

PEER CONSULTATION CLARIFYING QUESTIONS

This Peer Consultation is being conducted pursuant to the October 2004 Memorandum of Understanding (MOU) between the U.S. Environmental Protection Agency (EPA) and 3M Company and Dyneon LLC (the Companies) for a Perfluorooctanoic Acid (PFOA) Site-Related Environmental Assessment Program. According to the MOU, the purpose of the Peer Consultation Group (PCG) is to provide scientific input on the Assessment documents produced by the Companies in light of the following Charge set forth in Section V.A. of the MOU, and in particular, on the recommended data needs.

THE CHARGE:

Are current PFOA environmental releases and sources of those environmental releases from the Site and the presence of PFOA in environmental media on and around the Site sufficiently understood so that pathways of migration and exposure to PFOA associated with that Site are adequately characterized and assessed on a screening level basis?

The three Assessment documents that are the subject of the Peer Consultation are:

- Data Assessment Report
- Screening Level Human Exposure Assessment Report
- Future Data Needs Assessment Report

The PCG will evaluate the Assessments for technical accuracy and proper documentation, determine the extent to which the Charge has been fully addressed, and determine what additional work is needed in Phase III to fully address the Charge. Section V.D. of the MOU provides the required content of each assessment document. The PCG should determine if these requirements have been met and also evaluate if the Assessments adequately present assumptions, calculations, supporting documentation, extrapolations, alternative interpretations, methodology, acceptance criteria, as well as other conclusions.

To facilitate the PCG's discussion, Menzie-Cura prepared the following clarifying questions that clarify the Charge as it relates to each of the three Assessment documents. Individual PCG members are given responsibility for specific clarifying questions. However, every member of the PCG is encouraged to review and comment on all the clarifying questions. All discussions among PCG members regarding this Peer Consultation must take place in an open forum.

EPA and the Companies reviewed these clarifying questions to ensure that they are consistent with the scope of the MOU. EPA and the Companies have agreed upon terminology to establish the general scope of the PFOA Site-Related Environmental Assessment Program (see MOU Section V.A.2.a-d). The following terminology, repeated verbatim from the MOU, governs interpretation of the Charge:

“Associated With The Site,” as used in the Charge, includes any current environmental release or presence in Environmental Media of PFOA on and off the site resulting from Current or Past Manufacturing Activities at the site. “Current or Past Manufacturing Activities” at the site refers to all activities that may have resulted in the current presence of PFOA in environmental media both on and off the site without regard to distance from the site, including but not limited to waste disposal activities that occurred off-site, such as landfills that received materials from the site; land application materials originating from the site; off-site treatment facilities receiving waste material from the site; and air emissions that may have deposited off the site, except that “Current or Past Manufacturing Activities” does not encompass commercial products manufactured at the site and distributed in commerce.

“Environmental media,” as used in the Charge, refers to air, surface water, groundwater, soil, sediment, biota, wastewater, waste streams, landfills, landfarms, water discharges and offsite disposal of all types.

“Pathways of Migration,” as used in the Charge, refers to the routes by which PFOA moves from any Current or Past Manufacturing Activity through Environmental Media, and includes but is not limited to, leaching to surface water or groundwater from land-applied materials; discharge from areas with contaminated groundwater to surface waters or wells; releases from landfills to air, groundwater and surface water; and air deposition to soils and migration to groundwater.

“Exposure to PFOA Associated With The Site,” as used in the Charge, refers to current exposures and the potential for future exposures from the presence of PFOA in Environmental Media as a result of Current or Past Manufacturing Activities at the site, but does not include an assessment of exposures that may have occurred in the past. The Screening Level Exposure Assessment of current human Exposure to PFOA Associated With The Site shall include a quantitative assessment for any exposure pathway for which the data allow quantitative assessment, and a qualitative or semi-quantitative description of exposure where the data do not allow quantitative assessment. The Screening Level Exposure Assessment will be based on data necessary to understand sources of release associated with the site and Pathways of Migration of those releases. Although the Screening Level Exposure Assessment will focus primarily on human exposure, it will characterize the presence of PFOA in Environmental Media, including biota, on and off the site as a result of Current or Past Manufacturing Activities.

“Screening Level Exposure Assessment” is not included in the list of definitions provided in Section V.A.2 of the MOU. However, the MOU specifies that this assessment “shall characterize exposure and releases associated with the Site in accordance with EPA’s “Guidelines for Exposure Assessment”, EPA/600/Z-92/001 (May 1992) and using the scenario evaluation approach set forth in these EPA Guidelines at § 2.2.2” to provide “a quantitative, conservative assessment for any exposure pathway for which the data allow quantitative assessment. Where the data do not allow such quantitative assessment of an exposure pathway, the Screening Level Exposure Assessment for current human exposure will present a qualitative or semi-quantitative description of exposure.” EPA’s

1992 “Guidelines for Exposure Assessment” also do not provide a definition for the phrase “Screening Level Exposure Assessment” but they provide some discussion related to screening level analyses in Sections 3.1.1, 3.3, 3.5.3.2, 4.2.3, 5.3.4, and 6.2 (Attachment A includes text excerpted verbatim from these sections).

CLARIFYING QUESTIONS RELATED TO THE DATA ASSESSMENT REPORT

Please answer the clarifying questions in light of the Charge, the definitions given above, and the full MOU text. As you do this, consider whether the Assessments fully address the Charge or if further work is needed.

1. Are the data and information presented in this report relevant to the Screening Level Exposure Assessment and of sufficient quality, quantity, objectivity, utility, and integrity? Were sufficient samples of each environmental medium collected? Were the analytical procedures and levels of quantitation and detection adequate? Does the assessment adequately characterize the presence of PFOA associated with the site?
2. Are the characteristics of the on-site and off-site locations evaluated in this assessment described in a sufficient level of detail to understand potential human exposure pathways? These characteristics include, for example, land use patterns, characteristics of the local population, habitats, and general physical conditions.
3. Have the nature of the soil, sub-surface geological, sedimentary, and hydrological conditions been adequately described for the purposes of assessing pathways of migration?
4. Have the pathways of migration of PFOA from the following environmental media to other environmental media been adequately considered and represented?
 - a. Soil
 - b. Groundwater
 - c. Surface water
 - d. Sediment
 - e. Air
 - f. Biota
 - g. Wastewater treatment sludge and biosolids

CLARIFYING QUESTIONS RELATED TO THE SCREENING LEVEL HUMAN EXPOSURE ASSESSMENT REPORT

Site Conceptual Model

5. Does the site conceptual model adequately characterize sources associated with the site and exposure pathways linking these sources to on-site and off-site human receptors?
6. Have all appropriate receptors been identified? Do they include potentially highly exposed populations?
7. Do the selected exposure scenarios sufficiently cover the situations, behaviors, and conditions under which receptors are likely to be exposed?

Elements of Exposure Analysis and Utilization of Data

8. Are the monitoring data sufficient to quantify exposure?
 - a. Are the data representing each environmental medium sufficient to support the exposures that were quantified in the assessment? Are data needed for other environmental media?
 - i. Soil
 - ii. Groundwater
 - iii. Surface water
 - iv. Sediment
 - v. Biota
 - b. Of the data available to the authors, did they select the right data sets to quantify exposure? Should they have considered any of the data excluded from the analysis?
9. Were the data used appropriately to calculate exposure point concentrations (EPCs)?
 - a. Did the authors define reasonable exposure points that represent locations associated with current and future exposure?
 - b. Are the data sufficient to understand the presence and concentration of PFOA in environmental media at each exposure point?
 - c. Were EPC calculations and other statistical manipulations (e.g., treatment of results below detection limits, field duplicates, and qualified data) of these data performed accurately and appropriately?
 - d. Do the data indicate that there are exposure points other than those identified in this assessment?
10. Other than the EPCs, were the assumptions and exposure input parameters for each combination of pathway and receptor appropriate?
 - a. Was bioavailability of PFOA in the various exposure media (e.g., soil and sludge) addressed appropriately?
 - b. Have the appropriate age groupings been defined?
 - c. Are the selected receptor characteristics and exposure patterns (i.e., duration, frequency, and intensity) the most appropriate for use in this assessment?
 - d. Were the doses averaged over the appropriate time interval?
 - e. Overall, are the input data and assumptions valid and appropriate for all receptors?
11. Were the appropriate exposure pathways selected for quantifying dose? Was the justification for excluding exposure pathways from dose estimation reasonable?

12. For exposure pathways for which the data did not allow quantitative assessment, did the authors present a qualitative or semi-quantitative description of exposure?

Uncertainty Analysis and Data Needs to Remedy Uncertainty

13. The authors describe data needs for exposure pathways that were not quantified in this assessment. Do you agree with recommendations for further sampling and analysis designed to facilitate quantification of these other exposure pathways on a screening level basis? Do you have other recommendations for data collection, modeling and other analyses, and exposure pathway quantification?
14. Were all the significant sources of uncertainty identified and characterized? Are the authors' conclusions regarding the significance and impact of the uncertainties on the resulting assessment conclusions appropriate (See Table 9-1)? Given uncertainties, what is the likelihood that actual exposures have been over-estimated or under-estimated?

CLARIFYING QUESTIONS RELATED TO THE FUTURE DATA NEEDS ASSESSMENT REPORT

15. Does this Assessment identify additional data and/or other appropriate information necessary? Please identify any critical data gaps or potential pathways for exposure you feel have not been identified.
16. Does the Phase 3 Work Plan Outline contain all of the technical elements required for gathering the proposed additional data?

ATTACHMENT A

Excerpts from EPA's 1992 "Guidelines for Exposure Assessment" Related to Screening Level Analyses (EPA/600/Z-92/001, May 1992)

Peer Consultation Group members should consult the EPA, 1992 guidance in its entirety in reviewing the three Assessment documents, however the following excerpts related to screening level analyses are provided for convenience.

pp. 52-53: **3.1.1. Using Exposure Assessments in Risk Assessment**

If the exposure assessment is part of a risk assessment used as a screening device for setting priorities, the emphasis is more on the comparative risk levels, perhaps with the risk estimates falling into broad categories (e.g., semi-quantitative categories such as high, medium, and low). For such quick-sorting exercises, rarely are any techniques used other than modeling and scenario development. Decisions made in such cases rarely involve direct cleanup or regulatory action without further refinement of the risk assessment, so the scenario development approach can be a cost-effective way to set general priorities for future investigation of worst risk first.

pp. 55-56: **3.3. Level of Detail of the Assessment**

The level of detail, or depth of the assessment, is measured by the amount and resolution of the data used, and the sophistication of the analysis employed. It is determined by the purpose of the exposure assessment and the resources available to perform the assessment. Although in theory the level of detail needed can be established by determining the accuracy of the estimate required, this is rarely the case in practice. To conserve resources, most assessments are done in an iterative fashion, with a screening done first; successive iterations add more detail and sophistication. After each iteration, the question is asked, is this level of detail or degree of confidence good enough to achieve the purpose of the assessment? If the answer is no, successive iterations continue until the answer is affirmative, new input data are generated, or as is the case for many assessments, the available data, time, or resources are depleted. Resource-limited assessments should be evaluated in terms of what part of the original objectives have been accomplished, and how this affects the use of the results.

The level of detail of an exposure assessment can also be influenced by the level of sophistication or uncertainty in the assessment of health effects to be used for a risk assessment. If only very weak health information is available, a detailed, costly, and in-depth exposure assessment will in most cases be wasteful, since the most detailed information will not add significantly to the certainty of the risk assessment.

pp. 67-68: **3.5.3.2. Characterization and Model Selection**

Regardless of whether models are extensively used in an assessment and a formal modeling strategy is documented in the exposure assessment plan, when computer simulation models such as fate and transport models and exposure models are used in exposure assessments, the assessor must be aware of the performance characteristics of the model and state how the exposure assessment requirements are satisfied by the model.

If models are to be used to simulate pollutant behavior at a specific site, the site must be characterized. Site characterization for any modeling study includes examining all data on the site such as source characterization, dimensions and topography of the site, location of receptor populations, meteorology, soils, geohydrology, and ranges and distributions of chemical concentrations. For exposure models that simulate both chemical concentration and time of exposure (through behavior patterns) data on these two parameters must be evaluated.

For all models, the modeler must determine if databases are available to support the site, chemical, or population characterization, and that all parameters required by the model can be obtained or reasonable default values are available. The assessment goals and the results of the characterization step provide the technical basis for model selection.

Criteria are provided in U.S. EPA (1987b, 1988f) for selection of surface water models and ground-water models respectively; the reader is referred to these documents for details. Similar selection criteria exist for air dispersion models (U.S. EPA, 1986e, 1987c, 1991b).

A primary consideration in selecting a model is whether to perform a screening study or to perform a detailed study. A screening study makes a preliminary evaluation of a site or a general comparison between several sites. It may be generic to a type of site (i.e., an industrial segment or a climatic region) or may pertain to a specific site for which sufficient data are not available to properly characterize the site. Screening studies can help direct data collection at the site by, for example, providing an indication of the level of detection and quantification that would be required and the distances and directions from a point of release where chemical concentrations might be expected to be highest.

The value of the screening-level analysis is that it is simple to perform and may indicate that no significant contamination problem exists. Screening-level models are frequently used to get a first approximation of the concentrations that may be present. Often these models use very conservative assumptions; that is, they tend to overpredict concentrations or exposures. If the results of a conservative screening procedure indicate that predicted concentrations or exposures are less than some predetermined no-concern level, then a more detailed analysis is probably not necessary. If the screening estimates are above that level, refinement of the assumptions or a more sophisticated model are necessary for a more realistic estimate.

Screening-level models also help the user conceptualize the physical system, identify important processes, and locate available data. The assumptions used in the preliminary analysis should represent conservative conditions, such that the predicted results overestimate potential conditions, limiting false negatives. If the limited field measurements or screening analyses indicate that a contamination problem may exist, then a detailed modeling study may be useful.

A detailed study is one in which the purpose is to make a detailed evaluation of a specific site. The approach is to use the best data available to make the best estimate of spatial and temporal distributions of chemicals. Detailed studies typically require much more data of higher quality and models of greater sophistication.

pp. 82-83: **4.2.3. Selection of Models for Environmental Concentrations**

Selection of an appropriate model is essential for successful simulation of chemical concentrations. In most cases assessors will be able to choose between several models, any of which could be used to estimate environmental concentrations. There is no right model; there may not even be a best model. There are, however, several factors that will help in selecting an appropriate model for the study. The assessor should consider the objectives of the study, the technical capabilities of the models, how readily the models can be obtained, and how difficult each is to use (U.S. EPA, 1987b, 1988f).

The primary consideration in selecting a model is the objective of the exposure assessment. The associated schedule, budget, and other resource constraints will also affect model selection options. Models are available to support both screening-level and detailed, site-specific studies. Screening models can provide quick, easy, and cost-effective estimates of environmental concentrations. They can support data collection efforts at the site by indicating the required level of detection and quantification and the locations where chemical concentrations are expected to be highest. They are also used to interpolate chemical concentrations between measurements. Where study objectives require the best estimates of spatial and temporal distributions of chemicals, more sophisticated models are available. These models require more and better data to characterize the site, and therefore site-specific data may be needed in order to use them.

The technical capabilities of a model are expressed in its ability to simulate site specific contaminant transport and transformation processes. The model must be able to simulate the relevant processes occurring within the specified environmental setting. It must adequately represent the physical setting (e.g., the geometric configuration of hydrogeological systems, river widths and depths, soil profiles, meteorological patterns, etc.) and the chemical transformation processes. Field data from the area where doses are to be estimated are necessary to define the input parameters required to use the models. In cases in which these data are not available, parameter values representative of field conditions should be used as defaults. Assumptions of homogeneity and simplification of site geometry may allow use of simpler models.

In addition, it is important to thoroughly understand the performance characteristics of the model used. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements.

pp. 105-108: **5.3.4. General Methods for Estimating Exposure and Dose**

A variety of methods are used to obtain estimates of dose necessary for risk characterization. These range from quick screening level calculations and rules of thumb to more sophisticated techniques. The technique to be used in a given case is a matter of the amount of information available and the purpose of the assessment. Several of the methods are outlined in the following sections.

Normally it is neither practicable nor advisable to immediately develop detailed information on all the potential pathways, since not all may contribute significantly to the outcome of the assessment.³¹ Rather, evaluation of the scenario is done in an iterative manner. First, screening or

bounding techniques are used to ascertain which pathways are unimportant, then the information for the remaining pathways is refined, iteratively becoming more accurate, until the quantitative objectives of the assessment are met (or resources are depleted).

In beginning the evaluation phase of any assessment, the assessor should have a scenario's basic assumptions (setting, scope, etc.) well identified, one or more applicable exposure pathways defined, an equation for evaluating the exposure or dose for each of those exposure pathways, and the data and information requirements pertinent to solving the equations. Quality and quantity of data and information needed to substitute quantitative values or ranges into the parameters of the exposure equation will often vary widely, from postulated assumptions to actual high-quality measurements. Many times, there are several exposure pathways identified within the scenario, and the quality of the data and information may vary for each.

A common approach to estimating exposure and dose is to do a preliminary evaluation, or screening step, during which bounding estimates are used, and then to proceed to refine the estimates for those pathways that cannot be eliminated as of trivial importance.

5.3.4.1. Preliminary Evaluation and Bounding Estimates

The first step that experienced assessors usually take in evaluating the scenario involves making bounding estimates for the individual exposure pathways. The purpose of this is to eliminate further work on refining estimates for pathways that are clearly not important.

The method used for bounding estimates is to postulate a set of values for the parameters in the exposure or dose equation that will result in an exposure or dose higher than any exposure or dose expected to occur in the actual population. The estimate of exposure or dose calculated by this method is clearly outside of (and higher than) the distribution of actual exposures or doses. If the value of this bounding estimate is not significant, the pathway can be eliminated from further refinement.³²

The theoretical upper bounding estimate (TUBE) is a type of bounding estimate that can be easily calculated and is designed to estimate exposure, dose, and risk levels that are expected to exceed the levels experienced by all individuals in the actual distribution. The TUBE is calculated by assuming limits for all the variables used to calculate exposure and dose that, when combined, will result in the mathematically highest exposure or dose (highest concentration, highest intake rate, lowest body weight, etc.). The theoretical upper bound is a bounding estimate that should, if the limits of the parameters used are known, ensure that the estimate is above the actual exposures received by all individuals in the population. It is not necessary to go to the formality of the TUBE to assure that the exposure or dose calculated is above the actual distribution, however, since any combination that results in a value clearly higher than the actual distribution can serve as a suitable upper bound.

The bounding estimate (a limit of individual exposure, dose or risk) is most often used only to eliminate pathways from further consideration. This is often done in screening-level assessments, where bounding estimates of exposure, dose, or risk provide a quick and relatively easy check on whether the levels to be assessed are trivial relative to a level that would cause concern. If acceptably lower than the concern level, then additional assessment work is not necessary.

Bounding estimates also are used in other types of assessments. They can be used for deregulation of chemicals when pathways or concentrations can be shown to present insignificant or *de minimis* risk. They can be used to determine whether more information is needed to determine whether a pathway is significant; if the pathway's significance cannot be ruled out by a bounding estimate, test data may be needed to refine the estimate.

There are two important points about bounding estimates. First, the only thing the bounding estimate can establish is a level to eliminate pathways from further consideration. It cannot be used to make a determination that a pathway is significant (that can only be done after more information is obtained and a refinement of the estimate is made), and it certainly cannot be used for an estimate of actual exposure (since by definition it is clearly outside the actual distribution). Second, when an exposure scenario is presented in an assessment, it is likely that the amount of refinement of the data, information, and estimates will vary by pathway, some having been eliminated by bounding estimates, some eliminated after further refinement, and others fully developed and quantified. This is an efficient way to evaluate scenarios. In such cases, bounding estimates must not be considered to be equally as sophisticated as an estimate of a fully developed pathway, and should not be described as such.

Experienced assessors can often eliminate some obvious pathways more or less by inspection as they may have evaluated these pathways many times before.³³ In these cases, the assessor must still explain why the pathway is being eliminated. For less experienced assessors, developing bounding estimates for all pathways is instructive and will be easier to defend.

5.3.4.2. Refining the Estimates of Exposure and Dose

For those pathways not eliminated by bounding estimates or judged trivial, the assessor will then evaluate the resulting exposure or dose. At this point, the assessor will make estimates of exposure or dose that are designed to fall on the actual distribution. The important point here is that unlike a bounding estimate, these estimates of exposure or dose should focus on points in the actual distribution. Both estimates of central tendency and estimates of the upper end of the distribution curve are useful in crafting risk descriptors.

Consider Equation 2-6 for the lifetime average daily potential dose (LADD_{pot}), an equation often used for linear, nonthreshold carcinogen risk models. The assessor will use the data, ranges of data, distributions of data, and assumptions about each of the factors needed to solve the equation for dose. Generally, both central estimates and highend estimates are performed. Each of these estimates has uncertainty (perhaps unquantifiable uncertainty), and the better the quality and comprehensiveness of data used as input to the equation, the less uncertainty.

After solving the equation, the assessor will determine whether the uncertainty associated with the answer is sufficiently narrow to allow the risk descriptors to be developed (see Section 3.4) and to answer satisfactorily the questions posed in the exposure assessment statement of purpose. Evaluating whether the data, uncertainty, risk descriptors, and answers to the questions are good enough is usually a joint responsibility of the risk assessor and the risk manager.

Should the estimates of exposure or dose have sufficiently narrow uncertainty, the assessor can then proceed to develop the descriptors and finish the assessment. If not, the data or assumptions used usually will have to be refined, if resources allow, in an attempt to bring the estimated exposure or dose closer to what the assessor believes are the actual values in the population. Refining the estimates usually requires that new data be brought into consideration³⁴; this new information can be other studies from the literature, information previously developed for another, related purpose that can be adapted, or new survey, laboratory, or field data. The decision about which particular parts of the information base to refine should be based both on which data will most significantly reduce the uncertainty of the overall exposure or dose estimate, and on which data are in fact obtainable either technologically or within resource constraints.

After refinement of the estimate, the assessor and risk manager again determine whether the estimates provided will be sufficient to answer the questions posed to an acceptable degree, given the uncertainties that may be associated with those estimates. Refinements proceed iteratively until the assessment provides an adequate answer within the resources available.

³¹ There are some important exceptions to this statement. First, the public or other concerned groups may express particular interest in certain pathways, which will not normally be dropped entirely at this point. Second, for routine repetitive assessments using a certain standard scenario for many chemicals, once the general bounding has been done on the various possible pathways, it may become standard operating procedure to immediately begin developing information for particular pathways as new chemicals are assessed.

³² "Not significant" can mean either that it is so small relative to other pathways that it will not add perceptibly to the total exposure being evaluated or that it falls so far below a level of concern that even when added to other results from other pathways, it will be trivial. Note that a "level of concern" is a risk management term, and the assessor must discuss and establish any such levels of concern with risk managers (and in some cases, concerned groups such as the local community) before eliminating pathways as not significant.

³³ Experienced assessors may also be able to determine quickly that a pathway requires refined estimation.

³⁴ It also can involve new methods or additional methods for analyzing the old data.

pp.126: **6.2. Types of Uncertainty**

Uncertainty in exposure assessment can be classified into three broad categories:

1. Uncertainty regarding missing or incomplete information needed to fully define the exposure and dose (scenario uncertainty)
2. Uncertainty regarding some parameter (parameter uncertainty)
3. Uncertainty regarding gaps in scientific theory required to make predictions on the basis of causal inferences (model uncertainty)

Identification of the sources of uncertainty in an exposure assessment is the first step toward eventually determining the type of action necessary to reduce that uncertainty. The three types of uncertainty mentioned above can be further defined by examining some principal causes for each.

Exposure assessments often are developed in a phased approach. The initial phase usually involves some type of broad-based screening in which the scenarios that are not expected to pose a risk to the receptor are eliminated from a more detailed, resource-intensive review, usually through developing bounding estimates. These screening-level scenarios often are constructed to

represent exposures that would fall beyond the extreme upper end of the expected exposure distribution. Because the screening-level assessments for these nonproblem scenarios usually are included in the final exposure assessment document, this final document may contain scenarios that differ quite markedly in level of sophistication, quality of data, and amenability to quantitative expressions of uncertainty. These also can apply to the input parameters used to construct detailed exposure scenarios.