that either the *dose* of the HAP delivered to the organs or tissues of the

body, or the level or response, or both, may differ substantially between these two individuals, even though the individuals are exposed to exactly the same air.

Each of the above factors can depend on the age, gender, or ethnic group to which an individual belongs, as well as on that individual's lifestyle. These groups make up different *receptor populations* or *cohorts*, and the exposures and risks may be different for the different groups. There even are variations of all factors within a receptor population.

2.3 Which Components of Variability did the National-Scale Assessment Include?

EPA conducted NATA to understand how ambient air concentration, exposure, and risk vary geographically, but not between specific individuals. Still, many of the components of variation of risk were included. The U.S. was divided into Census tracts, and EPA calculated the ambient air concentrations for each Census tract based on the emission sources and meteorological conditions affecting those specific tracts. The ambient (outdoor) air concentrations, however, were time-averaged. The calculations of ambient air concentration, therefore, do not reflect temporal variation, but they do reflect geographic variation.

Individuals were placed at the centroid (center of population mass) of the Census tract in which they live. This reflects variation in geographic location of individuals *between* Census tracts, but it does not reflect variation in geographic location of individuals *within* a Census tract. Activity patterns were included for each of ten receptor populations defined by age and gender (racial/ethnic groups also were initially considered, but the activity patterns were not significantly different and so these groups were averaged), and even within a receptor population some variability in activity patterns between individuals was considered. Differences in susceptibility and sensitivity were not included in NATA because:

1) The study considers only geographic differences in HAP concentration, exposure and risk. The goal is to understand how these three factors differ as a person moves *between* geographic areas. This is reflected, as mentioned above, by keeping track of differences in air concentration in different Census tracts. This produces differences in the typical HAP concentrations, exposures, and risks in different tracts. Susceptibility and sensitivity, however, produce differences in risk between two individuals in the *same* Census tract, and NATA was not intended to report these differences.

2) Second, there is very limited information on differences in susceptibility and sensitivity between individuals. Even if it was decided to calculate and report differences among individuals in a Census tract, scientifically reliable information necessary to produce these calculations is not available for many of the HAPs. It is possible, given current information, to at least estimate variability in the rates at which people breathe air, but this is only a small component of the overall variation in susceptibility and sensitivity. It was decided, therefore, not to incorporate this source of variation between individuals.

Taking into consideration these limitations, EPA decided to incorporate differences in emissions and meteorology (resulting in differences in ambient air concentration) between Census tracts, as well as differences in location of typical individuals (resulting in differences in exposure) between Census tracts. In addition, variation in activity patterns for different age groups is reflected in the study. Variability in susceptibility and sensitivity is not, however, included for the reasons given above. In addition, temporal variation is included in the sense that it was used to develop time-weighted averages of emissions characteristics and meteorological conditions, but no temporal variation of ambient air concentration was estimated (only the time-weighted annual average). ****

2.4 How Can These Results be Interpreted?

The NATA analysis provides a picture of how ambient air concentration, exposure and risk vary throughout the United States. The study does not focus on individuals, or on the variation in exposure and risk among individuals. It focuses on variation between well-defined geographic areas, such as counties or states, based on calculations of ambient air concentration, exposure and risk in different Census tracts.

The information contained in the resulting maps and charts displaying predictions of risk, for example, are interpreted as follows: X% of the Census tracts are characterized by a typical lifetime excess cancer risk of less than R. For example, if X is 25% and R is 1 in a million, the result would be interpreted as: 25% of the Census tracts are characterized by a typical risk of less than 1 in a million. It does not necessarily mean that 25% of individuals in the U.S. have a cancer risk of less than 1 in a million. Some people in these Census tracts would be expected to have a risk above 1 in a million. While an individual might live in a Census tract where the typical risk is below 1 in a million, that individual might live nearer the source than the average person in the Census tract, or might have an activity pattern that leads to greater exposure, or might be more susceptible, or might be more sensitive. All of these factors would cause that individual to experience a risk above the typical value for that Census tract. Of course, the individual could also have a lower risk by living further from the source, or having an activity pattern that produces lower exposures, or being of lower susceptibility, or being of lower sensitivity.

It is important, therefore, to interpret the maps and charts of the NATA analysis as showing variation between values of ambient air concentration, exposure or risk in Census tracts or larger groupings such as counties. It allows the identification of geographic regions (counties or states) where these values are higher or lower than the national average for all Census tracts. It does not allow the identification of individuals who have higher or lower values of ambient air concentration, exposure and/or risk, and it does not allow identification of specific Census tracts that are higher or lower than average. Despite these limitations, it may still be said that individuals with a high risk are more likely to found in geographic regions characterized by a high risk than in those characterized by a low risk. The same may be said for exposure (*i.e.,* individuals with a high exposure are more likely to found in geographic regions characterized by a high exposure than in those characterized by a low exposure). You should review the information in the section on limitations for a better understanding of the meaning of these results.

3 Uncertainty

3.1 What are the Components of Uncertainty in Risk Assessment?

No scientific statement (in risk assessment or other areas of science) can be made with complete confidence. Uncertainties always exist in these statements due to issues that will be discussed below. Transparency and openness, therefore, require an explanation of these uncertainties and the ways in which they raise or lower confidence. The NATA analysis produced statements about variability in ambient air concentrations, exposures and risks across geographic regions for typical individuals, as described in the section on variability, so the uncertainty discussion is designed to address the confidence with which these statements may be made. It is important to note that uncertainty does not prevent a statement of risk from being made, nor does it prevent reasonable actions from being taken. It does, however, require that the nature of the uncertainty, and the implications for decisions, be understood so the degree of support for the statement is not misinterpreted.

Uncertainty arises from a variety of sources. To understand them, consider the process by which a study such as NATA is performed:

Problem Formulation**.** The problem to be addressed must first be defined. Is the problem one of human health effects being produced by industrial facilities? Is it one of ecosystem effects being produced by mobile sources? Is it some combination of these or other issues? It should be clear at the outset what the study is intended to address, and how the results will be used. This step in the analysis introduces *problem formulation uncertainty*. For NATA, the issue is dealt with in the section on limitations on this web site, where the question addressed in the assessment is defined as precisely as possible (*e.g.*, that the study is limited to estimates of health effects in human populations). The issue of problem formulation uncertainty is not considered further here.

Defining the factors to be considered. This step describes the parts of the world that influence the answer to the problem. In NATA, this includes emissions from a variety of sources (mobile, area, stationary, etc), atmospheric dispersion, activity patterns for different receptor populations, Unit Risk Estimates, Reference Concentrations, and so on. Where the science is poorly developed, it may be unclear what factors must be included. There may also be limitations in resources, making it infeasible to include all factors in the study. This step in the analysis introduces *conceptual uncertainty*. The issue is also dealt with in the limitations section, where the aspects of the problem that are (and are not) included in the study are addressed (*e.g.*, that the study addressed inhalation of HAPs only). The issue of conceptual uncertainty is not considered further here.

Selecting models. The NATA analysis is based on a series of mathematical models. There is a model that produces the emissions inventory, a model that calculates ambient air concentration (ASPEN), a model that calculates exposure (HAPEM4), and a model that calculates risk (for cancer and non-cancer effects). All scientific models involve uncertainties, since the model must reduce a very complex set of chemical, biological, physical and social processes down to manageable equations from which calculations may be performed. These simplifications introduce inaccuracies. There usually are competing models that can produce different results, and there is uncertainty as to which model result should be used. As a simple example, NATA uses a linear model relating exposure and cancer risk; *i.e.*, the cancer risk equals the exposure (air concentration) times a Unit Risk Estimate. Uncertainty analysis involves asking a series of questions: *Are we certain this linear relationship is correct? Could there be a quadratic relationship (risk equals exposure times the square of the dose)? Could there be a threshold relationship (there is no risk until the exposure gets sufficiently large)? What are the implications for estimates of risk if these different models are used? What are the implications for decisions if we cannot choose decisively from amongst these models?* And so on.

This step in the analysis introduces *model uncertainty*. In judging model uncertainty, there are both quantitative and qualitative issues. Qualitative issues involve the scientific plausibility of the model. *Does the model include all important processes? Does the model explain the phenomenon (e.g., atmospheric dispersion) well? Is the model well accepted in the scientific community, having passed critical tests and being subject to rigorous peer review?* And so on.

Quantitative issues involve comparisons of the model against sets of data (although this also involves issues of parameter uncertainty discussed in the next bullet). *Does the model generally predict these data accurately? Are the predictions accurate to within a factor of 2; a factor of 4? What is the effect of any approximation methods used in the model?* And so on. In the end, both the qualitative and quantitative aspects of model uncertainty are important.

Selecting parameter values. The models used in the NATA analysis require parameter inputs such as emission rates, stack heights, fractions of time spent indoors, and Unit Risk Estimates.

While models describe general relationships between properties of the world (*e.g.*, the linear relationship between exposure and cancer risk), parameters quantify these properties in specific cases (*e.g.*, the numerical value of the Unit Risk Estimate for benzene). They provide the numbers needed in the models. There always are competing bodies of data from which these parameters may be estimated, and the methods used to collect the data introduce uncertainties. This introduces *parameter uncertainty*.

While there are both quantitative and qualitative aspects of parameter uncertainty, it is common to characterize this source of uncertainty quantitatively, with some qualitative caveats. For example, the parameter uncertainty might be characterized by a confidence interval, saying that the true value of the parameter (such as the stack height for a facility) probably lies somewhere between 40 and 60 meters, or that the stack height is "known to within" a factor of 1.2, or that the stack height is "accurate to within" 20%. Attached to this quantitative characterization of uncertainty will be a qualitative caveat such as: *the estimate of this uncertainty is based on measurements made in 1990 at facilities similar to the one considered in this study, but there may have been a change in the design of stacks since 1990*. This qualitative statement gives some idea of the confidence with which the quantitative assessment of uncertainty can be applied.

3.2 Which Components of Uncertainty did NATA Include?

The uncertainties in NATA have been divided into three groups, based on the three steps leading from emissions to risk. There is uncertainty in ambient air concentration, which is due to uncertainty in both the emissions estimates and the ASPEN model. There is uncertainty in exposure, which is due to uncertainty in the activity patterns, the locations of individuals within a Census tract, and the microenvironment concentrations as reflected in the HAPEM4 model. And there is uncertainty in risk, which is due to uncertainty in the shape of the relationship between exposure and risk, the Unit Risk Estimate, and the Reference Concentration. These three groups of uncertainty are discussed below.

3.2.1 Ambient Air Concentration

Considering first the predictions of ambient air concentration, the specific sources of uncertainty considered in the uncertainty analysis were:

Uncertainties due to the emissions parameters. Emission rates and locations of sources were taken from the NEI database, which is a composite of estimates produced by State and local regulatory agencies, industry and the EPA. The quality of specific emissions rates and locations found in this database (*e.g.*, industrial emissions from a specific Census tract) has not been fully assessed. Some of the parameter values may be out of date, there may have been errors introduced in transcribing raw data to a computer file, and so on. This database is being updated continuously. In some cases, the locations were unknown and the source was placed into the centroid of a Census tract. Overall, slightly less than 10% of the point source sites have been assigned default locations.

There are also uncertainties inherent in emission models used to develop inventory estimates. For example, county-level nonroad equipment toxic air pollutant emissions are estimated by applying toxic fractions of total hydrocarbons (HC) to county level HC estimates for gaseous HAPs, and toxic fractions of particulate matter to county-level PM estimates for metals. The toxic fractions are derived from speciation data based on limited testing of a few equipment types. The county-level total organic gas (TOG) and PM estimates used come from EPA's draft NONROAD model. In NONROAD, there are uncertainties associated with emission factors, activity, and spatial allocation surrogates. National level emissions in NONROAD are allocated to the county level using surrogates, such as construction costs (to allocate emissions of

construction equipment) and employees in manufacturing (to allocate industrial equipment). Use of more specific local data on equipment populations and usage will result in more accurate inventory estimates. EPA strongly recommends that states undertake data collection to provide local data as is routinely done for highway motor vehicle activity and population.

For mobile and area sources the emissions rates usually were allocated from county- to Census tract-levels through a surrogate such as population or land use. This introduces an additional uncertainty, since the data on the surrogates carry their own uncertainties.

Uncertainties due to stack parameters. The ASPEN model requires information on stack height, gas temperature, gas velocity, etc, to estimate dispersion in the atmosphere. Again, the NEI database supplied these values, and in some cases default values were used either because the necessary data were not available or they were judged unreliable (*e.g.*, physically unrealistic values). If data were missing on stack parameters, they were supplied by making reasoned guesses from similar facilities. About two-thirds of the unique vertical stacks in the NEI include at least one stack parameter that is a default value.

Uncertainties due to particle size and reactivity parameters. The ASPEN model requires information on the physical properties of the pollutant. The proportion in gaseous, fine particulate or coarse particulate forms affects the extent to which pollutants are removed from the air by deposition. The chemical reactivity of the pollutant determines whether it will undergo reactions in the atmosphere, and what other pollutant it will become in the process. These parameters are not available in the NEI database, and so representative values were assigned. In addition, representative values of the deposition velocities for particles (the speed at which they settle to the ground) were used. Any one source, however, may actually have different values than the ones assumed.

Uncertainties due to chemical speciation parameters. The health effects of a HAP depend on its chemical form when inhaled. The NTI database does not include information on speciation for many sources, but only on the total rate of HAP emitted in all its forms. EPA staff, therefore, made assumptions about chemical speciation based on representative values at such sources. Any one source, however, may actually have different values than the ones assumed.

Uncertainties due to terrain parameters. The dispersion, or movement, of HAPs in the atmosphere depends on the degree to which the terrain surrounding a source is flat or hilly. The ASPEN model, however, does not take into account variations in local terrain. This can lead to uncertainties in predictions of ambient air concentration, particular in areas with hills or mountains.

Uncertainties due to background concentration parameters. The estimates of ambient air concentration use a background value that is added to the air in all Census tracts to reflect sources other than the ones modeled in NATA. These sources might, for example, be from long-range transport of compounds from other counties and states. We have improved the rigor of our background estimates for each successive NATA assessment, but irreducible uncertainties remain. For more details, see the section on background concentrations

Uncertainties due to meteorological parameters. The ASPEN model requires parameters on the direction and speed of airflow, and on the stability of the atmosphere (which affects how high gases rise once released). NATA uses meteorological data from the nearest available monitoring station. Uncertainties arise from the fact that the data usually were not for the precise location of a given source, and possibly not for the same year. In addition, other sources of these data exist, and so the uncertainty due to selection of a database for a specific source was included in the uncertainty analysis.

Uncertainty due to the ASPEN dispersion model equations. The ASPEN model uses a Gaussian dispersion equation to calculate ambient air concentration, taken from Version 2 of the Industrial Source Complex Long-Term (ISCLT2) computer model. The uncertainty in the ISCLT2 model has been studied extensively, and this uncertainty was used in the uncertainty analysis for NATA.

Uncertainty due to the ASPEN chemical transformation equations. For some of the HAPs, the chemical reactions in which they participate in the atmosphere are complex and non-linear. The ASPEN model, however, can treat only simpler, linear, reactions. For predicting the secondary formation of formaldehyde, the results of this model were compared to the results of a more detailed model (OZIPR) to estimate the uncertainty introduced by the simplifications of secondary formation in NATA.

3.2.2 Exposure

Considering the predictions of exposure, the specific sources of uncertainty due to the relationship between ambient air concentration and exposure (in addition to those considered for ambient air concentration) are:

Uncertainty due to microenvironment factor parameters. The HAPEM4 exposure model calculates the concentration in specific microenvironments (such as in a home or in a car) based on the ambient air concentration predicted by ASPEN. Parameter values needed in these relationships are not well developed for many of the HAPs. As a result, representative values were used in many cases based on measured values of similar compounds in similar situations. This introduces uncertainty into the analysis of exposures for compounds in which these representative values were used. In addition, the same values were applied to all Census tracts. Any one Census tract, however, may actually have different values than the representative ones assumed.

Uncertainty due to population cohort parameters. Each receptor population or cohort (10 cohorts in all) was assigned a representative activity pattern based on the EPA's CHAD database. The same activity pattern was assigned to that cohort in all Census tracts. Parameter uncertainty is introduced due both to limitations in the CHAD database and to the assignment of a national average to all Census tracts.

Uncertainty due to the activity pattern sequence for an individual. Annual average exposure for a typical individual in a receptor population or cohort was calculated by selecting a single day from the CHAD database for that cohort. The same value was used for a given individual on all 365 days. This process was repeated 30 times, to produce 30 different estimates of annual exposure for individuals in a receptor population or cohort. This process does not reflect the fact that an individual vary in activity pattern throughout a year. In addition, there is uncertainty introduced by using a sample size of 30 (rather than a much larger number of samples). This introduces uncertainty as to whether the resulting typical activity pattern represents the average activity pattern for an actual group of individuals.

3.2.2.1 Risk

Considering the predictions of risk, the specific sources of uncertainty due to dose-response relationships (in addition to those considered for ambient air concentration and exposure) are:

Uncertainty in hazard identification. The cancer risk estimates are based on the assumption that a compound is a carcinogen or produces a noncancer effect. This judgment was made based on the results of a hazard identification stage in which the evidence that a HAP produced either cancer and/or a noncancer effect is assessed. Since the evidence for either of these judgments is never perfect, there is always the possibility that a compound labeled a carcinogen, or

deemed to produce noncancer effects, might in fact produce no such effect in humans. This introduces uncertainty into the calculation of risk, since there is a possibility that the risk is zero. This possibility decreases as the evidence for the original claim (*i.e.*, that the compound produces the effect) increases.

Uncertainty in dose-response models for carcinogens. The cancer risk estimates are based on an assumption of linearity in the relationship between exposure and probability of cancer. In other words, the probability of cancer is assumed to be proportional to the exposure (equal to the exposure times a Unit Risk Estimate). This linear model is used routinely in regulatory risk assessment because it is believed to be conservative; *i.e.*, if the model is incorrect, it is more likely to lead to an overestimate of the risk than to an underestimate. Other scientifically valid, biologically-based models are available, and these produce estimates of cancer risk different from those obtained from the linear model. Uncertainty in risk estimates is, therefore, introduced by the inability to completely justify use of one model or the other (since there is at least some scientific support for each of many models). It is important to note here that this uncertainty is to some extent one-sided. In other words, it provides more confidence in the claim that the true risk is less than that predicted than in the claim that the risk is greater than that predicted.

Uncertainty in Unit Risk Estimate parameters. The linear cancer dose-response model uses a Unit Risk Estimate (URE) specific to each HAP. In some cases, these UREs are based on best (maximum likelihood) estimates of the slope of the dose-response relationship based on reliable data, and in other cases these estimates are based on “upper bound” estimates (*i.e.*, the slope is not the best estimate, but is a conservative value that is likely to lead to overestimates of risk) based on less reliable data. For some compounds the data are from human exposures, while for others they are from animal exposures. These issues cause the URE values to be uncertain, and the amount of uncertainty to vary among HAPs.

Uncertainty in Reference Concentration parameters. The noncancer effects model uses a Reference Concentration (RfC, and estimate of a chronic exposure that has no adverse effects) to calculate a Hazard Quotient (HQ) for a specific compound. The HQ is the ratio of the actual exposure to the RfC. The RfC, which like the URE is based on limited information, is uncertain, and as a result the value of HQ also is uncertain. It is important to bear in mind that the uncertainty in the RfC is to some extent one-sided. In other words, it provides more confidence in the claim that the true noncancer hazard is less than that predicted than in the claim that the risk is greater than that predicted.