be described and the similarities and differences discussed.

C. Quality of the Data Base and Degree of Confidence in the Assessment

The risk characterization should summarize the kinds of data brought together in the analysis and the reasoning on which the assessment is based. The description should convey the major strengths and weaknesses of the assessment that arise from availability of data and the current limits of our understanding of the mechanisms of toxicity.

Health risk is a function of the hazard characterization, dose-response analysis, and exposure assessment. Confidence in the results of a risk assessment is, thus, a function of confidence in the results of the analysis of these elements. Each of these elements should have its own characterization as a part of the assessment. Within each characterization, the important uncertainties of the analysis and interpretation of data should be explained, and the risk manager should be given a clear picture of consensus or lack of consensus that exists about significant aspects of the assessment. Whenever more than one view is supported by the data and choosing between them is difficult, all views should be presented. If one has been selected over the others, the rationale should be given; if not, then all should be presented as plausible alternative results.

D. Descriptors of Neurotoxicity Risk

There are a number of ways to describe risks. Several ways that are relevant to describing risks for neurotoxicity are as follows:

1. Estimation of the Number of Individuals

The RfD or RfC is taken to be a chronic exposure level at or below which no significant risk occurs. Therefore, presentation of the population in terms of those at or below the RfD or RfC ("not at risk") and above the RfD or RfC ("may be at risk") may be useful information for risk managers. This method is particularly useful to a risk manager considering possible actions to ameliorate risk for a population. If the number of persons in the at-risk category can be estimated, then the number of persons removed from the at-risk category after a contemplated action is taken can be used as an indication of the efficacy of the action.

2. Presentation of Specific Scenarios

Presenting specific scenarios in the form of "what if?" questions is particularly useful to give perspective to the risk manager, especially where criteria, tolerance limits, or media quality limits are being set. The question being asked in these cases is, at this proposed limit, what would be the resulting risk for neurotoxicity above the RfD or RfC?

3. Risk Characterization for Highly Exposed Individuals

This measure is one example of the just-discussed descriptor. This measure describes the magnitude of concern at the upper end of the exposure distribution. This allows risk managers to evaluate whether certain individuals are at disproportionately high or unacceptably high risk.

The objective of looking at the upper end of the exposure distribution is to derive a realistic estimate of a relatively highly exposed individual or individuals. This measure could be addressed by identifying a specified upper percentile of exposure in the population and/or by estimating the exposure of the highest exposed individual(s). Whenever possible, it is important to express the number of individuals who comprise the selected highly exposed group and discuss the potential for exposure at still higher levels.

If population data are absent, it will often be possible to describe a scenario representing high-end exposures using upper percentile or judgment-based values for exposure variables. In these instances caution should be used not to compound a substantial number of highend values for variables if a "reasonable" exposure estimate is to be achieved.

4. Risk Characterization for Highly Sensitive or Susceptible Individuals

This measure identifies populations sensitive or susceptible to the effect of concern. Sensitive or susceptible individuals are those within the exposed population at increased risk of expressing the toxic effect. All stages of nervous system maturation might be considered highly sensitive or susceptible, but certain subpopulations can sometimes be identified because of critical periods for exposure, for example, pregnant or lactating women, infants, children.

In general, not enough is understood about the mechanisms of toxicity to identify sensitive subgroups for all agents, although factors such as nutrition, personal habits (e.g., smoking, alcohol consumption, illicit drug abuse), or preexisting disease (e.g., diabetes, sexually transmitted diseases) may predispose some individuals to be more sensitive to the neurotoxic effects of various agents.

5. Other Risk Descriptors

In risk characterization, dose-response information and the human exposure estimates may be combined either by comparing the RfD or RfC and the human exposure estimate or by calculating the margin of exposure (MOE). The MOE is the ratio of the NOAEL from the most appropriate or sensitive species to the estimated human exposure level. If a NOAEL is not available, a LOAEL may be used in calculating the MOE. Alternatively, a benchmark dose may be compared with the estimated human exposure level to obtain the MOE. Considerations for the evaluation of the MOE are similar to those for the uncertainty factor applied to the LOAEL/NOAEL or the benchmark dose. The MOE is presented along with a discussion of the adequacy of the data base, including the nature and quality of the hazard and exposure data, the number of species affected, and the dose-response information.

The RfD or RfC comparison with the human exposure estimate and the calculation of the MOE are conceptually similar but are used in different regulatory situations. The choice of approach depends on several factors, including the statute involved, the situation being addressed, the data base used, and the needs of the decision maker. The RfD or RfC and the MOE are considered along with other risk assessment and risk management issues in making risk management decisions, but the scientific issues that must be taken into account in establishing them have been addressed here.

If the MOE is equal to or more than the uncertainty factor \times any modifying factor used as a basis for an RfD or RfC, then the need for regulatory concern is likely to be small. Although these methods of describing risk do not actually estimate risks per se, they give the risk manager some sense of how close the exposures are to levels of concern.

E. Communicating Results

Once the risk characterization is completed, the focus turns to communicating results to the risk manager. The risk manager uses the results of the risk characterization along with other technological, social, and economic considerations in reaching a regulatory decision. Because of the way in which these risk management factors