EARTHJUSTICE

March 22, 2016

Administrator Gina McCarthy
Dr. Thomas Burke, Science Advisor
Dr. Michael Broder, Office of the Science Advisor
ORD Docket
Environmental Protection Agency
ord.docket@epa.gov

Submitted online via Regulations.gov
Docket ID: EPA-HQ-ORD-2015-0684

Re: Draft Guidelines for Human Exposure Assessment

Dear Administrator McCarthy, Dr. Burke, and Dr. Broder:

We appreciate that the U.S. Environmental Protection Agency is in the process of updating its Guidelines for Human Exposure Assessment. We support EPA's proposed update and also urge EPA to strengthen these guidelines further than it has proposed in order to address the key issues identified below and as elaborated in the attached comments previously submitted to the agency. We also urge EPA to bring other important risk assessment guidelines up to date, before another year passes with EPA offices using obsolete and incomplete guidelines to make important decisions about human health.

The update in EPA's guidelines at hand is long overdue and greatly needed by all Americans exposed to toxic chemicals, including pesticides. The prior EPA guidelines were created more than twenty years ago, in 1992. Many other guidelines EPA is using – such as its guidance on age-dependent adjustment factors for only mutagenic carcinogens; its guidance failing to apply an *in utero* adjustment factor; and its list of persistent, bioaccumulative toxins, among others – are also seriously out of date and not in line with current science.

- Since the 1990s, scientific research and knowledge have advanced dramatically. EPA knows much more now about human exposure to chemicals and contaminants, and the harm this can cause.

- EPA now knows that children are not little adults. Babies and children, particularly *in utero*, are both more exposed and more vulnerable to harm from toxic exposure because they are growing and developing.

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- The onslaught of toxic chemicals in our air, water, soil, food, and consumer products affects all Americans, but often hits communities of color and low-income communities the most. In recent years, EPA has affirmed its commitment to advance environmental justice. Updating outdated risk assessment protocols to ensure better assessment of community impacts, improve transparency, and require public review and comment of all draft risk assessments are important and necessary ways to fulfill this Administration's promise to continue working toward environmental justice.

- During the last two decades, it is also true that more and more chemicals – many known to be harmful and others virtually untested and unassessed – have been released into commerce and into the environment. It is urgent for EPA to use current scientific research to assess and regulate these chemicals. It is also critical that EPA use current scientific research when it considers whether to register pesticides and during registration review.

- And, during this time, methods to address and prevent exposure have been continuing to improve, as industries innovate in response to a growing call from the public for less chemical exposure, and as technological advancements make it possible to reduce human exposure to a greater extent. There is no good reason why EPA should be using outdated information to protect health when tools are available both to assess risks and to avoid them.

It is essential that EPA bring these Guidelines, and other risk assessment guidelines that are also obsolete or incomplete, up to date based on current scientific advice and knowledge. Since 2009, EPA has had before it the advice of independent scientists at the National Academy of Science.[1] The NAS advised EPA to update its approach to close serious gaps in assessing human health risks from chemical exposure. It is not acceptable science to recognize health risks exist and not account for them at all – whether they stem from a particular pathway of exposure, a particular chemical, a kind of vulnerability or from combined impacts for disproportionately exposed and vulnerable communities of color and low-income communities who are bombarded by multiple sources of contaminants. Uncertainties do not justify inaction. EPA must use the best available information to account for risks, through the use of default factors where necessary to fill gaps so that action relying on risk assessments will not fail to protect public health by ignoring risks.

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[1] *See* National Research Council of the National Academies of Science, Science and Decisions: Advancing Risk Assessment (2009) (authored by Committee on Improving Risk Analysis Approaches Used by the U.S. EPA; Board on Environmental Studies and Toxicology; Division on Earth and Life Studies; National Research Council), DOI: 10.17226/12209, http://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

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In recent decades, expert state regulators (such as California's Office of Health Hazard Assessment) have surpassed EPA in addressing early life exposure and vulnerability, as well as aggregate and cumulative exposure to multiple chemicals, multiple pathways, and multiple sources. There is a wealth of information and advice before the agency from its own internal experts, such as the Children's Health Advisory Protection Committee which has spoken extensively on lead, and individual offices that have acknowledged the need in some instances to account for *in utero* exposure (even as offices like OAR and OPPT continue to fail to account for such exposure in certain actions).[2] For example, the Office of Pesticide Programs has agreed to consider aggregate risks from the same pesticide used in agricultural, commercial, and/or residential settings; cumulative risks from exposure to pesticides with common mechanisms of toxicity; and the unique risks posed to infants and children due to their potentially increased sensitivity to pesticides. In updating these guidelines and others, EPA must act based on current information to protect children, and not continue to ignore *in utero* and early-life exposures that its guidelines do not currently consider.

EPA also should engage with scientific experts and affected community members and work to update its approach overall to acknowledge that many chemicals, from lead to arsenic and many others, do not have a safe level of exposure for carcinogenic, neurological, or other kinds of chronic risk. If EPA's risk assessment guidelines are to have any meaning going forward, they must follow the most current science.

EPA's guidelines on risk assessment decide how much health protection people receive from toxic chemicals they are exposed to in the air, water, soil, food, workplace, and in everyday products in their homes and schools. EPA must ensure that its staff makes decisions under the Clean Air Act, Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and other statutes pursuant to the best available current science, as discussed in the example recent comments attached as an Appendix to this letter.

In recent years, Earthjustice, working closely with national and local allies, has raised these concerns and provided important examples where EPA's approaches and guidelines are outdated and must be strengthened, especially in action to address toxic air pollution under the Clean Air Act (42 U.S.C. § 7412(f)(2)), toxic chemicals under TSCA, and pesticides under FIFRA. We have provided those comments again, here, and respectfully urge the Office of Science Advisor to address and incorporate the scientific information they contain – from peer-reviewed scientific research and expert state regulators – into the guidelines at hand, and other guideline updates in progress. We also request that the Science Advisor follow through on its

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[2] *See, e.g.*, EPA, Notice of Availability, Policy Paper on Revised Risk Assessment Method for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses, 74 Fed. Reg. 65121 (Dec. 9, 2009); Letter from Sheela Sathyanarayana, Chair of Children's Health Protection Advisory Committee, to Administrator McCarthy, Re: National Ambient Air Quality Standards for Lead (Jan. 8, 2015), https://www.epa.gov/sites/production/files/2015-01/documents/naaqs_for_lead_letter.pdf.

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plan to ensure the best possible treatment and consideration of cumulative risks based on available science, in response to the 2013 request for comment that this Office issued.

More than 100 local, regional, and national organizations across the United States with whom Earthjustice is working on these issues believe that updating EPA's guidelines to ensure the agency addresses real-world health risks and impacts, and fully implementing the current science in EPA's rulemakings and other actions are critical priorities to protect public health. There is a particular shared concern for the people most exposed and most likely to be harmed from this exposure, including vulnerable children, overburdened communities, and workers. Addressing this issue this year would help advance the Administrator's objectives to make a visible difference for all local communities with toxic exposure and workers exposed to chemicals and pesticides on the job, and to provide long-overdue environmental justice for communities highly exposed to toxic contaminants.

Before this Administration leaves office, we therefore call on you to complete all necessary and important updates to EPA's risk assessment guidelines. Please exercise the leadership necessary to bring these guidelines and others like them in line with the best available current scientific advice. We would welcome the opportunity to meet with the Office of the Science Advisor and other agency staff working on these important concerns to discuss these comments.

We have provided the major sources cited, all of which themselves summarize and include further scientific citations, as an accompanying Appendix. Please contact us if we can provide any additional information or to arrange a meeting at your convenience.

Thank you for your time and consideration of this matter.

Sincerely,

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SOURCES PROVIDED AS AN APPENDIX

1. Sarah Janssen et al., NRDC Issue Paper: Strengthening Toxic Chemical Risk Assessments to Protect Human Health (Feb. 2012), http://www.nrdc.org/health/files/strengthening-toxic-chemical-risk-assessments-report.pdf.

2. Comments of Earthjustice, NRDC, et al. on Request for Information and Citations on Methods for Cumulative Risk Assessment, EPA-HQ-ORD-2013-0292 (May 1, 2013), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2013-0292-0132 (filed June 28, 2013). Earthjustice submitted these comments on behalf of the following organizations: AIR ALLIANCE HOUSTON, ALASKA COMMUNITY ACTION ON TOXICS, AMERICAN BOTTOM CONSERVANCY, CALIFORNIA COMMUNITIES AGAINST TOXICS, CALIFORNIA SAFE SCHOOLS, THE CITY PROJECT, COMMUNITY IN-POWER AND DEVELOPMENT ASSOCIATION, DEEP SOUTH CENTER FOR ENVIRONMENTAL JUSTICE, DEL AMO ACTION COMMITTEE, DOWNWINDERS AT RISK, IRONBOUND COMMUNITY CORPORATION, LOUISIANA BUCKET BRIGADE, LOUISIANA ENVIRONMENTAL ACTION NETWORK, LOS JARDINES INSTITUTE, LOWER MISSISSIPPI RIVERKEEPER, MISSOURI COALITION FOR THE ENVIRONMENT, NATURAL RESOURCES DEFENSE COUNCIL, NEIGHBORS FOR CLEAN AIR, NEW MEXICO ENVIRONMENTAL LAW CENTER, NORTH CAROLINA ENVIRONMENTAL JUSTICE NETWORK, OAK GROVE NEIGHBORHOOD ASSOCIATION, POVERTY & RACE RESEARCH ACTION COUNCIL, PUBLIC INTEREST LAW CENTER OF PHILADELPHIA, ROYAL OAK CONCERNED CITIZENS ASSOCIATION, RURAL EMPOWERMENT ASSOCIATION FOR COMMUNITY HELP, SIERRA CLUB, SOUTHERN ENVIRONMENTAL LAW CENTER, WEST END REVITALIZATION ASSOCIATION.

3. Earthjustice *et al.* Comments on EPA's Draft EJ 2020 Action Agenda Framework at 22-25 (filed July 14, 2015), https://www3.epa.gov/environmentaljustice/ej2020/. Earthjustice submitted these comments on behalf of the following organizations: AIR ALLIANCE HOUSTON; ALASKA'S BIG VILLAGE NETWORK; APOSTOLIC FAITH CENTER; CALIFORNIA COMMUNITIES AGAINST TOXICS; CALIFORNIA KIDS IAQ; CALIFORNIA SAFE SCHOOLS; CATA – THE FARMWORKERS SUPPORT COMMITTEE; CENTER FOR EFFECTIVE GOVERNMENT; CITIZENS AGAINST RUINING THE ENVIRONMENT; CITIZENS' ENVIRONMENTAL COALITION; CITIZENS FOR CLEAN AIR; CLEAN AIR COUNCIL; CLEAN AND HEALTHY NEW YORK; CLEAN WATER AND AIR MATTER; COALITION FOR A SAFE ENVIRONMENT; COMITE CIVICO DEL VALLE; COMITÉ DIÁLOGO AMBIENTAL, INC.; COMMUNITY DREAMS; COMMUNITY IN-POWER AND DEVELOPMENT ASSOCIATION; COMMUNITY SCIENCE CENTER; CONSERVATION LAW FOUNDATION MASSACHUSETTS; DEL AMO ACTION COMMITTEE; DESERT CITIZENS AGAINST POLLUTION; DIESEL HEALTH PROJECT; DOWNWINDERS AT

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RISK; EAST YARD COMMUNITIES FOR ENVIRONMENTAL JUSTICE; 48217 COMMUNITY AND ENVIRONMENTAL HEALTH ORGANIZATION; FARMWORKER ASSOCIATION OF FLORIDA; INSTITUTE OF NEUROTOXICOLOGY &NEUROLOGICAL DISORDERS; JESUS PEOPLE AGAINST POLLUTION; KENTUCKY ENVIRONMENTAL FOUNDATION; LABADIE ENVIRONMENTAL ORGANIZATION;MARTINEZ ENVIRONMENTAL GROUP;MIDWEST COALITION FOR RESPONSIBLE INVESTMENT;MOSSVILLE ENVIRONMENTAL ACTION NOW; NATURAL RESOURCES DEFENSE COUNCIL; NEIGHBORS FOR CLEAN AIR; NEW MEXICO ENVIRONMENTAL LAW CENTER; NORTH CAROLINA COASTAL FEDERATION; OHIO VALLEY ENVIRONMENTAL COALITION; PENDERWATCH &CONSERVANCY; PESTICIDE ACTION NETWORK NORTH AMERICA; SIERRA CLUB; SOUTHEASTERN NORTH CAROLINA ENVIRONMENTAL JUSTICE COALITION; SOUTHERN APPALACHIAN MOUNTAIN STEWARDS; STEPS COALITION; TEXAS ENVIRONMENTAL JUSTICE ADVOCACY SERVICES; THE CITY PROJECT; THE ORIGINAL UNITED CITIZENS OF SOUTHWEST DETROIT; TRI-VALLEY CARES; WEST END REVITALIZATION ASSOCIATION.

EXAMPLE CLEAN AIR ACT COMMENTS AND PETITIONS PROVIDING ADDITIONAL DETAIL ON THESE ISSUES:

4. Comments on EPA, Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards; Proposed Rule, 79 Fed. Reg. 36,880 (June 30, 2014), https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2010-0682-0568, Earthjustice submitted these comments on Oct. 28, 2014 on behalf of the following organizations: AIR ALLIANCE HOUSTON, APOSTOLIC FAITH CENTER, CALIFORNIA COMMUNITIES AGAINST TOXICS, CALIFORNIA KIDS IAQ, CLEAN AIR COUNCIL, COALITION FOR A SAFE ENVIRONMENT, COMMUNITY DREAMS, COMMUNITY IN-POWER AND DEVELOPMENT ASSOCIATION, DEL AMO ACTION COMMITTEE, ENVIRONMENT TEXAS, GOOD NEIGHBOR STEERING COMMITTEE (BENICIA), LOUISIANA BUCKET BRIGADE, LOUISIANA ENVIRONMENTAL ACTION NETWORK, LOWER MISSISSIPPI RIVERKEEPER, NATIONAL WILDLIFE FEDERATION, NATURAL RESOURCES DEFENSE COUNCIL, SIERRA CLUB, TEXAS ENVIRONMENTAL JUSTICE ADVOCACY SERVICES, UTAH PHYSICIANS FOR A HEALTHY ENVIRONMENT, EARTHJUSTICE, AND ENVIRONMENTAL INTEGRITY PROJECT; Additional comments raising the need for EPA to update and strengthen its health risk assessment approach to address real-world health risks caused by hazardous air pollution under its Clean Air Act authority were submitted on behalf of over 90 national and community organizations, and the full list is available by request.

5. Petition for Reconsideration of and Petition for New Final Rule for Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards; Final Rule, Docket ID No. EPA-HQ-OAR-2010-0682, filed on behalf of 11 organizations on

Feb. 1, 2016 (Air Alliance Houston, California Communities Against Toxics, Clean Air Council, Coalition For A Safe Environment, Community In-Power & Development Association, Del Amo Action Committee, Environmental Integrity Project, Louisiana Bucket Brigade, Sierra Club, Texas Environmental Justice Advocacy Services, and Utah Physicians for a Healthy Environment).

6. Petition for Reconsideration of National Emissions Standards for Hazardous Air Pollutant Emissions From Secondary Lead Smelting, 77 Fed. Reg. 556 (Jan. 5, 2012), Dkt. ID No. EPA-HQ-OAR-2011-0344, filed on March 5, 2012, by Earthjustice on behalf of: California Communities Against Toxics, Frisco Unleaded, Missouri Coalition for the Environment Foundation, Sierra Club, and Natural Resources Defense Council.

EXAMPLE FIFRA COMMENTS:

7. Farmworker and Conservation Comments on Seven Organophosphate Pesticides: Chlorpyrifos-methyl (EPA-HQ-OPP-2010-0119), Dicrotophos (EPA-HQ-OPP-2008-0440), Dimethoate (EPA-HQ-OPP-2009-0059), Ethoprop (EPA-HQ-OPP-2008-0560), Profenofos (EPA-HQ-OPP-2008-0345), Terbufos (EPA-HQ-OPP-2008-0119), Tribufos (EPA-HQ-OPP-2008-0883) (Feb. 22, 2016).

8. Comments from the Natural Resources Defense Council (NRDC) on the Draft Pesticide Cumulative Risk Assessment: Framework for Screening Analysis EPA-HQ-OPP-2015-0422, at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2015-0422-0015 (Sept. 28, 2015).

EXAMPLE TSCA COMMENTS:

9. Comments from Earthjustice, Natural Resources Defense Council and Washington Toxics Coalition on Problem Formulation and Initial Assessment Documents for Three Flame Retardant Clusters (November 18, 2015) Docket IDs: EPA-HQ-OPPT-2015-0068, EPA–HQ–OPPT-2015-0081 and EPA-HQ-OPPT-2014-0730, http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2015-0068-0013

10. Earthjustice et al., Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (April 30, 2015), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0848 (Comments were filed by Earthjustice on behalf of: Farmworker Justice, Natural Resources Defense Council, Pesticide Action Network, California Rural Legal Assistance Foundation, Farm Labor Organizing Committee, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers).