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Comments from the Natural Resources Defense Council on an invitation to submit Visionary Ideas and nominations for participation in the Community Workshop to the NIEHS

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More information at http://www.niehs.nih.gov/about/od/strategicplan/index.cfm

Focus toxicity testing on replacement chemicals and newly identified contaminants. We are in a desperate need for research to understand the potential health impacts of more recently recognized contaminants such as polybrominated diphenyl ethers (PBDE's), perfluorinated chemicals (e.g., PFOA and PFOS), halogenated flame retardants, and nanomaterials, cyclosiloxanes, and newer plasticizers that are replacement chemicals for phthalates and other plasticizers. Research strategies must include studies to determine the effects of in utero and perinatal exposures on the later development of childhood and adult diseases. Improved understanding the health effects of less studied chemicals still in commerce and to which many people are exposed will result in a tangible worker and public health impact.

Prioritize research on identifying vulnerable populations, including life stage and epigenetic variability. More research to improve our scientific understanding of the biological response to disease progression should be a priority, to help identify vulnerable individuals, populations, life stages, disease states, etc. Identifying genetic and epigenetic differences between individuals can help identify vulnerable individuals, populations, life stages, disease states, etc. Identifying "windows of vulnerability", that is, life stages associated with changes in the biological system that may make it more susceptible to environmental exposures. This research should continue to be a priority for NIEHS as it improves its existing traditional toxicity testing and develops new testing and screening methods.

Formulate a strategy for using predictive toxicity testing for regulatory decisions. The new predictive toxicity testing and screening methods will bring their own new set of challenges. Regulatory acceptance and the reliability of new predictive toxicology approaches must be a very high priority for NIEHS. The NIEHS must formulate a strategy on how these new data should be used in the decision making process. It is not good enough to produce huge volumes of toxicity data for the regulatory Agencies; the reliability of these data for assessing human health effects must be validated by NIEHS. While promises on the value and utility of predictive toxicology are being promoted, it is necessary for NIEHS to describe now how they will measure success.

Include endocrine disruption, PBT, low-dose, and immunotoxic endpoints in high throughput screens. When conducting new toxicology tests, predictive toxicology, and rapid or high throughput screening tests, NIEHS should be able to state with certainty how many different endpoints will need to be assayed, how many different cell types will need to be evaluated, and how multi-pathway events involved in disease processes and effects at different stages of multi-step processes will be integrated into overall evaluations of health risks. Specific targets for NIEHS and NTP research and toxicity testing should be expanded to include identifying environmental agents that are endocrine disrupting chemicals, immunotoxic agents, neurotoxic agents, persistent and bioaccumulative toxicants (PBTs), or demonstrate low dose or non-linear toxicity.

What is the NIEHS strategy that will insure that potential health effects at all organ sites, as a function of life stage, inter-individual susceptibility, and exposure to multiple agents will be properly addressed by new toxicology approaches? If such a strategy doesn't exist, then now is the time to develop it.

Retain traditional toxicity tests until replacements can be used for regulations. NTP must not abandon the tried-and-true bioassay and traditional toxicity tests until their replacements can be relied upon by regulatory agencies to be equal or better at identifying and describing hazardous chemicals and setting health-protective regulations. Despite the obvious value of mechanistic and in vitro data, at this time these data do not currently replace traditional approaches to toxicological evaluation that are the basis for most decisions related to product safety, environmental and occupational hazard assessments, and priority setting for detailed chemical toxicity testing.

Stimulate research to identify early indicators of disease associated with toxic exposures. Research is needed to identify early clinical biomarkers of effect associated with toxic chemical exposure. These biomarkers could be signatures of alterations in toxicity pathways that can be clearly linked to disease endpoints. Ultimately this can be used to identify early indicators of health effects in people that are exposed to toxic chemicals in their workplaces, homes, and communities. These data can potentially be paired with biomonitoring data in cross-sectional surveys. The goal would be to chip away at the long lag time between exposure and disease by identifying markers that occur in closer proximity to the exposure event.

Continue NIEHS' climate-health research, especially among vulnerable communities. Research is needed to identify pathogenic interactions and rising disease rates among immunologically naïve populations arising from global climate change. Such studies could include the degree to which aeroallergen production and allergenicity increases in response to rising temperatures and CO2 concentrations; identification of earlier allergic sensitization of individuals to longer aeroallergen seasons, in response to rising temperatures; and increased volatilization of agricultural chemicals as temperature rise, which may potentially lead to increased application by managers, and subsequently increased runoff and pollution by nutrient-enriched waters into ground and surface waterways.

Prioritize models assessing exposures to mixtures, especially with bioaccumulation. The development of biologically based dose-response models can be used for trans-species extrapolations of toxic or carcinogenic effects, and can address inter-individual differences in susceptibility as well as the effects of exposures to mixtures. Studies on time dependence should cover the time interval between exposure and elimination of the agent under study, at least over a 24-hour cycle (longer for bio-accumulating agents or for agents in which continuous exposure affects their metabolic elimination), and at multiple life stages to capture effects of age-related changes.