

June 11, 2013

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Re: Comments on “Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Docket ID No. EPA-HQ-2013-0320” for Science Advisory Board Environmental Justice Technical Review Panel

To Dr. Sue Shallal:

I write regarding the U.S. Environmental Protection Agency’s Technical Guidance for Assessing Environmental Justice in Regulatory Analysis (“Technical Guidance”) so that the Science Advisory Board Environmental Justice Technical Review Panel can consider these comments when it convenes the public meeting on June 19, 2013 and June 20, 2013. To place these comments into context, I have a B.S. in biology, a M.S. in environmental science, and a J.D. with a certificate concentration in environmental law and an interest in environmental justice (EJ) concerns.

My comments will address various parts of EPA’s Draft Technical Guidance for Assessing Environmental Justice in Regulatory Analysis published in the Federal Register in May 2013. Page numbers in these comments refer to the page numbers in the Technical Guidance.

I. Pages 2, 3, 4: The EPA should clarify when certain actions are “feasible”

On page 2, the Technical Guidance states that the analyst should ascertain the extent to which a potential EJ concern is associated with environmental stressors by assessing the exposures, relevant health and environmental outcomes, and other relevant effects by population group in the baseline and assessing the differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups in the baseline “when feasible”.

On page 2, the Technical Guidance also states that for each regulatory option under consideration, to inform the extent to which a potential EJ concern is created or mitigated for the affected stressors, the analyst should assess exposures, relevant health and environmental outcomes, and other relevant effects by population group for each option, assess differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups for each option, and assess how estimated differences in these exposures, outcomes, and other effects across population groups increase or decrease as a result of each option as compared to the baseline “when feasible.” On page 2, the Technical Guidance states that analysts should follow identified best practices “when feasible and applicable.”

On pages 17 and 18, the Technical Guidance states that certain factors may influence susceptibility to an environmental stressor, such as “genetics, diet, nutritional status, pre-existing

disease, psychological stress, co-exposure to similarly acting toxics, and cumulative burden of disease resulting from exposure to all stressors throughout the course of life.” On page 17, the Technical Guidance also states that exposure to a specific stressor from one source can inaccurately characterize the potential for health risks if the populations for which risk is being estimated are also exposure to a stressor from multiple sources and that the presence of crime may increase individuals’ stress hormones and immunological responses to chemical exposures. On page 34, the Technical Guidance also state that age, chronic disease, immune status, medication status, occupation, income, educational level, lack of access to resources, such as health care, and negative social conditions can influence the likelihood of exposure and risk of adverse health outcome that may result from this exposure. Page 41 of the Technical Guide recommends obtaining data on hospital and emergency admissions.

EPA should define the term “feasible” in all three places so that concerned individuals, community members, and others will know when an EPA analyst plans to make this assessment so that they may be able to complete their own assessment or voice their concerns about the lack of an assessment and so that there will not be an inequitable completion of these assessments for individuals and communities facing similar problems or stressors. The stated purpose of the Technical Guidance, as displayed on page 3, is to provide analysts with information on how to address the analytic objectives and to identify (1) which adverse health and environmental outcomes and other relevant effects are associated with the regulated stressor or source for the population groups of concern relative to a comparison population group, (2) whether these outcomes are differentially distributed across population groups, and (3) whether any differences are potentially disproportionate. To satisfy these objectives for all individuals in these population groups of concern, the analysts should assess potential EJ concerns and effects of environmental stressors on all population groups of concern. The extent of the analysis should not vary among these population groups of concern. Contrary to the statement on page 3 that the six recommendations are not prescriptive and do not mandate the use of a specific approach, analysts should have a uniform protocol to follow in conducting the environmental justice assessments so that all individuals in low-income, minority, and indigenous communities are protected from disproportionate harm from environmental stressors so that analysts should always conduct high quality analysis, rather than conducting the “highest quality analysis feasible.”

To satisfy these purposes, the EPA should add the following language or similar language following the sentences discussed above on page 2: “An assessment is feasible when a Census Blockgroup has a minority population of greater than 40% (*see e.g.*, U.S. Census Bureau 5-year Estimates from the American Community Survey (ACS), Percent Minority includes all race/ethnicities except non-Hispanic White persons, Available by Blockgroup, by Tract, and by County Tables) or a Census Tract has 40 of its population below 150% of the federal poverty level (*see e.g.*, U.S. Census Bureau 5-year Estimates from the American Community Survey (ACS), Ratio of Income to Poverty Level of Families in the Past 12 Months Table) and in all American Indian reservation and subreservation areas or where there is a Medically Underserved Population as shown in EPA’s EJView found at <http://epamap14.epa.gov/ejmap/ejmap.aspx?wherestr=Baltimore%2C%20MD>.” The EPA should provide its analysts with a single place on its server where it can obtain the data from EPA, the Census Bureau, and other locations necessary for the analyses to save time, resources,

to ensure that the analyses are as uniform as possible, and to ensure that the analyses are conducted for all population groups of concern.

On page 3, the Technical Guidance states that analysts should present information on estimated health and environmental risks, exposures, outcomes, benefits and other relevant effects disaggregated by race/ethnicity and income “when feasible.” Similarly, on page 4, the Technical Guidance lists best practices to characterize the distribution of risks, exposures, or outcomes across individuals, gender, life stages, or other relevant categories within each population group “when feasible,” to disaggregate data to reveal important spatial differences “when feasible and appropriate,” and to conduct sensitivity analysis for key parameters or assumptions that may affect findings “when feasible.”

To satisfy the purposes of the Technical Guidance, the EPA should present information on estimated health and environmental risks, exposures, outcomes, benefits, and other relevant effects when a Census Blockgroup has a minority population of greater than 40% or a Census Tract has 40 of its population below 150% of the federal poverty level and for all American Indian reservation and subreservation areas and Medically Underserved Population areas as explained above. In addition to adding this language, the EPA should add a sentence that states “It is feasible to present information on estimated health and environmental risks, exposures, outcomes, benefits, and other relevant effects by race/ethnicity for the six and sixty-three race/ethnicity groups surveyed in the 2010 Census and by income for those below the federal poverty level, below 125 percent of the federal poverty level, below 150 percent of the federal poverty level, below 200 percent of the federal poverty level, below 300 percent of the federal poverty level, and 300 percent of the federal poverty level and above, for both males and females, for children under age 5, age 5-14 years old, age 15 to 19 years old, age 20 to 44 years old, age 45 to 49 years, age 50 to 64, and age 65 and older, for those with any lung condition such as asthma, chronic bronchitis, emphysema, heart disease, or lung cancer for any air pollutant stressor or liver or kidney disease for any water pollutant, for those who consume fish, shellfish, and/or game above the recommended level in areas where there is an advisory, for those who are experiencing under-nutrition, a food desert, or low-food access, for those who lack adequate access to health care or are in a Medically Underserved Area or in a Medically Underserved Population, by the percentage of the population in the area that stayed at a hospital or used the emergency room, by the number of stressors exposed to, and by the crime rate in the area or stress hormone level.”

Data on race/ethnicity, gender, income, educational attainment, and occupation are available from the American Community Survey. Data on health care access, health status, Medically Underserved Areas and Populations, and hospital and emergency room visits are available at the Medical Expenditure Panel Survey Household Component and Health Professional Shortage Areas & Medically Underserved Populations websites. Data on nutrition, food deserts, and food access are available at the Food Access Research Atlas and Food and Nutrition Surveys websites. Data on crime rate by Metropolitan Statistical Area, city, or county is available at the FBI Crime Justice Information Services Division website.

See, e.g., U.S. EPA, Technical Guidance, page 18; U.S. Census Bureau, 2010 Census Summary File 1, Tbl. PCT11: Hispanic or Latino By Specific Origin, available at

http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_PCT11&prodType=table; U.S. Census Bureau, 2007-2011 American Community Survey 5-Year Estimates, Tbl. S0101: Age and Sex, *available at* http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_11_5YR_S0101&prodType=table; Iyad Kheirbek et al., PlaNYC & NYC Health, Air Pollution and the Health of New Yorkers: The Impact of Fine Particles and Ozone, *available at* <http://www.nyc.gov/html/doh/downloads/pdf/eode/eode-air-quality-impact.pdf>; AL Braga et al., *Health Effects of Air Pollution Exposure on Children and Adolescents in São Paulo, Brazil*, 31(2) *Pediatric Pulmonology* 106 (2001); Congressional Budget Office, Social Security Disability Insurance March 2012 Baseline (2012), *available at* http://www.cbo.gov/sites/default/files/cbofiles/attachments/43061_DisabilityInsurance.pdf; Kathy Ruffing, Center on Budget and Policy Priorities, Don't Forget Demographics' Role in Rising Disability Costs (May 2, 2012, 13:57), *available at* <http://www.offthechartsblog.org/dont-forget-demographics-role-in-rising-disability-costs/>; Kathy Ruffing, Center on Budget and Policy Priorities, No Surprise: Disability Beneficiaries Experience Higher Death Rates (Apr. 4, 2013, 16:17), *available at* <http://www.offthechartsblog.org/category/social-security/page/3/>; Alcoholic Liver Disease In-Depth Report, <http://health.nytimes.com/health/guides/disease/alcoholic-liver-disease/print.html>; General Recommendations for Patients with Advanced Cirrhosis, *The N.Y. Times*, <http://louisville.edu/medschool/gimedicine/documents/Cirrhosis%20Recommendations.pdf>; End Stage Renal Disease, Johns Hopkins Medicine, http://www.hopkinsmedicine.org/healthlibrary/conditions/kidney_and_urinary_system_disorders/end_stage_renal_disease_esrd_85,P01474/ (last visited June 10, 2013); USDA Economic Research Service, Food Access Research Atlas, <http://www.ers.usda.gov/data-products/food-access-research-atlas.aspx> (last updated May 8, 2013); USDA National Agricultural Library, Food and Nutrition Surveys, <http://fnic.nal.usda.gov/surveys-reports-and-research/food-and-nutrition-surveys> (last modified June 11, 2013); U.S. HHS, Medical Expenditure Panel Survey Household Component, HealthData.gov, <http://www.healthdata.gov/data/dataset/medical-expenditure-panel-survey-household-component> (last updated Sept. 27, 2012); U.S. Census Bureau, Search: American Community Survey: Educational Attainment, <http://factfinder2.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t> (last visited June 11, 2013); U.S. HHS Health Resources and Services Administration, Shortage Designation: Health Professional Shortage Areas & Medically Underserved Populations, <http://www.hrsa.gov/shortage/> (last visited June 11, 2013); U.S. DOJ, FBI, Criminal Justice Information Services Division, 2008 Crime in the United States, <http://www2.fbi.gov/ucr/cius2008/> (last visited June 11, 2013).

EPA should obtain this data from available surveys or studies or should provide a sufficient sample of individuals in the population groups of concern with the opportunity to get a health screening (e.g., 10 individuals in each of the 63 race/ethnicity groups and six income groups) and should monitor the air/water of the area and conduct a representative survey of the area to obtain the necessary information to complete the assessment. Setting a uniform standard for when information is presented for population groups of concern will avoid an indiscriminate display of information and determination of when quantitative and qualitative analysis should be used. Obtaining sufficient information from surveys, studies, health screenings, and/or monitoring will eliminate the need to evaluate risk or exposure using inadequate metrics such as the prevalence

of affected facilities as a function of race/ethnicity or income or evidence of unique or unusual consumption patterns or contract rates if those metrics will not lead to a finding that there is a disproportionate impact on population groups of concern.

II. Best Practices

A. Latest demographic data

The best practices list on page 4 states to use the latest demographic data available. EPA may not want to use the latest demographic data if other data are more informative. For example, 5-year census estimates might be more informative than 1-year estimates.

B. Selecting comparison group

The variety of comparison group example shown on page 9 and the statement on that page that “[t]here are a variety of ways to define a comparison group indicate that more guidance is needed on the selection of comparison groups.”

The Technical Guidance does state on page 9 that the comparison groups are important to evaluate risk, exposure, and health outcomes and should be carefully selected:

The comparison group definition can have important implications for evaluating the distribution of risk, exposure, and health outcomes across population groups of concern in the baseline and under various policy options. In selecting a comparison group, an analyst should evaluate how the use of different comparison groups affects the way information is conveyed to the decision maker.

On page 10, the Technical Guidance states that the analyst should “carefully document the criteria used to choose the comparison group for a particular regulatory action” and “may wish to conduct sensitivity analysis using alternate definitions of the comparison group “when appropriate and practical.”

Page 49 of the Technical Guidance states that between-group comparisons between individuals with different socioeconomic characteristics may be more relevant than within-group comparisons with individuals with similar socioeconomic characteristics because it is the differences across groups that is of primary importance. The Technical Guidance also states on that page that restricting the comparison group to a sub-national level may be preferable given the heterogeneity in industrial development and economic growth and differences in socioeconomic composition across geographic regions and that restricting the comparison groups may reduce sample sizes and the power of statistical tests or bias the results by reducing variation in socioeconomic variables of concern.

Pages 17-18 describes the many different factors that may influence susceptibility to environmental stressors.

To abide by these suggestions, the Technical Guidance should require that the comparison group(s) be selected so that the impact on local population groups of concern by the stressor can be accurately estimated. Multiple comparison groups should be selected if needed for estimating the impact on all potentially affected population groups of concern. To also follow the statements on pages 9 and 10 that the comparison groups are important and should be carefully selected, the comparison groups should be selected so that effects can be accurately estimated on all susceptible/sensitive individuals and different life stages, socioeconomic status, diet, nutrition, consumption patterns, access to health care, education, gender, work experience, exposure to multiple sources, such as occupationally and residentially, and the presence of crime in the area (which EPA states on page 17 may change individuals' immunological response due to the increased presence of stress hormones) or stress hormones of population groups of concern. For example, children under the age of 6 of different races, genders, etc should be compared in areas near the environmental stressor of lead and in areas not near the environmental stressors because as explained on page 18, children of that age are more likely to experience adverse neurological health effects from certain levels of lead. Because counties may contain Census Tracts and Blockgroups that have people of different races, incomes, poverty levels and that face different degrees of high mortality risk for reasons related or unrelated to the regulatory action, such as due to consumption patterns, nutrition experiences, access to health care, life stages, and diseases, the comparison group discussed in Text Box 2.1 on page 9 might not be appropriate and the agency should provide a carefully considered and standard set of comparison groups for analysts to evaluate the risks to population groups of concern.

The analyst should analyze and present differences at a sub-national and national level because of the possible differences in geographic regions. Comparison groups can be conducted nationally to obtain a larger sample size, but in areas where low-income and minority communities exist, more sampling can be conducted in those areas to eliminate the possibility of low sample size in those areas.

Both within-group and between-group comparisons should be made because activities that have significant within-group effects mean individuals are adversely affected by the activity and evaluating whether individuals of a specific socioeconomic category living near an environmental stressor have different exposure and health impacts compared to individuals in the same socioeconomic category not living near environmental stressors provides a good estimate of the impact of the environmental stressor.

C. Statistical analyses used for comparison analyses

The best practices state that the analyst should “[p]resent summary metrics (e.g. risk ratios and measures of statistical significance) for relevant population groups of concern and the comparison group, not just data on each population group or area.”

The Technical Guidance should provide details on the statistical analyses to use on the different types of data likely to be collected and analyzed so that they are systematically performed correctly. Also, the data (instead of just the summary metrics) should be presented and the summary metrics should include estimates of mean, median, and mode and variance estimates such as the standard deviation and five-number summary so the data can be adequately analyzed

and accurate conclusions can be made from the data. *See, e.g.*, P.B. Stark, Chapter 4: Measures of Location and Spread, <http://www.stat.berkeley.edu/~stark/SticiGui/Text/location.htm> (last updated Jan. 21, 2013).

D. Distribution of risks, exposures, or outcomes across sensitive populations (asthma, emphysema, heart conditions, etc)

The best practices on page 4 state that the analyst should “[c]haracterize the distribution of risks, exposures, or outcomes across individuals, life stages, gender, or other relevant categories within each population group when feasible, not just average impacts.”

The Technical Guidance should require the characterization of the distribution of risks, exposures, or outcomes across sensitive populations in addition to characterizing the distribution of risks, exposures, or outcomes across individuals, life stages, and gender. The Technical Guidance should require the assessment of both disaggregated data and aggregated data/cumulative effects. *See* Kheirbek et al., *supra*; Ruffing, No Surprise: Disability Beneficiaries Experience Higher Death Rates, *supra*; Alcoholic Liver Disease In-Depth Report, *supra*; General Recommendations for Patients with Advanced Cirrhosis, *supra*; End Stage Renal Disease, *supra*.

III. Key Analytic Principles

A. Principles for EJ Regulatory Analyses

On page 5, the key analytic principles state that “[t]he basic principles that guide analysis of potential EJ concerns are the same as those used to guide all aspects of regulatory analysis at the Agency.” Some of the purposes of regulatory analysis in general are to consider “benefits and costs.”

Yet, the Technical Guidance states that the “purpose of regulatory analysis is to ‘anticipate and evaluate the likely consequences of rules’ in a way that informs the public and decision makers.” Also, E.O. 12,898 and EJ assessments require that the EPA identify and address disproportionately high and adverse human health effects of its programs, policies, and activities on low-income and minority populations. In addition, according to page 5, E.O. 12,866 expects agencies to consider “equity” and “distributive impacts” when choosing among different regulatory approaches, unless prohibited by statute and OMB’s Circular A-4 states that regulatory analysis should provide a separate description of distributional effects of “how both benefits and costs are distributed among sub-populations of particular concern.” In administrative law settings, as rules implement statutes and are promulgated under statutory authority and courts interpret statutes so that all statutory requirements and purposes remain effective and not a nullity, courts favor interpreting ambiguous rules so that they implement competing statutory provisions, and courts give effect to all parts of a rule, a rule must be promulgated by considering all of the purposes – no one purpose is superior. Therefore, EJ assessments and human health assessments should implement all statutory and regulatory requirements and purposes, including the environmental justice ones, including identifying adverse health outcomes and relevant effects associated with a regulated stressor for population

groups of concern as compared to a comparison group and disproportionate differential distribution of these outcomes and effects across population groups. *See, e.g.,* Technical Guidance, *supra*, at 3.

B. Weighing of Different Factors

On pages 17 and 18, the Technical Guidance states that certain factors may influence susceptibility to an environmental stressor, such as “genetics, diet, nutritional status, pre-existing disease, psychological stress, co-exposure to similarly acting toxics, and cumulative burden of disease resulting from exposure to all stressors throughout the course of life.”

EPA should provide guidance on how to weigh the importance of the factors life stage, socioeconomic status, diet, nutrition, consumption patterns, access to health care, susceptibility/sensitivity, education, gender, work experience, exposure to multiple sources, such as occupationally and residentially, and the presence of crime in the area or stress hormones in response to exposure. For example, the EPA should explain for the analysts and the individuals, population groups of concern, and others how the papers by Schwartz et al. indicate socioeconomic status, diet, nutrition, access to health care, and health status interact with environmental exposures.

C. Understanding Root Causes and Contributors

On page 6, the Technical Guidance states that it is important to recognize the underlying causes and contributors that may lead to EJ concerns to properly assess them and design regulatory options.

EPA should describe how the root causes and contributors will be determined?

D. Identifying Data, Methods, Analytical Needs, Population Groups of Concern, and Comparison Groups

Page 6 of the Technical Guidance states that identifying data, methods, analytical needs, population groups of concern, and comparison groups early in the process is important, that data and methods influence the scope and thoroughness of the assessment and identifying the groups can inform data collection and analysis. The Technical Guidance states that it might be useful to analyze minority, low-income, and indigenous population groups of concern in combination, such as low-income minority populations or evaluate the categories based on diversity within the groups, such as gender, life stages, or vulnerability to adverse effects and should rely on OMB, Census Bureau or other federal agency definitions of the population groups of concern. On pages 6-8, the Technical Guidance discusses that OMB has defined six race and ethnic categories and provided guidance on how to aggregate 63 race/ethnicity categories into a smaller subset and provides several definitions for minority, geographic proximity, and income without clearly stating whether all of them will be used for the Technical Guidance. The Technical Guidance states that analysts may characterize low-income “more broadly than just those that fall below the poverty threshold” to “include families whose income is above the poverty threshold but still below the average household income for the U.S.” It also discusses the Supplemental Poverty

Measure that counts co-resident unrelated children in households and uses a broader resource measure and adjusts for differences in housing prices by metropolitan area and family size and composition. On page 8, the Technical Guidance states that socioeconomic characteristics such as educational attainment, baseline health status, health insurance coverage, age, gender, and work experience may also be useful for characterizing populations and that it may be important to identify chronically poor individuals. The Technical Guidance also states that EPA has conducted consumption surveys and that other agencies may have consumption survey data, but that analysts should verify the data use appropriate parameters and methods.

EPA should describe in the Technical Guidance how the data, methods, and analytical needs will be determined so that analysts will follow the same protocol and so that potentially affected individuals, communities, and others will know the protocol and help ensure they are appropriate. The Technical Guidance should include a flowchart that provides a step-by-step guide for analysts to follow in identifying the data, methods, and analytical needs. One of the earliest steps should be to describe how the analysts will identify the population groups of concern for pollutants from specific media sources such as what exact sources of information and modeling data are available to identify the geographic area and populations to assess. The next step should be to describe how the analyst will identify the comparison groups. The next step should be to identify what data are available, what data need to be collected, and how the data will be collected. The next step should be to state the statistical analyses that should be conducted and the minimum sample size needed to detect statistically significant differences between the population groups and comparison groups. The next step should be to describe how the analysts should communicate with individuals in the population groups of concern and comparison groups to discuss the potential concerns and the assessments and receive any information the individuals or communities would like to share and to maintain an ongoing dialogue throughout and after the assessment. EPA recognizes on page 22 of the Technical Guidance that proper identification of this information is necessary to conduct an adequate human health risk assessment.

The EPA should identify in the Technical Guidance how the population groups of concern will be identified when rules have nationwide or broad impact. The EPA should analyze data for all population groups of concern that may be affected or an adequate sample of the population groups if some of the population groups are similar.

EPA should identify in the Technical Guidance how the comparison groups will be determined. For example, EPA should identify whether the comparison groups will be in the same geographic area with similar impacts and should use comparison groups to be able to assess health effects on all possible categories of individuals, such as susceptible/sensitive individuals and different life stages, socioeconomic status, diet, nutrition, consumption patterns, access to health care, education, gender, work experience, and exposure to multiple sources, such as occupationally and residentially.

The EPA should assess health effects on individuals based on both the six and 63 categories of race/ethnicity. Impacts that affect certain groups with certain genetic sensitivities may be masked by aggregating the different categories. The EPA should use all of the definitions for minority population listed in the Technical Guidance in setting the scope for the EJ analysis.

EPA should describe in the Technical Guidance how income will be determined. EPA should use the federal poverty guidelines, the Supplemental Poverty Measure, a percentage of the poverty level for households that are above the poverty level but still in economic distress (e.g., the 133% of the poverty level that many federal benefit programs use or 125% and 150% of the poverty level that some federal benefit programs use and that is measured and reported in the ACS data).

The EPA should provide a central repository for the consumption data and contact information for other agencies to save time and resources and ensure consistency among assessments and analysts and a protocol on when to use consumption data. How will the EPA determine whether fish and wildlife consumption is a substantial concern for a particular regulatory action. Will it be based on whether the media of concern is water or vegetated land browsed by wildlife and the level of consumption in those areas?

E. Disproportionate Impacts

On page 10, the Technical Guidance states that the term “disproportionate” is not defined in E.O. 12,898 nor EJ guidance implementing the Executive Order. It discusses several factors to determine when human health effects are disproportionately high and adverse in a National Environmental Policy Act (NEPA) assessment, including whether health effects are “significant” or “above generally accepted norms,” whether the risk by a population group of concern is “significant” and “appreciably exceeds or is likely to appreciably exceed the risk or rate to the general population or other appropriate comparison group,” and whether health effects in a population group of concern are affected by “cumulative or multiple adverse exposures.” The Technical Guidance then states that the term “significant” may be different from how it is defined under NEPA. The Technical Guidance states that disproportionate impacts may be assessed by using mean or median exposures or risks to relevant population groups or “acceptable surrogates” when such data are not available. It recognizes that differences between population groups may only occur in the tail of the distribution. It also states that unique pathways, cumulative exposure, and behavioral or biological factors may make population groups of concern more vulnerable to exposure. The Technical Guidance states that the relative weight of these or other criteria will likely vary with the specific attributes of the rulemaking under consideration. The Technical Guidance concludes that the determination of a disproportionate impact is ultimately a policy judgment informed by analysis. On page 11, the Technical Guidance also states that the EPA’s statutory and regulatory authorities provide a broader basis for protecting human health and do not require a demonstration of disproportionate impacts to protect the health of any population and may address adverse impacts in the context of developing an action without the need for showing that the impacts are disproportionate.

The EPA should define disproportionate impacts in the Technical Guidance instead of just stating that NEPA guidance defines disproportionate impact and stating the factors “may” be useful to provide a uniform determination of disproportionate impacts by the analysts. It should use all of the NEPA definitions and define the terms “significant,” “appreciably exceeds or is likely to exceed the risk or rate, and when populations are “affected.” More specific standards for evaluating the disproportionate impact factors are needed so that the decision maker has the

most accurate and representative data available when making a decision about whether or not there is a disproportionate impact. The analysts should provide both mean and median and variance estimates because disproportionate impacts may not be shown, even if they exist, when comparing medians alone because they may not identify individuals with low or high body concentration levels of a pollutant. Also, the Technical Guidance should ensure that disproportionate impacts to children are investigated because EPA states on page 18 that children from low-income and minority communities often bear a disproportionate burden of environmental exposures and resulting health problems. The Technical Guidance should not require a finding of disproportionate impact to protect people as it has stated the EPA may do when a stressor has affected any individual in the population group of concern.

F. Meaningful involvement

On pages 12 and 13, the Technical Guidance discusses the need for meaningful involvement of affected community members and discusses various ways that this can be achieved. The Technical Guidance states that in promulgating the Final Mercury and Air Toxics Standards (MATS) Rule, to promote meaningful involvement, the EPA publicized the rulemaking via EJ listserves, newsletters, and the internet, including the Office of Policy's Rulemaking Gateway Web site (<http://yosemite.epa.gov/opei/RuleGate.nsf/>) and the EPA discussed the proposed rule via a conference call with communities, a community-oriented webinar, and three public hearings to receive additional input on the proposed rule.

The Technical Standard should include minimum standards for meaningful involvement. They should include publicizing a rulemaking via newsletters, EJ listserves, and the internet as was performed for the MATS rule along with advertising in the actual communities affected prior to conference calls and webinars and community meetings held in each affected community on a date and time when and with enough warning and information so that interested community members can attend and voice concerns (by asking for suggested dates and times from the affected communities).

IV. Contributors to Higher Exposure

On pages 14-17, the Technical Guidance discusses five different types of contributors to higher exposure status among population groups of concern: (1) proximity to emission sources, (2) unique exposure pathways, (3) physical infrastructure such as housing conditions and water infrastructure, (4) exposure to multiple stressors/cumulative exposures, and (5) community capacity to participate in decision making. The Technical Guidance also states that exposure to a specific stressor from one source can inaccurately characterize the potential for health risks if the populations for which risk is being estimated are also exposed to a stressor from multiple sources and that the presence of crime may increase individuals' stress hormones and immunological responses to chemical exposures.

The EPA should provide a standard protocol for the weight to give to these five contributors so that they are adequately considered by analysts.

V. Human Health Risk Assessment (HHRA)

A. Quantitative v. Qualitative Evaluations of Risk

On page 20, the Technical Guidance states that an HHRA can include both quantitative and qualitative expressions of risk.

Because quantitative expressions of risk can more definitely determine whether individuals or population groups of concern are impacted, the Technical Guidance should require a quantitative expression of risk for an HHRA.

B. Bottom-up v. Top-down Risk Assessments

On page 21, the Technical Guidance discusses that risk assessments can occur using a bottom-up approach starting with exposure information or a top-down approach starting with epidemiological data to focus first on health outcomes. It states that the bottom-up approach can evaluate the impact of single stressors, but, in contrast to the top-down approach, does not capture cumulative effects from exposure to multiple stressors.

The Technical Guidance should state that an HHRA should be performed using a bottom-up and top-down approach so that the single and cumulative impacts of stressors or pollutants can be assessed.

C. Disproportionate Impacts to Children

On page 22, the Technical Guidance states that children from low-income and minority communities often bear a disproportionate burden of environmental exposures and resulting health problems.

The Technical Guidance should require that HHRA specifically evaluate the impact on low-income and minority children because they often bear the burden of environmental exposures and resulting health problems.

D. Risk Assessment Methods Used and Planning and Scope of Assessment

On page 23, the Technical Guidance states that the specific risk assessment methods used to consider EJ will vary with the environmental problem being addressed, such as whether the issue is local or national. It also stated that the scope of the HHRA will be affected by statutory mandates and any limitations in data, methods, time and resources. It also states that planning and scoping steps are briefly discussed, but that analysts should consult EPA guidance documents on risk assessment for more information. On page 24, the Technical Guidance states that analysts should develop statements of risk management and analytical objectives that incorporate potential EJ concerns to determine how the pending decision will affect potentially disproportionate human health risks among population groups of concern, clearly identify anticipated assessment outputs, identify evidence to be collected, the direction and structure of the evaluation, the analytical methods to be employed such as between socioeconomic group comparisons, the type of data required, and the scope of the analysis, such as national or local.

To meet the requirements and purposes of E.O. 12,898, its implementing guidance, and this Technical Guidance, and other health and environmental statutory and regulatory requirements, the scope of the HHRA should not be affected by limitations in data, methods, time, and resources, and lack of consultation with stakeholders as discussed on page 28. The Technical Guidance should include a written minimum HHRA protocol and data collection procedure to ensure that EJ concerns are adequately addressed. The steps of planning and scoping for an HHRA should be explained in detail or other documents cited to more specifically so that HHRAs will be standardized and not arbitrarily and capriciously performed. The Technical Guidance should conduct an HHRA analysis of all affected population groups of concern whether the environmental problem is a local or national issue.

E. Scoping

On page 25, the Technical Guidance states that scoping is an important step in the planning process for a risk assessment and involves determining what population groups, health effects, chemicals, and exposure pathways are included in the assessment.

The Technical Guidance on page 26 states that it can be helpful to consult with representatives from affected population groups and other stakeholders when identifying exposure routes, pathways and other information to construct exposure scenarios for an HHRA to provide information not known to an analyst or not in the literature, such as unusual pathways or unique behavior patterns that may alter exposure and may affect estimates of intake or pathways to be examined.

The Technical Guidance also states that EJ is cross-disciplinary because of its cultural, demographic, and economic elements and that early identification of needed skill sets enables managers to identify the most appropriate analytical team.

On page Appendix B-2, the Technical Guidance recommends that analysts consider whether pesticides bioaccumulate to increase exposure and risk for certain population groups such as life stages, subsistence consumers of fish, shellfish, and/or game and whether they have an atypical or unusual use pattern that could result in unusual exposures for certain population groups.

As scoping is so important for the assessment, the Technical Guidance should include a standardized protocol for scoping that determines the population groups, health effects, chemicals, and exposure pathways to be included in an HHRA. The Technical Guidance should state that an analyst conducting an HHRA should consult with representatives from affected population groups to identify exposure routes, pathways, and other information for constructing exposure scenarios because they often have information that may not be otherwise known and affected communities should be involved in assessing their own community concerns. How will the budget for each HHRA be set – based on the number of people potentially affected, the number of regulated entities, the degree of risk from the stressor, the amount and type of data that must be collected? To meet the requirements and purposes of E.O. 12,898, its implementing guidance, this Technical Guidance, and other health and environmental statutory and regulatory requirements, the assessments should be conducted so that impacts to the individuals and population groups of concern can be adequately determined without regard to costs.

EPA should establish in the Technical Guidance the types of experts to involve for specific types of stressors and media and to assist the agency with demographic, cultural, and economic areas. The Technical Guidance should require that analysts consider bioaccumulation and atypical or unusual use pattern results in exposures for all stressors, not just pesticides.

F. Data Identification

On pages 28-29, the Technical Guidance states that lack of data may affect methodology development and/or affect results and that assessing potential EJ concerns relies on rapidly developing data and tools and lists some of the models, tools, and technical resources for evaluating potential EJ concerns within a HHRA. On page 30, the Technical Guidance states that a lack of data may prompt a decision to limit the scope of an evaluation for EJ within an HHRA and that lack of data should be clearly documented. The Technical Guidance reiterates the importance of stakeholder involvement to identify stressor sources and adverse health effects and address risk perception issues. The Technical Guidance states that the EPA should consider the ability of community members to participate fully in the rulemaking process by considering time and resource constraints, lack of information, lack of trust, language barriers, and difficulty accessing and understanding technical, scientific, and legal resources.

The Technical Guidance should require the analyst conducting the HHRA to check each of the resources in Text Box. 4.4 for relevant data and the EPA should provide in a central repository a summary of the data available on each of those websites for the analyst, potentially affected individuals and communities, and others. The EPA should not limit the EJ evaluation because of lack of data. It should seek out data from other agencies, individuals, or groups or should collect the data itself. The Technical Guidance should require that the EPA ask the community's members days and times when it would like to attend a public hearing and discuss their concerns and information with the EPA and those involved on the analytical team. The EPA should provide information in another language if anyone requests it and may ask a community member for help translation assistance.

G. Problem Formulation

Pages 31-35 of the Technical Guidance discuss problem formulation. Pages 31 and 32 discuss the importance of problem formulation in ensuring an analyst develops a clear set of goals and endpoints for the HHRA and that all relevant risks are identified and assessed. Text Box 4.5 provides questions that may be raised during problem formulation in the context of proximity of pollution sources. On page 33, the Technical Guidance identifies differences in exposures that may lead to disproportionate risks, such as proximity to pollution sources, employment in certain occupations, exposures to multiple sources, cultural practices, consumer product use, group differences in body burdens, life stage, gender, race/ethnicity or across multiple social strata such as low-income minority. The Technical Guidance also states that background exposure may be evaluated using bio-monitoring data and that others may have relevant monitoring data. On page 34, the Technical Guidance discusses the population characteristics that may influence the likelihood of exposure and risk of adverse health outcome that may result from this exposure, such as age, pre-existing disease conditions, chronic disease, immune status, medication status, occupation, income, educational level, lack of access to resources (e.g., health care), negative

social conditions, age of housing as a function of race/ethnicity and income, and access to transportation.

The Technical Guidance should require analysts to evaluate the questions in Text Box 4.5 for formulating the problem and to evaluate all of the factors that may influence differential and disproportionate exposures. Background exposure should be evaluated using bio-monitoring data, when available. As discussed above, the agency should provide a central location of data available from others and contact information for others that may have relevant data. The Technical Guidance should require the assessment of the population characteristics on page 34.

VI. Conducting Regulatory Analyses to Assess Potential Environmental Justice Concerns

A. Evaluating the Feasibility of an Assessment of Potential EJ Concerns

On page 37, the Technical Guidance states that the main purpose of analyzing the effects of a regulation on population groups of concern is to examine how changes in risk to human health or indicators of environmental quality are distributed across population groups and, “when relevant and feasible,” within population groups, such as within life stages and genders. It also states that an analyst may be able to characterize the baseline and likely response to a change in exposure quantitatively for each policy option “[w]hen information on risk and incidence by groups is available.” It also states that analysts should present benefits information disaggregated by race/ethnicity and income “[w]hen feasible.”

EPA should define the term “when relevant and feasible” and “feasible,” and should ensure that information on risk and incidence by groups is available so that concerned individuals, community members, and others will know when an EPA analyst plans to make this assessment so that they may be able to complete their own assessment or voice their concerns about the lack of an assessment and so that there will not be an inequitable completion of these assessments for individuals and communities facing similar problems or stressors. To satisfy the purposes of the Technical Guidance, the EPA should present information on estimated health and environmental risks, exposures, outcomes, benefits, and other relevant effects when a Census Blockgroup has a minority population of greater than 40% or a Census Tract has 40% of its population below 150% of the federal poverty level and for all American Indian reservation and subreservation areas and Medically Underserved Population areas as explained above.

The EPA should add a sentence that states “It is feasible to present benefits information by race/ethnicity for the six and sixty-three race/ethnicity groups surveyed in the 2010 Census and by income for those below the federal poverty level, below 125 percent of the federal poverty level, below 150 percent of the federal poverty level, below 200 percent of the federal poverty level, below 300 percent of the federal poverty level, and 300 percent of the federal poverty level and above, for both males and females, for children under age 5, age 5-14 years old, age 15 to 19 years old, age 20 to 44 years old, age 45 to 49 years, age 50 to 64, and age 65 and older, for those with any lung condition such as asthma, chronic bronchitis, emphysema, heart disease, or lung cancer for any air pollutant stressor or liver or kidney disease for any water pollutant, for those who consume fish, shellfish, and/or game above the recommended level in areas where there is

an advisory, for those who are experiencing under-nutrition, a food desert, or low-food access, for those who lack adequate access to health care or are in a Medically Underserved Area or in a Medically Underserved Population, by the number of stressors exposed to, and by the crime rate in the area or stress hormone level.”

EPA should obtain this data from available surveys or studies or should provide a sufficient sample of individuals in the population groups of concern with the opportunity to get a health screening (e.g., 10 individuals in each of the 63 race/ethnicity groups and six income groups) and should monitor the air/water of the area and conduct a representative survey of the area to obtain the necessary information to complete the assessment. Setting a uniform standard for when information is presented for population groups of concern will avoid an indiscriminate display of information and determination of when quantitative and qualitative analysis should be used. Obtaining sufficient information from surveys, studies, health screenings, and/or monitoring will eliminate the need to evaluate risk or exposure using inadequate metrics such as the prevalence of affected facilities as a function of race/ethnicity or income or evidence of unique or unusual consumption patterns or contract rates if those metrics will not lead to a finding that there is a disproportionate impact on population groups of concern.

B. Cost analysis

On page 40, EPA states that it is not possible to estimate each affected individual’s total monetized welfare in the baseline and under regulatory option and that economists often estimate society’s willingness to pay for a change in environmental quality.

EPA should also estimate the cost of environmental outcomes by estimating the cost of health care, value of lost income, restricted activity, and bed days for the affected persons due to the change and the cost of reduction in lifespan or quality health. *See* Memorandum from Science Advisory Board, EPA, to Stephen L. Johnson, Administrator (Oct. 12, 2007); Centers for Disease Control and Prevention, Overweight and Obesity: Causes and Consequences, <http://www.cdc.gov/obesity/adult/causes/index.html> (last updated Apr. 27, 2012).

C. Methods to Assess Potential EJ Concerns

1. Quality of Input Data

On pages 41 and 43, the Technical Guidance states that the scope and complexity of the information presented depends on the quality and specificity of the input data, including data on demographic characteristics, baseline health data, income data, risk coefficients stratified by socio-economic variables, distribution of health effects (or the available proxy such as emissions, ambient concentrations, biomarkers, proximity) in the baseline and under each regulatory option, and distribution of costs, when relevant. The Technical Guidance also states that an analyst should present basic summary information for the baseline and each regulatory option for the relevant endpoints for the population groups of concern relative to a comparison “[w]hen data are available.”

The Technical Guidance should provide more specific details to provide a minimum standard for the information presented that is described in some detail on page 41.

2. Summary Statistics

On page 44, the Technical Guidance states that if particular communities are substantially affected, summary statistics can be shown at a locally disaggregated level as well as for the nation as a whole.

If particular communities are substantially affected, summary statistics should be shown locally and nationally.

3. Geographic Scope and Proximity-Based Analysis

On page 46, the Technical Guidance states that analysts should decide what distance from the facility most accurately reflects the community's exposure to a stressor. On pages 47 and 48, the Technical Guidance states that statistical tests on summary data can be used to identify whether, on average, there are statistically discernible differences in the characteristics of groups located near and far from the source.

The Technical Guidance should explain how analysts will determine the distance from the facility that most accurately reflects the community's exposure to a stressor. Statistical tests should be conducted on the raw data underlying the summary data instead of on the summary data.

D. Analytical Considerations

1. Geographic Scope

On page 49, the Technical Guidance states that sometimes the geographic scope will be national and sometimes it will be at a sub-national level when some regulatory actions are more regional in scope or have effects that are expected to be concentrated in particular states or regions.

The Technical Guidance should state that when regulatory actions are expected to be concentrated in particular regions or states, analysis should be conducted at a national and subnational level.

2. Comparison Group – Highly Correlated Variables

On page 50, the Technical Guidance states that many of the demographic and socioeconomic characteristics that are often included in these types of regressions are highly correlated with each other and that makes it difficult to interpret the meaning of a coefficient on any given variable.

Factor analysis can be used along with regression to assess the meaning of a coefficient on a given variable.

VII. Appendix B: Example Approaches to Address Potential EJ Concerns When Conducting Exposure and Dose-Response Assessments

A. Biomonitoring data analysis

On page B-3, the Technical Guidance states a scoping question and key consideration to integrate into an exposure assessment to evaluate dietary risks from pesticide residues: Are bio-monitoring data available for the population groups of concern, including those with potentially elevated exposures? In discussing this question/consideration, the Technical Guidance states that an analyst may use simple, well-established comparative methods such as ratios to examine between-population group comparisons when using exposure biomarkers to draw inferences about exposure differences in the context of source-specific regulation. The Technical Guidance also states that comparisons may focus on particular segments of the distribution, (e.g., 95th percentile of minorities and non-minorities) or on the percent of a population group represented within a percentile group (e.g., percent minorities compared to percent non-minorities in the 10th percentile of the population). It also states that “[c]ombining inferences from different surveys should be done with a clear and cautious understanding of the key attributes of each survey, including its design, the intended use of the data, how this intended use may bias the sample, statistical characteristics of each survey, and use of validated laboratory methods, among other considerations.”

The Technical Guidance should state that the analyst should not just use simple ratios when data are available that allow statistical analyses such as analysis of variance (ANOVA), regression, or other appropriate analyses. The Technical Guidance should state that analysts should analyze all members of the population groups of concern as well as sensitive groups that might be outliers in the 90th or 95th or 5th or 10th percentile of the population group. The EPA should maintain a list of “other considerations” that its analysts should consider in understanding data from various sources and can circulate it to the analysts via a central location or agency memoranda that go through the notice-and-comment rulemaking process.

Thank you for the opportunity to provide comments.

Sincerely,

/s/

Cheryl Cortemeglia