

June 23, 2017

To: EPA's Science Advisory Board  
SAB Risk and Technology Review Methods Panel  
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Re: SAB Risk and Technology Review Methods Panel's review of EPA's *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis (May 2017)*

## **Summary**

We appreciate the opportunity to offer comments and appreciate the time and work of this Panel. For years, the Natural Resources Defense Council (NRDC) and Earthjustice have tracked and engaged in advocacy regarding the type of Clean Air Act rule for which EPA is seeking scientific review of its health risk assessment method. We have partnered in this work with other national environmental and local fence-line community groups whose members live, work, and raise children near major industrial sources of hazardous air pollution around the United States.

NRDC is a non-profit organization with over 2.8 million members and activists whose mission includes working to protect public health. Earthjustice is a nonprofit environmental law organization whose mission and activities include representing and working with national and local environmental, health, and community groups to strengthen health protections from air pollution.

Our comments aim, first to provide context on the importance of EPA's health risk assessment method for public health protection. Then, we highlight the following three major points.

1. EPA's Clean Air Act hazardous air pollution risk assessment methods have improved in recent years in certain ways to better account for health risks. The Scientific Advisory Board should provide positive feedback on the components of EPA's method that will ensure the agency is more likely to account for, assess, and provide information regarding health risks to regulators, decision-makers, and the affected public reviewing and commenting on EPA's regulatory proposals.

2. The document before the Board also includes procedures EPA proposes to use to reduce agency costs rather than to follow or implement current science to better assess and account for health risks. Those methods are not improvements on EPA's approach and we are concerned that the use of these procedures will lead the agency to underestimate health risks and fail to reach an assessment that can be used effectively for informed public comment and regulatory decisionmaking. We ask that the Board advise EPA on methods that ensure a comprehensive review of health risks for communities exposed to hazardous air pollution based on the best available current science, rather than cutting out important scientific steps of the analysis needed to create a full health risk assessment for a source category. Choosing to apply the necessary time or resources (which the agency can and should do to fulfill its Clean Air Act obligations) to complete a health risk assessment that addresses each of the real-world risks posed by hazardous air pollution from an industrial source category, including multipathway risks, is far preferable to performing a full regulatory process without even having that basic information in hand at the start.
3. After eight years, EPA still has not yet implemented many of the National Academy of Sciences' Report Science and Decisions (known as the Silver Book) recommendations in its Clean Air Act risk assessment methods, or incorporated other current scientific information on pollutants, hazards, and vulnerability, all of which are issues the SAB could point out to help support the agency's implementation and use of the best available current science. We have attached and cited background materials submitted to the agency in recent years, as additional information.

**Background: Why the Clean Air Act 112(f)(2) risk assessment matters to protect public health**

EPA's hazardous air pollution program under section 112 of the Clean Air Act is critical to protect public health and reduce exposure to hazardous chemicals through air pollution. Strengthened by Congress in 1990 Amendments signed by President George H.W. Bush, this part of the Act generally targets pollutants that can cause health impacts at low levels of exposure (pounds or less), and it was enacted to address a range of serious health impacts, including cancer, respiratory, neurological harm, and other kinds of chronic and acute health risks.

This section governs and requires EPA to directly regulate hazardous air pollution emitted by various industrial stationary source categories, from oil refineries, coal plants, coke ovens, and chemical manufacturers to boilers, incinerators, lead smelters, cement plants, pesticide plants, resin manufacturers, and pulp-paper mills.<sup>1</sup> These types of facilities are located across the United States, and are often concentrated near people, in urban communities, such that

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<sup>1</sup> See EPA's list of National Emission Standards for Hazardous Air Pollutants, by industrial source category, <https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9>,

communities of color and low-income people are disproportionately exposed to hazardous air pollution they emit.<sup>2</sup>

The health risk assessment and health protection rulemaking required by the Clean Air Act for major sources of hazardous air pollution (also known as “residual risk”) is an important legal obligation of the agency under section 112(f)(2), 42 U.S.C. § 7412(f)(2). EPA generally performs this and the “technology review” rulemaking under section 112(d)(6), § 7412(d)(6), at the same time for a given industrial source category, but each action separately must meet the independent legal tests set by the Act.

Under section 112(f)(2), EPA performs the risk assessment to inform its decision whether EPA should reduce the hazardous air pollution emitted by a given industrial source category. After completing the health risk assessment which is supposed to be based on current scientific methods, EPA determines, first, whether the health risks, to the person most exposed to emissions from an industrial source category, are “unacceptable.” If the risks are unacceptable, EPA must reduce the emissions from that industrial sector so all unacceptable risks are removed and prevented. In this analysis, costs may not be considered; only public health.<sup>3</sup>

If risks are not unacceptable or once reduced below the level of unacceptability, EPA must evaluate the health risks still present, and determine whether to set emission standards “to provide an ample margin of safety to protect public health,” or “to prevent, taking into

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<sup>2</sup> See, e.g., Union of Concerned Scientists & TEJAS, *Double Jeopardy in Houston: Acute and Chronic Chemical Exposures Pose Disproportionate Risks for Marginalized Communities* (2016), <http://www.ucsusa.org/center-science-and-democracy/connecting-scientists-and-communities/double-jeopardy#.WU1esU2WyUK> (a study of four Houston communities shows that both short- and long-term chemical risks are unevenly distributed along racial and economic lines); see also EPA, Summary of Results for the 2011 National-Scale Assessment at 4 (2015) (estimating that at least half a million people face an increased risk above 100-in-1 million, and due to the overall average national cancer risk from industrial sources, approximately 1 in every 25,000 people have an increased likelihood of contracting cancer as a result of breathing air toxics from outdoor sources if exposed to 2011 emission levels over the course of their lifetime); EPA NATA 2011 Fact Sheet, <https://www.epa.gov/national-air-toxics-assessment/2011-nata-fact-sheet> (EPA estimates 130 census tracts with cancer risks greater than 100-in-1 million); Second Integrated Urban Air Toxics Report at xv, <https://www.epa.gov/urban-air-toxics/second-integrated-urban-air-toxics-report-congress> (“Some areas around the country have elevated levels of risks from air toxics.”); Comments of Earthjustice, NRDC, et al. on Request for Information and Citations on Methods for Cumulative Risk Assessment at 4, EPA-HQ-ORD-2013-0292 (May 1, 2013), <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2013-0292-0132> (filed June 28, 2013 on behalf of Air Alliance Houston and 27 additional groups) (“CRA Comments”). As a note on the NATA data: Although it provides helpful data showing the ongoing problem of high risks in particular exposed communities, Commenters believe it underestimates health risks for the same reasons discussed later in these comments and so the specific risks and affected communities are likely higher than shown in the cited documents.

<sup>3</sup> See, e.g., EPA, Refineries Proposed Rule, 79 Fed. Reg. 36,880, 36,884 (June 30, 2014) (“If risks are unacceptable, the EPA cannot consider cost in identifying the emissions standards necessary to bring risks to an acceptable level.”).

consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.”<sup>4</sup>

### **Comments on the SAB Review Charges**

#### **1. EPA’s approach includes some important scientific updates.**

##### ***Charge questions 4 and 5:***

We have advocated for years for EPA to perform a multipathway assessment that accounts for urban non-inhalation exposure, *i.e.*, exposure through non-inhalation pathways as a result of the deposition of hazardous air emissions in the urban environment. We have urged EPA to focus on children’s exposure from soil, due to hand-to-mouth.<sup>5</sup> EPA’s recognition that it must account for additional urban non-inhalation exposure to hazardous air pollution is important and science supports this inclusion.

We are concerned that assessing the urban gardening scenario is not enough, however. EPA should be advised to account for children’s exposure through ingestion and other pathways (in addition to ingestion of fruits and vegetables grown in an urban environment). It is important to assess the health risks from early-life exposure to contaminated soil in playgrounds, schoolyards, backyards, with lead, arsenic, and other metals, and we are concerned that the urban gardening scenario alone does not do this.

**Generally:** On any other improvements not identified explicitly here but discussed as concerns in the comments we have previously submitted, we would appreciate the Board providing input that can affirm scientific methods within EPA’s approach that ensure assessment of health risks, as well as advice that can help update and strengthen its approach to better assess and account for health risks based on current science, with the goal of performing an assessment that can ensure decisionmakers and the public have information needed to be able to meet the statutory requirement to provide an “ample margin of safety to protect public health.”

#### **2. Some components of EPA’s proposed approach where scientific guidance and improvements are needed.**

##### ***Charge question 1:***

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<sup>4</sup> 42 U.S.C. § 7412(F)(2)(A), <https://www.gpo.gov/fdsys/granule/USCODE-2011-title42/USCODE-2011-title42-chap85-subchapl-partA-sec7412>.

<sup>5</sup> See, *e.g.*, 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> (filed on Oct. 28, 2014 on behalf of NRDC and 19 additional organizations including fence-line community groups); CRA Comments at 30-31, *supra* note 2.

EPA's multipathway risk assessment method is the procedure it uses to assess health risks from the air deposition of persistent or bioaccumulative chemicals from industrial sources into soil, water, and other resources to which people are exposed. It performs this separately from an inhalation-based risk assessment (which assesses the health risks from breathing hazardous air pollutants emitted into the air).

As EPA's charge document attachment (at p. 1, 4) makes clear, it is seeking SAB approval to avoid completing a full or refined multipathway assessment for industrial sources of hazardous air pollution because they "are very costly" and "can take several months to complete." Instead, EPA seeks approval to do tiered screening, which it believes will allow it to avoid doing an actual assessment for any individual facility, and thus avoid doing this for some entire industrial source categories covered by EPA's residual risk rulemaking authority.

What it means when EPA screens out a source category is that it does not come up with any value at all for the non-inhalation risk for one or all of the persistent or bioaccumulative pollutants emitted by that source category. Instead, it states that the facility screened out at one of the tiers. There is little information or analysis provide to the public or stakeholders. And EPA avoids reaching a determination of any lifetime cancer risk value (maximum individual risk or MIR) from that single pollutant or all pollutants due to multipathway exposure that should be added to the inhalation MIR for cancer to complete the picture of carcinogenic risk that a source category causes.

We have seen an example of this in the recent petroleum refineries risk assessment where EPA decided, without any scientific basis, not to add the cancer risk from inhalation (100-in-1 million) with the cancer risk from non-inhalation or multipathway (4-in-1 million).<sup>6</sup> Because EPA did not add the multipathway & inhalation risk for cancer, it determined health risks from refineries are "acceptable" because it found cancer risk to be right at the 100-in-1 million level for the most-exposed people – even though the full aggregate exposure would have put the risk level over the upper end of what EPA considers to be acceptable risk (which itself is too high for any given industrial source category, as separately discussed in the attached comments).<sup>7</sup> Consequently, although EPA updated the regulatory framework in other ways, EPA did not reduce emissions from the pollutants causing that level of health risk, leaving millions of Americans exposed to high cancer risk from oil refineries, alone.<sup>8</sup> Many community members are also exposed to other sources simultaneously which increases their exposure and vulnerability – see the Manchester/Galena Park neighborhood example in Houston – such as chemical plants, oil and gas operations, and more.<sup>9</sup>

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<sup>6</sup> Refineries Reconsideration petition on EPA's refineries air toxics rule at pp. 37-40, available at regulations.gov as EPA-HQ-OAR-2010-0682-0860.

<sup>7</sup> See, e.g., CRA Comments, *supra* note 2, at 38-40.

<sup>8</sup> See Refineries Risk Assessment at 49; Feb. 2016 Earthjustice *et al.* 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 (and comments filed Dec. 2016 in the docket on this).

<sup>9</sup> See UCS & TEJAS, *Double Jeopardy*, *supra* note 2.

A similar problem occurs for non-cancer chronic risks, such as neurological harm, although there EPA's current approach (using a reference exposure level which assumes there is a safe level for non-carcinogens) makes it even more difficult to combine or recognize the cumulative impact of inhalation and multipathway risk due to the method EPA uses to assess those ("total organ-specific hazard index" for inhalation, and a "hazard quotient" or other risk value for multipathway).<sup>10</sup>

For lead, EPA's approach is inscrutable and uniquely problematic: rather than assessing the lead-based health risks for people, including children, exposed to lead-emitting industrial sources as it does for all other pollutants, EPA simply assesses whether there is an exceedance of the Lead NAAQS near a source.<sup>11</sup> As lead has no safe level of exposure, that fails to account for or put any risk value on the actual real-world risk the source is causing for nearby communities. Further, because the 2008 Lead NAAQS should be strengthened by an order of magnitude, and in other ways, as EPA's Office of Children's Health Protection Advisory Committee has explained,<sup>12</sup> EPA's approach likely allows dangerous levels of exposure to new lead emissions going into the air in communities near industrial sources like lead smelters, refineries, coal plants, and more.

By using a tiered screening method pollutant by pollutant, EPA may screen out at one of the tiers a source that is on EPA's threshold level for each of a series of pollutants alone, and ignore the cumulative impact of the multipathway exposure to all of those pollutants for people near the facility. We are concerned that EPA's screening approach could lead to screening out a facility based on a single pollutant without considering aggregate or cumulative risks at all.

EPA asks the SAB to approve of a default approach for screening that has the goal of helping the agency avoid completing a multipathway risk assessment approach for industrial source categories. The result will be that it will have only inhalation risk values for many risk assessments. Since these assessments are often the only regulatory mechanism, at any level of government, to assess health risks from industrial air pollution in heavily exposed areas, communities, as well as scientists, researchers, and state and federal regulators, need and deserve a thorough and transparent assessment of health risks from all exposure pathways. This is particularly true because not having a full picture of each type of risk means EPA is regulating based on incomplete information, and an assumption that certain risks are low when that may well not be the case if a full assessment is performed. Therefore, it should be rare

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<sup>10</sup> See, e.g., Refineries Risk Assessment at 49 tbl. 3.2-4 (Summary of Refined Multipathway Results).

<sup>11</sup> See, e.g., 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; Refineries Comments at 74-75.

<sup>12</sup> [Letter from Sheela Sathyanarayana, Chair, Children's Health Prot. Advisory Comm., to Administrator Gina McCarthy \(Jan. 8, 2016\), https://www.epa.gov/sites/production/files/2015-01/documents/naaqs\\_for\\_lead\\_letter.pdf](https://www.epa.gov/sites/production/files/2015-01/documents/naaqs_for_lead_letter.pdf); Letter from Dr. Melanie A. Marty, Chair, Children's Health Protection Advisory Comm., to Administrator Stephen L. Johnson, (June 16, 2008), <http://www2.epa.gov/sites/production/files/2014-05/documents/61608.pdf>.

that EPA screens out, and thus fails to complete a multipathway risk assessment that contains risk values, for any source category that is emitting persistent or bioaccumulative chemicals, such as arsenic, mercury, dioxins, PAHs, cadmium, and lead.<sup>13</sup>

EPA should be advised, as a general matter, to do the full multipathway risk assessment to ensure that, for example, it comes up with the additional carcinogenic risk that should be added to the inhalation-based carcinogenic risk, before determining whether risks are acceptable or not. It should not screen out any facility with any potential for carcinogenic or other health risks from non-inhalation exposure. Even a supposedly small amount of extra cancer, neurological or other health risks may be dangerous when added with inhalation risks.

As noted above, EPA's exposure scenarios omit exposure to children from soils contaminated due to deposition of PB-HAP emissions from industrial sources. The significance of omitting this pathway was seen when comparing risk estimates performed by USEPA for the Secondary Lead Smelting Sector with the facility specific assessments performed under California's Toxic Air Contaminant Program. The cancer risk estimates from the California facilities greatly exceeded those identified for the whole sector by USEPA. Closer review illustrated that this discrepancy was the result of California's appropriate assessment of risk from contact with arsenic-contaminated soils, in addition to inhalation, resulting from facility emissions.

Failing to perform the multipathway risk assessment for pollutants like lead, arsenic, mercury, and more, could mean the difference between setting an emission limit that protects children's health or not. This component of EPA's method is important and we urge the Board to provide advice to assist EPA in evaluating these health risks and in reaching a complete assessment that can then inform reasoned agency decisionmaking on emission standards.

***Charge 3:***

As part of evaluating EPA's "Tier 2" multipathway screening scenario, EPA seeks input on assessments for exposure to chemicals in food and in fish (i.e., separate assessment of "fisher" and "farmer" scenarios). Because people who are exposed to industrial sources are often exposed through both such pathways, EPA should be advised not to isolate these values as part of a risk assessment, but to recognize potential combined or aggregate exposures in this analysis. For example, the same people may be exposed through catching and eating fish in an urban river like the Anacostia, and also growing vegetables or being exposed to soil in their yards. There are instances around the country of indigenous communities engaging in subsistence fishing and farming, and having both types of exposures. Assuming people are not exposed through both pathways is likely to underestimate real-world health risks. EPA should assume exposure where there is a scientific basis to do so to take a precautionary approach,

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<sup>13</sup> As noted repeatedly in the prior comments, EPA also should update the list of PB-HAPs for which it performs this assessment.

rather than ignoring the likelihood of greater exposure and thus health risks from such exposure.

Regarding other components of the charge that will strengthen EPA's assessment of risks due to exposure to emissions from multiple facilities, or the same facility through multiple lakes, those are positive steps forward. The Board should advise on what other components of such exposure EPA's approach is not currently evaluating as part of the approach under peer review. Such gaps often lead to the underestimation of health risk, and the potential screening out of facilities and source categories that well may be causing significant health risks.

**3. In addition to the specific issues identified, EPA should be advised to incorporate and follow the most current science on risk assessment methods, to avoid underestimating or missing health risks as has often occurred in past risk assessments.**

There are a number of ways in which EPA's current approach underestimates the health risks of hazardous air pollution exposure from industrial sources, and this has led to EPA not setting any emission limits or setting too-weak emission standards for air pollutants ranging from toxic metals like lead, hexavalent chromium, arsenic, manganese, and cadmium, to volatile organic compounds like benzene, toluene, xylenes, and PAHs, as well as other chemicals like mercury, hydrogen cyanide, and chloroprene.<sup>14</sup>

We have attached comments we submitted to the agency in recent years providing overall summaries of gaps in its risk assessment methods that are leading the agency to underestimate health risks and to miss setting important health protections from hazardous air pollution. These cite relevant scientific information for the SAB's review.

Following the release of *Science and Decisions* (2009), NRDC staff scientists evaluated and published a summary of ways in which EPA's risk assessment methods need to be updated to follow the NAS recommendations.<sup>15</sup> For years, Earthjustice, NRDC, and ally groups have submitted comments to EPA in individual source category rulemaking records and to the Office of Science Advisor as it requested information and comment on (1) cumulative risk assessment methods and (2) its proposed update to the Human Exposure Assessment Guidelines.<sup>16</sup>

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<sup>14</sup> 42 U.S.C. § 7412(b)(1); List of HAPs, <https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications>. As one example, EPA did not assess any cancer risk at all for chloroprene before there was a complete IRIS assessment, and instead assumed these risks were zero; years later it found a chloroprene-emitting source was causing an extremely high level of cancer risk in a Louisiana community such that: "The top . . . census tracts with the highest NATA-estimated cancer risks nationally are in Louisiana due to Denka (formerly DuPont) chloroprene emissions." <https://www.epa.gov/la/laplace-louisiana-frequent-questions>.

<sup>15</sup> Sarah Janssen et al., *NRDC Issue Paper: Strengthening Toxic Chemical Risk Assessments to Protect Human Health* (Feb. 2012), <http://www.nrdc.org/health/files/strengtheningtoxic-chemical-risk-assessments-report.pdf>.

<sup>16</sup> See NRDC Scientists (2016) & Earthjustice (2016) Comments on EPA's Human Exposure Assessment Guidelines and attachments.

Overall, gaps in EPA's approach cause the agency to underestimate health risks due to: early-life exposure, including in utero<sup>17</sup>; multiple pathway exposure; multiple pollutant exposure; and multiple source exposure.<sup>18</sup> Although we recognize there is no perfect scientific method to evaluate each of these alone or cumulatively, on each of those issues there are well-supported scientific approaches that EPA could and should take to better account for the real-world health risks than it is currently doing. Because of the importance of the health risk assessments at issue here to inform regulatory protections from hazardous air pollution, EPA should be encouraged to use the best available methods to assess health risks, rather than ignoring any known risks or waiting for years until there is some future approach created (while communities lose protections in the meantime from rulemakings that ignore or underestimate health risks). Given the narrow scope of the charge questions and that EPA's complete risk assessment methods have not been independently evaluated since 2009, we urge SAB to be very clear in the review about the scope and nature of the feedback being provided.

EPA also should be advised to further strengthen its risk assessment methods by implementing National Academy of Sciences recommendations. In addition to other sources cited in the attached comments, resources for improving the assessment of exposures and health risk from hazardous air pollutants to protect children's health are available from California EPA's guidelines for the preparation of health risk assessments under the Toxic Air Contaminant Program.<sup>19</sup>

Thank you for your time and consideration of these comments and the matter before this panel. We are planning to call in to offer public comment during your meeting if technology allows, and we are also glad to offer any additional information before or after that may be helpful. Please feel free to contact us at your convenience.

Sincerely,

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<sup>17</sup> See, e.g., CHPAC Letter to EPA (Oct. 21, 2010), <http://www2.epa.gov/sites/production/files/2014-05/documents/61608.pdf>.

<sup>18</sup> See Comments cited, *supra* note 16 and attached.

<sup>19</sup> Cal. EPA, OEHHA, Air Toxics Hot Spots Program Guidance Manual for the Preparation of Health Risk Assessments (2015), <https://oehha.ca.gov/air/cnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0>.